NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

October 11-12, 2023

Zoom
https://zoom.us/j/5886256671
Meeting ID: 5886256671

Please do not remove the book from the meeting room.

Nevada State Board of Pharmacy

985 DAMONTE RANCH PARKWAY • SUITE 206 • RENO, NEVADA 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
E-mail: pharmacy@pharmacy.nv.gov • Website: bop.nv.gov

Date Posted: September 27, 2023

AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, October 11, 2023, at 9:00 am. The meeting will continue, Thursday, October 12, 2023, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

Please Note:

In regulating the practice of pharmacy, the Nevada State Board of Pharmacy has a duty to carry out and enforce the provisions of Nevada law to protect the health, safety, and welfare of the public.

Please note that items on this agenda may be taken out of order, two or more agenda items may be combined for consideration, and/or items may be removed from the agenda or delayed for discussion at any time.

The Board may convene in closed session pursuant to NRS 241.030 to consider the character, alleged misconduct, professional competence or physical or mental health of any person named on this agenda.

The Board will take public comment on any matters within their jurisdiction, control, or advisory power. Public comments may be limited to three minutes per person. Public comment may also be submitted to the Board at pharmacy@pharmacy.nv.gov.

The Board may refuse to consider public comment related to a contested case pursuant to NRS 233B.126 until the Board has rendered a decision in the contested case.

1. Call to Order and Roll Call – Establishment of Quorum

2. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

◈ CONSENT AGENDA ◈

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

3. Approval of the September 6-7, 2023, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

4. 4.1 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-appearance **(FOR POSSIBLE ACTION)**

A. HealthDyne Pharmacy – Lakeland, FL
B. Prism Medical Products, LLC – Elkin, NC
C. Prism Medical Products, LLC – Fresno, CA
D. Sunrise Respiratory Care, Inc. – Irvine, CA
E. VasoCare, LLC – Baton Rouge, LA

4.2 Applications for Out-of-State Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**)

Background Check Not Required by Law.

4.2.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))

Applied Medical Distribution Corporation – Middletown, NY

4.2.2 Manufacturer (NAC 639.593(7)(d))

F. AirLife – Grand Rapids, MI
G. Almaject, Inc. – Morristown, NJ
H. Altor BioScience, LLC – Culver City, CA
I. Applied Medical Distribution Corporation – Irvine, CA
J. BioHorizons Implant Systems Inc. – Birmingham, AL
K. BioLineRx USA, Inc. – Waltham, MA
L. Carl Zeiss Meditec, Inc. – Dublin, CA
M. Catalent Greenville, Inc. – Greenville, NC
N. Catalent Greenville, Inc. – Greenville, NC
O. Chewy Wholesale, LLC – Goodyear, AZ
P. Chewy Wholesale, LLC – Pittston, PA

Q. Coloplast Corp. – Ontario, CA
R. Diamond Animal Health, Inc. – Des Moines, IA
S. DJO, LLC – Vista, CA
T. GlaxoSmithKline LLC – Durham, NC
U. Luye Pharma USA, Ltd. – Princeton, NJ
V. Medivant Healthcare – Phoenix, AZ
W. MidAmerica Pharmaceuticals LLC – Oak Park, IL
X. Mobius Therapeutics, LLC – St. Louis, MO
Y. Omnivium Pharmaceuticals, LLC – Rahway, NJ
Z. Philips Healthcare Informatics, Inc. – Pleasanton, CA
AA. PMI Branded Pharmaceuticals, Inc. – Allegan, MI
BB. Respironics Logistics Services, LLC – Mt. Pleasant, PA
CC. Sagent Pharmaceuticals, Schaumburg, IL
DD. UPS Supply Chain Solutions, Inc. – Woolwich Township, NJ
EE. ViiV Healthcare Company – Durham, NC
FF. VYGAAN Pharmaceuticals, LLC – Skillman, NJ
GG. Westmed Inc. – Tucson, AZ

4.2.3 Publicly Traded (NAC 639.593(7)(a))

HH. Actelion Pharmaceuticals US, Inc. – Titusville, NJ
II. ARS Pharmaceuticals Operations, Inc. – San Diego, CA
JJ. Bristol Myers Squibb – Devens, MA
KK. McKesson Medical-Surgical Inc. – Orlando, FL

4.2.4 VAWD-Accredited (NAC 639.593(7)(c))

LL. Amatheon Animal Health, LLC – Miami, FL

4.2.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))

MM. CVS TN Distribution, LLC – Knoxville, TN

4.2.6 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

NN. Dentsply LLC – York, PA
OO. RxSight, Inc. – Aliso Viejo, CA

4.2.7 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))

4.2.8 Background checks completed in compliance with NRS 639.500.

PP. Akron Pharma Inc. – Hauppauge, NY
QQ. Elanco US Inc. – Elwood, KS
RR. MFG TPL – High Point, NC
SS. MR Unlimited LLC – Brenham, TX

4.3 Applications for Nevada Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**)

4.3.1 Manufacturer (NAC 639.593(7)(d))

4.3.2 **Background checks completed in compliance with NRS 639.500.**

4.4 Application for Nevada Pharmacy License (NRS 639.230) – Non-appearance **(FOR POSSIBLE ACTION)**

TT. All Westcare Pharmacy – Las Vegas, NV
UU. ER at North Las Vegas, an Extension of Valley Hospital – North Las Vegas, NV
VV. Genoa Healthcare LLC – Las Vegas, NV
WW. Prime Care Pharmacy – Las Vegas, NV

4.5 Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-appearance **(FOR POSSIBLE ACTION)**

XX. Prism Medical Products, LLC – Las Vegas, NV

4.6 Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Non-Appearance – **(FOR POSSIBLE ACTION)**

YY. Curexa – Gilbert, AZ

4.7 Application for Out-of-State Pharmacy License (NRS 639.2328) – Non-appearance **(FOR POSSIBLE ACTION)**

ZZ. CarelonRx Pharmacy, Inc. – Tucson, AZ
AAA. Chewy Pharmacy, LLC – Pittston, PA

4.8 Application for Ambulatory Surgery Center License (NAC 639.4992) – Non- Appearance **(FOR POSSIBLE ACTION)**

4.9 Recommended Denial of Registration/Licensure Due to Material Omissions in Application – Non-Appearance **(FOR POSSIBLE ACTION)**

BBB. LeeAnn Carlos
CCC. Jonathan Mukendi
DDD. Rikki Ramirez

◈ REGULAR AGENDA ◈

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

A. Itzel Casian, PTT (22-401-PTT-A-S)
B. Osvaldo Hernandez, PTT (22-401-PTT-B-S)

C. Phil Chen, DO (23-016-CS-S)
D. James Eells, MD (19-081-CS-S)
E. Delta Drugs (20-168-PH-S)
F. Shahin Banayan, RPH (20-191-RPH-S)
G. Walgreens Pharmacy #10783 (20-191-PH-S
H. Mona Matar, RPH (22-370-RPH-S)
I. Walgreens Pharmacy #04755 (22-370-PH-S)
J. Justine Stanevich, PT (22-041-PT-S)
K. Justine Stanevich, PT Order to Show Cause (20-135-PT-S)
L. Walgreens Pharmacy #3844 (22-096-PH-S)
M. Kerry Otero, RPH (22-096-RPH-S)
N. Morgan Towler, PTT (22-096-PTT-S)
O. Edward Victoria (23-113-CS-S)
P. Raymond Graber (23-340-CS-N)
Q. Genoa Healthcare LLC (20-022-PH-S)
R. Michael Brinkmann (22-237-CS-S)

6. Appeal hearing pursuant to NRS 639.2895(2) (**FOR POSSIBLE ACTION**)

Mobility Prosthetics and Orthotic Services (23-089-S)

7. Application for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

A. BioPlus Specialty Pharmacy Services, LLC – Las Vegas, NV
B. Mesa Ridge Pharmacy – Mesquite, NV

8. Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

A. 1st Choice Pharmacy – Holiday, FL
B. Strive Pharmacy – Gilbert, AZ

9. Application for Nevada Compounding Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

Partell Specialty Pharmacy – Las Vegas, NV

10. Application for Out-of-State Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

A. Med-Plus Pharmacy, Inc. – Covina, CA
B. Seven Hills Pharmacy, LLC – Sharonville, OH

11. Application for Out-of-State Outsourcing Facility (NRS 639.100) – Appearance (**FOR POSSIBLE ACTION**)

A. BPI Labs, LLC – Largo, FL
B. OurPharma LLC – Fayetteville, AR

12. Applications for Out-of-State Wholesaler License (NRS 639.233) – Appearance (**FOR POSSIBLE ACTION**)

    Daiichi Sankyo, Inc. – Basking Ridge, NJ – Background Check Not Required - Manufacturer (NAC 639.593(7)(d))

13. Applications for Pharmaceutical Technician in Training Registration (NAC 639.242) – Appearance. (**FOR POSSIBLE ACTION)**

    Joshua Satsatin

14. Application for Pharmacist Registration by Reciprocation NRS 639.134) – Appearance (**FOR POSSIBLE ACTION**)

    A. Matthew Dulin
    B. Erin Sosebee

15. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

    A. Daisy de Guzman

16. Application for Dispensing Practitioner Registration – Appearance (**FOR POSSIBLE ACTION**)

    A. Vincent Alexis
    B. Daisy de Guzman

17. Applications for Advance Practice Registered Nurse – Prescribe Registration (NAC 639.850) – Appearance. **(FOR POSSIBLE ACTION)**

    A. Rebecca Ann Martinez
    B. Camilo Murillo

18. Application for Controlled Substance Registration Renewal (NRS 453.226) – Appearance (**FOR POSSIBLE ACTION**)

    Raymond Graber

◈ WORKSHOP ◈

Thursday October 12, 2023 – 9:00 am

19. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2)

(FOR POSSIBLE ACTION):

A. **REGULATIONS relating to Governor Lombardo's Executive Order 003-2023. Changes in these Regulations streamline and clarify licensing requirements while ensuring public safety; and providing other matters properly relating thereto.**

Executive Order 003-2023

SECTION 1
Every executive branch department, agency, board and commission shall undertake a comprehensive review of the regulations subject to its enforcement. On or before, May 1, 2023 each department, agency, board and commission shall provide a report to the Governor's office detailing how the regulation subject to its enforcement can be streamlined, clarified, reduced or otherwise improved to ensure those regulations provide for the general welfare of the State without unnecessarily inhibiting economic growth.

SECTION 2:
As part of its report, every executive branch department, agency, board and commission shall provide a list of not less than ten (10) regulations recommended for removal, ranking them in descending order of priority.

B. **Amendment to Nevada Administrative Code (NAC) 453.** The proposed amendments relate to controlled substances adding synthetic cannabinoids to the controlled substances listed in Schedule I.

20. General Counsel Report. Note: The Board may exclude the public for a report on potential or existing litigation pursuant to NRS 241.015(3)(b)(2).

21. Executive Secretary Report:

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. 2024 Board Meeting Calendar

22. Date and Location of Next Scheduled Board Meeting:

December 6-7, 2023 – Las Vegas, NV

23. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

24. Adjournment

Note: We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements for the meeting are necessary, please notify the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206, Reno, NV, 89521, or call Kristopher Mangosing at (775) 850-1440, as soon as possible.

Supporting materials or additional information regarding the meeting may be obtained from Shirley Hunting at (775) 850-1440, email shunting@pharmacy.nv.gov or 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada, 89521.

Continuing Education credit will be given for in-person attendance at this Board meeting pursuant to NAC 639.330(1)(b)(2).

This notice has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to NRS 241.020 (4).

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206, Reno, NV 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

MINUTES

September 6-7, 2023

BOARD MEETING

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, September 6, 2023, at 9:00 am. The meeting will continue, Thursday, September 7, 2023, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

Board Members Present:

Helen Park	Krystal Freitas	Jade Jacobo	Wayne Mitchell
Rolf Zakariassen	Richard Tomasso	Gener Tejero	

Board Staff Present:

Dave Wuest	Yenh Long	Shirley Hunting	Kristopher Mangosing
Brett Kandt	Peter Keegan	Gregory Zunino	Darlene Nases
Joe Dodge	Dena McClish	Kenneth Scheuber	Leo Basch
Luis Curras	Darla Zarley	Rosalie Bordelove	

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

Dave Wuest stated that this Board Meeting is being held over Zoom and is in compliance with the Governor's directive and Open Meeting Laws for Nevada.

1. Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. All Board members were present, and a quorum was established.

2. Public Comment September 6, 2023, 9:00 AM

Ken Kunke from the Nevada Pharmacy Alliance wanted to share two events with the public: 1) September 22-23, 2023, an annual meeting with the Nevada Pharmacy Alliance, Nevada Society and Health-System Pharmacist, and the America Society of Consultant Pharmacists in Henderson, NV which will provide six hours of continuing education (CE) credits, and one hour of Law CE credit; and 2) October 23, 2023, a meeting called "Addressing the Opioid Epidemic" which will be pharmacist focused.

◈ CONSENT AGENDA ◈

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

3. Approval of the July 12-13, 2023, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Board discussion ensued.

Board Action:

Motion: Wayne Mitchell moved to approve July 12-13, 2023, Board Meeting minutes.

Second: Jade Jacobo

Action: Passed unanimously.

4. 4.1 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-appearance **(FOR POSSIBLE ACTION)**

A. Healthcare HD LLC – Dunedin, FL

4.2 Applications for Out-of-State Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**)

Background Check Not Required by Law.

4.2.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))

B. QuVa Pharma, Inc. – Phoenix, AZ

4.2.2 Manufacturer (NAC 639.593(7)(d))

C. Albiero Pharma, Inc. – Boston, MA
D. Ascend Laboratories LLC – Parsippany, NJ
E. Brainlab Inc. – Westchester, IL
F. Cerapedics Inc. – Westminster, CO
G. Coloplast Corp. – Lithia Springs, GA
H. Coloplast Corp. – Minneapolis, MN
I. Coloplast Corp. – North Mankato, MN
J. Corium, LLC – Boston, MA
K. Cranbury Pharmaceuticals, LLC – Monmouth Junction, NJ
L. Fidia Pharma USA Inc. – Florham Park, NJ
M. Medline Industries, LP – Mundelein, IL
N. Neotech Products LLC – Valencia, CA
O. OxyGo HQ Florida LLC – Orlando, FL
P. Philips Healthcare, a division of Philips North America LLC – Bothell, WA
Q. Philips Healthcare, a division of Philips North America LLC – Cambridge, MA
R. Philips Image Guided Therapy Corporation – Rancho Cordova, CA
S. Philips Ultrasound LLC – Bothell, WA
T. Phoenix Assurance, LLC – Memphis, TN
U. Respironics Logistics Services, LLC – Mt. Pleasant, PA
V. UPS Supply Chain Solutions, Inc. – Mira Loma, CA
W. Verity Pharmaceuticals Inc. – Ewing, NJ

4.2.3 Publicly Traded (NAC 639.593(7)(a))

4.2.4 VAWD-Accredited (NAC 639.593(7)(c))

X. AmerisourceBergen Drug Corporation – Denver, CO
Y. Gemco Medical – Hudson, OH
Z. Maks Pharma and Diagnostics Inc. – Baldwin, NY

4.2.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))

AA. Apotex Corp. – Plainfield, IN
BB. AstraZeneca Pharmaceuticals LP – Shepherdsville, KY

4.2.6 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

CC. Aadi Bioscience, Inc. – Pacific Palisades, CA
DD. Boston Scientific Corporation – Brooklyn Park, MN
EE. Chemocentryx Inc. – San Carlos, CA

4.2.7 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))

4.2.6 Background checks completed in compliance with NRS 639.500.

FF. Fountain Medical Supplies Inc. – Orem, UT
GG. MD Logistics LLC – Garner, NC
HH. Skyline Pharmaceuticals, Inc. – Ft. Lauderdale, FL

4.3 Applications for Nevada Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**)

4.3.1 Manufacturer (NAC 639.593(7)(d))

4.3.2 **Background checks completed in compliance with NRS 639.500.**

4.4 Application for Nevada Pharmacy License (NRS 639.230) – Non-appearance **(FOR POSSIBLE ACTION)**

II. Dignity Specialty Pharmacy – Las Vegas, NV
JJ. ER at Damonte Ranch, an Extension of Northern Nevada Sierra Medical Center – Reno, NV

4.5 Application for Nevada Compounding Pharmacy License (NRS 639.230) – Non-appearance **(FOR POSSIBLE ACTION)**

KK. Sky Vista Pharmacy – Las Vegas, NV

4.6 Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-appearance **(FOR POSSIBLE ACTION)**

4.7 Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Non-Appearance – **(FOR POSSIBLE ACTION)**

LL. Brava CA LLC – Novato, CA
MM. Kings Park Slope, LLC – Brooklyn, NY

4.8 Application for Out-of-State Pharmacy License (NRS 639.2328) – Non-appearance **(FOR POSSIBLE ACTION)**

NN. Ascension Rx 1001 – Austin, TX
OO. Brightside Specialty Pharmacy – Santa Ana, CA
PP. Burt's Pharmacy Moorpark – Moorpark, CA
QQ. PRxP of CA, LLC – Ontario, CA
RR. SKNV Pharmacy, LLC – Deerfield Beach, FL
SS. URGENTMEDRX, LLC – Boca Raton, FL

4.9 Application for Ambulatory Surgery Center License (NAC 639.4992) – Non- Appearance **(FOR POSSIBLE ACTION)**

TT.Surgery Center of Reno, LLC – Reno, NV

4.10 Request to Engage in the Practice of Pharmacy at a Site Other than a Licensed Pharmacy – Non-appearance **(FOR POSSIBLE ACTION)**

UU. Trenie Kunke
VV. Zachary Rosko

4.11 Recommended Denial of Registration/Licensure Due to Material Omissions in Application – Non-Appearance **(FOR POSSIBLE ACTION)**

WW. Alonda Holt
XX. Jennifer Jaycox
YY. Vesta Johnson
ZZ. Rebeka Ojakhyan

Krystal Freitas recused herself from Agenda Item 4JJ due to her employment.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Consent Agenda excluding Agenda Item 4JJ.

Second: Wayne Mitchell

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to approve the Consent Agenda Item 4JJ.

Second: Wayne Mitchell

Action: Passed unanimously (Freitas recused).

◈ REGULAR AGENDA ◈

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

H. Genoa Healthcare LLC (20-022-PH-S)

This matter was continued to a future Board meeting.

I. Craig Pivo, RPh (20-022-RPH-S)

Craig Pivo appeared by Zoom and requested a Zoom appearance on this disciplinary matter as he has retired and relocated to Hawaii.

President Park commented that appearances related to discipline are to be in-person, but she will approve this request.

Craig Pivo appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case regarding a misfill of alprazolam that was delivered to and ingested by a minor, causing patient harm.

Mr. Zunino presented a proposed Stipulation and Order for the Board's consideration.

The proposed stipulated penalties for Craig Pivo, Certificate of Registration No. 09999, are the following: 1) pay a fine of $1,000 for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and investigative costs.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Stipulation and Order for Craig Pivo, Certificate of Registration No. 09999, as presented by Mr. Zunino.

Second: Wayne Mitchell

Action: Passed unanimously.

C. Walgreens Pharmacy #6425 (22-359-PH-S)
D. Juan Peidra Flores, RPh (22-359-RPH-S)

President Park disclosed that she knows Juan Peidra Flores but can participate in this matter fairly and without bias.

Gener Tejero disclosed that he has a professional business relationship with William Stilling but can participate fairly and without bias.

Juan Peidra Flores appeared and was sworn in by President Park prior to answering questions and offering testimony.

William Stilling appeared as counsel on behalf of the Respondents.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case regarding Flores' overriding drug utilization review (DUR) warnings resulting in patient harm.

Mr. Kandt presented a proposed Stipulation and Order for Walgreen's Pharmacy #6425 and Mr. Flores for the Board's consideration.

The proposed stipulated penalties for Walgreen's Pharmacy #6425 License No. PH01594 are the following: 1) pay a fine of $2,000; and 2) pay $1,000 to partially reimburse the Board for recoverable attorney's fees and investigative costs.

The proposed stipulated penalties for Juan Peidra Flores Certificate of Registration No. 20887 are the following: 1) pay a fine of $1,000 for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and investigative costs.

Mr. Flores provided a statement to the Board regarding changes to his practice to ensure that this error will not occur again.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Walgreen's Pharmacy #6425 License No. PH01594 and Juan Peidra Flores Certificate of Registration No. 20887 as presented by Mr. Kandt.

Second: Krystal Freitas

Action: Passed unanimously.

L. Ryan Ross, PT (20-027-PT-S)

Ryan Ross appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt prosecuted the case regarding Mr. Ross falsely representing himself as a Registered Pharmacist to the public.

Mr. Kandt presented a proposed Stipulation and Order for Ryan Ross for the Board's consideration.

The proposed stipulated penalties for Ryan Ross Certificate of Registration No. PT20827 are the following: 1) Certificate of Registration No. PT20827 is suspended, suspension is stayed and is placed on probation for one year; 2) Respondent accepts this Stipulation and Order as a public reprimand; 3) pay a fine of $500 the violations in an agreed upon payment plan; 4) pay $500 to partially reimburse the Board for recoverable attorney's fees and investigative costs in an agreed upon payment plan; and 5) respondent shall comply with all federal and

state statutes and regulations regarding the practice of pharmacy, and have no additional charges filed against him while on probation.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Stipulation and Order for Ryan Ross Certificate of Registration No. PT20827 as presented by Mr. Kandt.

Second: President Park

Action: Passed unanimously.

J. Smith's Pharmacy #390 (22-429-PH-N)

Andrea Adams, Pharmacy Practice Coordinator for Northern Nevada, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino prosecuted the case regarding Smith's Pharmacy #390, which operated without a qualified managing pharmacist between March 2, 2022, and April 11, 2022. There were alleged violations by Chance Warr, RPH, who may have been operating as the managing pharmacist on an expired temporary registration; however, Smith's presented evidence to refute the allegations against Mr. Warr, so the case was dismissed against him.

Mr. Zunino presented a proposed Stipulation and Order for Smith's Pharmacy #390 for the Board's consideration.

The proposed stipulated penalties for Smith's Pharmacy #390, License No. PH01126, are the following: 1) pay a fine of $2,000 for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and investigative costs.

Ms. Adams provided a statement to the Board outlining the changes at Smith's Pharmacy #390 to ensure that this will not happen again.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order for Smith's Pharmacy #390, License No. PH01126, as presented by Mr. Zunino.

Second: Rolf Zakariassen

Action: Passed unanimously.

K. Delta Drugs (20-168-PH-S)

This matter was continued to a future Board meeting.

M. Preferred Homecare (22-415-MP-N)

Jay DeVoy appeared as counsel on behalf of Preferred Homecare.

Peter Keegan, General Counsel for the Nevada Board of Pharmacy, prosecuted the case regarding Preferred Homecare operating without an approved MDEG Administrator for more than ten days.

Mr. Keegan presented a proposed Stipulation and Order for Preferred Homecare for the Board's consideration.

The proposed stipulated penalties for Preferred Homecare License No. MP00426 are the following: 1) pay a fine of $1,000 for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and investigative costs.

Board discussion ensued.

Board Action:

Motion: Rolf Zakariassen moved to approve Stipulation and Order for Preferred Homecare License No. MP00426 as presented by Mr. Keegan.

Second: Jade Jacobo

Action: Passed unanimously.

N. Carson Tahoe Regional Medical Center (23-004-PH-N)
O. Kelly Schott, RPh (23-004-RPH-N)

Wayne Mitchell recused himself from this matter due to his previous employment with Carson Tahoe Regional Medical Center.

John Cotton appeared as counsel on behalf of Carson Tahoe Regional Medical Center and Kelly Schott.

Scott Mattes, Operations Administrator, and Kelly Schott, Managing Pharmacist, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Peter Keegan prosecuted the case and presented the prior discipline for Carson Tahoe Regional Medical Center in 18-041-PH-N where they entered a Stipulation to resolve

allegations of improperly compounded bupivacaine epidurals during administration by an anesthesiologist. In addition, Mr. Keegan presented the current charges for the hearing alleging Carson Tahoe's Pharmacy acting through Ms. Schott and/or other pharmacy employees gave an unlicensed certified registered nursing anesthetist physician/practitioner access to controlled substances through the Pyxis machines which resulted in patient harm.

Mr. Keegan presented a proposed Stipulation and Order for Carson Tahoe Regional Medical Center and Kelly Schott for the Board's consideration.

The proposed stipulated penalties for Carson Tahoe Regional Medical Center License No. IA00531 are the following: 1) pay a fine of $10,000 for the violations; 2) pay $3,500 to partially reimburse the Board for recoverable attorney's fees and investigative costs; 3) shall update internal policies and procedures to eliminate any inconsistencies with Nevada Senate Bill 336 (2023) and to ensure greater pharmacy oversight of the credential process and user access to its Pyxis machines; 4) Carson Tahoe shall undergo one (1) additional pharmacy inspection, to include a review of their user access and credentialing policies for the hospital's various Pyxis machines, within 90 days of the Order at the cost of the respondent; 5) respondent accepts this as a public reprimand; and 6) respondent acknowledges this Stipulation and Order constitutes a public record of discipline that is reportable to the National Practitioner Data Bank.

The proposed stipulated penalties for Kelly Schott Certificate of Registration No. 15719 are the following: 1) pay a fine of $2,500 for the violations; 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and investigative costs; and 3) respondent acknowledges this Stipulation and Order constitutes a public record of discipline that is reportable to the National Practitioner Data Bank.

Board discussion ensued.

Ms. Schott and Mr. Mattes provided a statement to the Board on the process changes at the hospital and the pharmacy to ensure that this will not happen again.

Board Action:

Motion: Richard Tomasso moved to approve the Stipulation and Order for Kelly Schott Certificate of Registration No. 15719 and Carson Tahoe Regional Medical Center License No. IA00531 with an update to Carson Tahoe's Stipulation to correct paragraph C with Nevada Assembly Bill 336.

Second: Jade Jacobo

Action: Passed unanimously.

P. Edward Victoria, MD (23-113-CS-S)

This matter was continued to a future Board meeting.

7. Stipulated Rehearing **(FOR POSSIBLE ACTION)**

A. Las Vegas Scripts Rx (19-243-PH-S)
B. Nathan Edouard, RPH (19-243-RPH-S)

Ayesha Medhi appeared as counsel on behalf of Las Vegas Scripts Rx and Nathan Edouard.

Nathan Edouard appeared and was sworn in by President Park prior to answering questions and offering testimony.

Peter Keegan prosecuted the case and presented a Stipulated First Amended Findings of Fact, Conclusions of Law and Order for the Board's consideration.

The proposed stipulated penalties for LV Scripts' Pharmacy License No. PH03930 and Nathan Edouard License No. 19462 are the following: 1) LV Scripts' Pharmacy License No. PH03930 is suspended; however, the suspension is stayed and is placed on probation for one year; 2) LV Scripts' Pharmacy shall pay a fine of $5,000 for the violations; 3) LV Scripts' Pharmacy shall pay $2,500 to partially reimburse the Board for recoverable attorney's fees and investigative costs; 4) Nathan Edouard shall accept this Order as a public reprimand; 5) Nathan Edouard shall pay a fine of $2,500 for the violations; and 6) Nathan Edouard shall pay $900 to partially reimburse the Board for recoverable attorney's fees and investigative costs.

Rolf Zakariassen commented that paragraph 5 of the Order should state monthly payments of $250.00.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulated First Amended Findings of Fact, Conclusions of Law and Order with amendment to paragraph 5 to update the monthly payments to reflect $250.00.

Second: President Park

Action: Passed unanimously.

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

A. Maria Cruz RPh (18-021-RPH-D-S)

William Stilling appeared as counsel on behalf of Maria Cruz.

Maria Cruz was not present for the hearing.

Gener Tejero disclosed that he has a professional relationship with William Stilling but can participate in this matter fairly and without bias.

Brett Kandt prosecuted the case alleging Ms. Cruz failed to identify the duplication of prescriptions upon final product review.

The parties stipulated to the admission into evidence of Exhibit 1 (bate stamped 008-009 and 023-026) which are the actual prescription records of #1874629 for the first duplicated prescription, Exhibit 2 (bate stamped 010-11, 019-022) which are the actual copies of the prescription for prescription #1863870, Exhibit 3 (bate stamped 012-013 and 030-032) which are the copies of the original prescription related to #1896898 for the second duplicated prescription, Exhibit 4 (bate stamped (014-015 and 027-029) which are copies of the original prescription related to #1886042, Exhibit 5 (bate stamped 033-039) which are statements from employees provided by Walgreen's Pharmacy #4854 in the course of the investigation.

President Park admitted Exhibits 1-5 into the record.

Mr. Stilling and Mr. Kandt provided their arguments on the alleged violations.

Board discussion ensued.

Board Action:

Motion: President Park moved to make Findings of Fact consistent with the evidence and the admissions in Respondents' Answer and Notice of Defense.

Second: Rolf Zakariassen

Action: Passed unanimously.

Board discussion ensued on whether Ms. Cruz was guilty of Count Two.

Board Action:

Motion: Rolf Zakariassen moved to find that the facts do not support the alleged violations of law and find Maria Cruz not guilty of Count Two.

Second: Gener Tejero

Action: Passed unanimously.

B. Roosevelt Watson, MD (22-112-CS-S)

No representative was present on behalf of Roosevelt Watson.

Brett Kandt prosecuted the case and noted that no Answer and Notice of Defense was filed in response to the charges that Dr. Watson prescribed 119 controlled substances for six family members whom he did not have a bona fide therapeutic relationship, executed a DEA From 104 surrendering his DEA Registration No. FW4079427 for cause as included in the record on page 1876 of the Board's supporting materials, and received a suspension of his Certification of Registration No. CS12287 as included in the record on page 1875.

Mr. Kandt called Shirley Hunting, Board Coordinator for the Nevada Board of Pharmacy, as a witness.

Shirley Hunting appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Hunting testified as to service of the Notice of Intended Action and Accusation.

Mr. Kandt requested admission into evidence of Exhibit 1, documenting service of the Notice of Intended Action and Accusation.

President Park admitted Exhibit 1 into the record.

Mr. Kandt called Kristopher Mangosing, Assistant Board Coordinator for the Nevada Board of Pharmacy, as a witness.

Kristopher Mangosing appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Mangosing testified as to service of the 21-day Notice of the Hearing.

Mr. Kandt requested admission into evidence of Exhibit 2, documenting the service of the 21-day Notice of the Hearing.

President Park admitted Exhibit 2 into the record.

Mr. Kandt requested the Board make the Findings of Fact consistent with paragraphs 1-4 of the Notice of Intended Action and Accusation and find that the Respondent was given notice of this hearing in compliance with the law.

Board Action:

Motion: Jade Jacobo moved to make Findings of Fact consistent with paragraphs 1-4, and respondent was given notice of this hearing in compliance with law.

Second: Krystal Freitas

Action: Passed unanimously.

DRAFT

Mr. Kandt requested the Board find Dr. Watson guilty of Counts One through Seven consistent with paragraphs 15-22 of the Notice of Intended Action and Accusation.

Board Action:

Motion: Jade Jacobo moved to find Dr. Roosevelt Watson guilty of Counts One through Seven consistent with paragraphs 15-22 of the Notice of Intended Action and Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Kandt requested the Board to revoke Dr. Watson's Certificate of Registration No. CS12287 and respondent cannot petition for reinstatement for a period of five years, effective immediately.

Board Action:

Motion: Jade Jacobo moved to revoke Roosevelt Watson's Certificate of Registration No. CS12287, and he cannot petition for reinstatement for a period of five years, effective immediately.

Second: Krystal Freitas

Action: Passed unanimously.

6. Appeal hearing pursuant to NRS 639.2895(2) (**FOR POSSIBLE ACTION**)

A. Cobalt Medical Supply Inc. (23-122-O)

No representative was present for Cobalt Medical Supply Inc.

Gregory Zunino provided background on the appearance regarding unlicensed wholesale practice and their request for an appeal from their citation and fine order.

Mr. Zunino called Kristopher Mangosing, Assistant Board Coordinator for the Nevada Board of Pharmacy, as a witness.

President Park reminded Kristopher Mangosing that he is still sworn in from an earlier matter.

Mr. Zunino questioned Mr. Mangosing on serving the 21-day Notice of Hearing to Cobalt Medical Supply Inc.

Mr. Zunino presented a Declaration by Mui Lee regarding her findings on Cobalt Medical Supply Inc.

Mr. Zunino requested the admission of the 21-day Notice of Hearing as Exhibit 1 and Declaration of Mui Lee as Exhibit 2.

President Park admitted the documents as Exhibit 1 and 2.

Rosalie Bordelove, Deputy Attorney General for the Attorney's General's Office, recommended amending the motion to include that respondent was adequately notified of the hearing.

Board Action:

Motion: Jade Jacobo moved to uphold the $5000 Citation and Fine for Cobalt Medical Supply Inc. and moved to find that respondent was adequately notified of the hearing based on Board counsel's recommendation.

Second: Wayne Mitchell

Action: Passed unanimously.

21. Executive Secretary Report:

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. COVID-19 Response
F. Licensing Software Update
G. Licensing Activities Report
H. PMP Integration
I. Citations & Fines issued pursuant to NRS 632.2895

Dave Wuest, Executive Secretary for the Nevada Board of Pharmacy, provided the Executive Secretary Report to the Board's satisfaction.

17. Discussion and possible action to request an Attorney General Opinion pursuant to NRS 228.150 on the authority of a Nevada-licensed homeopathic physician to prescribe or dispense a controlled substance or dangerous drug. **(FOR POSSIBLE ACTION)**

Brett Kandt provided background on the Attorney General Opinion request to the Board.

Rosalie Bordelove, Deputy Attorney General for the Attorney's General's Office, responded with some informational background.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to request an Attorney General Opinion pursuant to NRS 228.150 on the authority of a Nevada-licensed homeopathic physician to prescribe or dispense a controlled substance or dangerous drug

Second: Krystal Freitas

Action: Passed unanimously.

4. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

E.	CVS Pharmacy #8804	(19-131-PH-S)
F.	Sandra Le, RPh	(19-131-RPH-A-S)
G.	Khanh V. Pham, RPh	(19-131-RPH-B-S)

Rolf Zakariassen and Jade Jacobo recused themselves from these matters due to their employment with CVS.

Krystal Freitas disclosed that she knows Khanh Pham but stated that she can participate in this matter fairly and without bias.

William Stilling appeared as counsel on behalf of CVS Pharmacy #8804.

Sandra Le and Khanh Pham appeared and were sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino prosecuted the case regarding a patient undergoing in vitro fertilization (IVF) and prescribed endometrin; however, she received a misfill of misoprostol, a medication used to terminate a pregnancy, not to assist with fertility treatments.

Mr. Zunino requested the admission of stipulated Exhibits 1-14 into the record.

President Park admitted Exhibits 1-14.

Mr. Zunino called the complaint witness, Timika Thomas.

Timika Thomas appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Zunino questioned Ms. Thomas on the events that occurred with the misfill.

Mr. Stilling cross-examined Ms. Thomas.

Ms. Thomas answered Mr. Zunino’s questions and provided a statement regarding the misfill.

Mr. Zunino called Sandra Le as a witness.

President Park reminded Ms. Le that she is still sworn in from previously.

Mr. Zunino questioned Ms. Le on the exhibits and the events that occurred with the misfill.

Mr. Stilling re-crossed Ms. Le.

The Board questioned Ms. Le.

Mr. Zunino called Khanh Pham as a witness.

President Park reminded Mr. Pham that he is still sworn in from previously.

Mr. Zunino questioned Mr. Pham on the exhibits and the events that occurred with the misfill.

Mr. Still re-crossed Mr. Pham.

The Board questioned Mr. Pham.

Mr. Zunino called Ms. Le as a witness again and questioned her.

Board discussion ensued.

Board Action:

Motion: President Park moved to make Findings of Fact consistent with paragraphs 5-13 of the Notice of Intended Action and Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Board discussion ensued on whether they found Sandra Le guilty of Counts One and Two.

Board Action:

Motion: Krystal Freitas moved to find Sandra Le guilty of Count One and Count Two.

Second: Wayne Mitchell

Action: Passed unanimously.

Board discussion ensued on whether they found Khanh Pham guilty of Count Three.

DRAFT

Board Action:

Motion: Wayne Mitchell moved to find Khanh Pham guilty of Count Three.

Second: Krystal Freitas

Action: Passed unanimously.

Board discussion ensued on whether they found CVS Pharmacy #8804 guilty of Count Four.

Board Action:

Motion: Krystal Freitas moved to find CVS Pharmacy #8804 guilty of Count Four.

Second: Wayne Mitchell

Action: Passed unanimously.

Board discussion ensued on the proposed discipline for Sandra Le Certificate of Registration No. 18241.

Rosalie Bordelove read NAC 639.955(1)(d) into the record.

Board Action:

Motion: Wayne Mitchell moved to award the attorney fees and costs of $1,056.60 on the basis that they were reasonable, necessary, and actually incurred.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Wayne Mitchell moved to make the following penalties for Sandra Le Certificate of Registration No. 18241: 1) pay a fine of $2,000 for the violations; 2) 5 hours of Continuing Education (CE) courses relating to safe medication practice within twelve months of the Order; 3) Certificate of Registration No.18241 is revoked, revocation is stayed, and respondent is placed on probation for one year, effective immediately; and 4) pay $352.20 to partially reimburse the Board for recoverable attorney's fees and investigative costs.

Second: Richard Tomasso

Action: Passed unanimously.

DRAFT

Board discussion ensued on the proposed discipline for Khanh Pham Certificate of Registration No. 16235.

Board Action:

Motion: Wayne Mitchell moved to make the following penalties for Khanh Pham Certificate of Registration No. 16235: 1) pay a fine of $750 for the violations; 2) pay $352.20 to partially reimburse the Board for recoverable attorney's fees and investigative costs; 3) 3 hours of Continuing Education (CE) courses relating to safe medication practice; and 4) Certificate of Registration No.16235 is revoked, revocation is stayed, and respondent is placed on probation for one year, effective immediately.

Second: Richard Tomasso

Action: Passed unanimously.

Board discussion ensued on the proposed discipline for CVS Pharmacy #8804, License No. PH01093.

Board Action:

Motion: Wayne Mitchell moved to make the following penalties for CVS Pharmacy #8804 License No. PH01093: 1) pay a fine of $10,000 for the violations; and 2) pay $352.20 to partially reimburse the Board for recoverable attorney's fees and investigative costs.

Second: Richard Tomasso

Action: Passed unanimously.

Public Comment September 6, 2023, 4:41 PM.

There was no public comment.

President Park recessed the meeting for the night and reconvened the meeting the next morning.

Board Members Present:

Helen Park Krystal Freitas Wayne Mitchell Rolf Zakariassen
Richard Tomasso Jade Jacobo

Board Members Absent:

Gener Tejero

DRAFT

Board Staff Present:

Dave Wuest	Yenh Long	Shirley Hunting	Kristopher Mangosing
Brett Kandt	Peter Keegan	Gregory Zunino	Darlene Nases
Joe Dodge	Dena McClish	Kenneth Scheuber	Leo Basch
Luis Curras			

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

Dave Wuest stated that this Board Meeting is being held over Zoom and follows the Governor's directive and Open Meeting Laws for Nevada.

Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. All Board members were present except Gener Tejero, and a quorum was established.

Public Comment September 7, 2023, 9:00 AM

There was no public comment.

Thursday September 7, 2023 – 9:00 am

19. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2) **(FOR POSSIBLE ACTION):**

    A. **Amendment to the Nevada Administrative Code ("NAC") 639.** The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto. (LCB File No. R196-22)

Dave Wuest provided background on the public hearing item.

President Park opened the floor to public comment.

There was no public comment.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt the proposed Amendment to Nevada Administrative Code (NAC) 639. (LCB File No. R196-22)

Second: Wayne Mitchell

Action: Passed unanimously.

◈ WORKSHOP ◈

Thursday September 7, 2023 – 9:00 am

18. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2) **(FOR POSSIBLE ACTION):**

A. **Amendment of Nevada Administrative Code (NAC) 639.694: Administrator required.** The proposed amendment to NAC 639.694 will allow for an inventory of certain durable medical equipment to be stored at a licensed hospital and provided to patients upon discharge from the hospital.

Gregory Zunino provided background on proposed regulation workshop item.

President Park opened the floor to public comment.

There was no public comment.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt proposed regulation with the following amendments: 5(a) the administrator is limited to five locations within a 50-mile radius, remove 5(b), and 5(c) will put the contractual obligation on the applicant.

Second: Wayne Mitchell

Action: Passed unanimously.

B. **Amendment of Nevada Administrative Code (NAC) 639.520: Security of Prescription Departments Administrator required.** Current law imposes certain requirements for the security of a pharmacy. The Board will solicit comments regarding these requirements.

Dave Wuest provided background on proposed regulation workshop item.

President Park opened the floor to public comment.

Liz McMenamin, Retail Association of Nevada, commented that this will be costly for consumers/pharmacies. These laws will not deter people from stealing drugs in these pharmacies. She would like the Board to work with the Retail Association on this item.

Lauren Paul, Executive Director of Regulatory Affairs at CVS Health, suggests combining two sections in Nevada law relating to the security of the premises and the security of the prescription departments which personnel ensures the security of the pharmacy, must have a barrier of some type, and must have some type of locking mechanism on the doors but not the specificity of the five-foot wall or dead bolt lock. She suggests shrinking the specificity of NAC 639.520 and combining the similar language of NAC 639.470 into one. Also, an opportunity can be brought before the Board to provide alternate security, processes, or systems if the Board should wish for review.

Board discussion ensued.

Mr. Wuest will meet with the industry on the proposed regulation and report to the Board at a future meeting.

C. **Amendment of Nevada Administrative Code (NAC) 639.XXX: Administrative Fine in Lieu of Disciplinary Action.** The proposed amendment clarifies the circumstances when the Board may assess an administrative fine pursuant to NRS 639.2895 in lieu of taking formal disciplinary action against a holder of a certificate, certification, license, or permit issued by the Board. With respect to minor violations, the proposed amendment further limits the amount of the fine that could otherwise be imposed pursuant to NRS 639.2895.

Gregory Zunino provided background on proposed regulation workshop item.

President Park opened the floor to public comment.

There was no public comment.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt proposed regulation Amendment of Nevada Administrative Code (NAC) 639.XXX: Administrative Fine in Lieu of Disciplinary Action as presented by Mr. Zunino.

Second: Krystal Freitas

Action: Passed unanimously.

D. **Amendment of Nevada Administrative Code (NAC) 639.XXX: Assembly Bill No. 156 (2023) – An Act Relating to Substance Use Disorders.** This law

requires the Board to adopt regulations related to: (a) The requirements to register with the Board to engage in the activity authorized by this section; and (b) Establishing a protocol for the actions authorized by the bill.

Dave Wuest provided background on proposed regulation workshop item.

President Park opened the floor to public comment.

Krystal Riccio is in favor of the proposed language, but she suggests changing “medication for addiction treatment” to “medication assisted treatment” or “medication substance abuse disorder” to be more medical about it rather than use stigmatizing language.

Liz McMenamin from the Retail Association of Nevada is in favor of the proposed language.

Zach Rosko, Pharmacist, is in favor of the proposed language.

Ken Kunke from the Nevada Pharmacy Alliance is in favor of the proposed language.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt proposed regulation Amendment of Nevada Administrative Code (NAC) 639.XXX: Assembly Bill No. 156 (2023) – An Act Relating to Substance Use Disorders.

Second: President Park

Action: Passed unanimously.

12. Applications for Nevada Wholesalers License (NRS 639.233) Appearance **(FOR POSSIBLE ACTION)**

Reliable Healthcare Logistics, LLC – Reno, NV

Lizbeth Hernandes, Compliance Specialist, and Cheryl Oleski, Director of Quality, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Peter Keegan questioned Ms. Hernandes and Ms. Oleski on if they are allowed to speak on behalf of the company and requested a Letter of Authorization.

Mr. Keegan provided background on the application and questioned their business model.

Ms. Hernandes and Ms. Oleski answered questions to the Board’s satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Nevada wholesaler application for Reliable Healthcare Logistics, LLC.

Second: Krystal Freitas

Action: Passed unanimously.

10. Application for Out-of-State Outsourcing Facility (NRS 639.100) – Appearance (**FOR POSSIBLE ACTION**)

    E. Hikma Pharmaceuticals USA Inc. – Cherry Hill, NJ
    B. Hikma Injectables USA Inc. – Dayton, NJ

Cindy Mitman (Managing Pharmacist for Dayton, NJ location), Mahmoud El Rouby (Managing Pharmacist for Cherry Hill, NJ location), Jenny Giuffre (Associate Director of Microbiology and Environmental Monitoring), and John Kalis (Senior Director of Regulatory Affairs) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge, Nevada Board of Pharmacy Inspector, questioned Hikma Pharmaceuticals USA Inc. on their business, their FDA inspection results, and their New Jersey Board Inspection results.

The Board questioned Hikma Pharmaceuticals USA Inc. on their application regarding their compounding questionnaire.

Mr. El Rouby answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the out-of-state outsourcing facility for Hikma Pharmaceuticals USA Inc.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Dodge questioned Hikma Injectables USA Inc. on their business, their FDA inspection results, and their New Jersey Board Inspection results.

Board Action:

DRAFT

Motion: Jade Jacobo moved to approve out-of-state outsourcing facility for Hikma Injectables USA Inc.

Second: Krystal Freitas

Action: Passed unanimously.

13. Applications for Pharmaceutical Technician in Training Registration (NAC 639.242) – Appearance. (**FOR POSSIBLE ACTION)**

A. Adrianna Rivera

Adrianna Rivera appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino provided background on the application and her disclosure regarding a DUI.

Mr. Zunino questioned Ms. Rivera about the events that occurred with her DUI and why she wants to be a Pharmaceutical Technician.

The Board questioned if she is seeking treatment with alcohol counseling or has any other issues with alcohol.

Ms. Rivera answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the pharmaceutical technician in training application for Adrianna Rivera pending favorable PRN-PRN or equivalent evaluation.

Second: Rolf Zakariassen

Action: Passed unanimously.

B. Bernice Benscoter

This matter was withdrawn.

8. Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

A. Brava NC LLC – Morrisville, NC

Natalie Young, Managing Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge provided background on the application and questioned the business model, Ms. Young's pharmacist experience, and their North Carolina's pharmacy inspection results.

Ms. Young answered questions to the Board's satisfaction.

Board Action:

Motion: Krystal Freitas moved to approve the out-of-state compounding pharmacy license for Brava NC LLC.

Second: Jade Jacobo

Action: Passed unanimously.

15. Petition for Reinstatement of Controlled Substance Registration – Appearance. **(FOR POSSIBLE ACTION)**

Ronald Smith

Ronald Smith appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt provided background on the application and Dr. Smith's petition for reinstatement with the Board.

The Board questioned Mr. Smith about what has changed since the Board revoked his controlled substance registration and what he intends to do if he is reinstated.

Mr. Smith answered the Board's questions.

Mr. Kandt commented that Dr. Smith's application is incomplete as all disciplinary documents are not provided.

Board discussion ensued.

The Board will table this application and will return to this matter.

8. Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

B. Primera Professional Pharmacy – Sugar Land, TX

Paula Hooper, Managing Pharmacist, and Patty Heinz, Vice President of Operations, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge provided background on the application and questioned the business model, Ms. Hooper's disclosure, and their policies and procedures.

Ms. Hooper and Ms. Heinz answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the out-of-state compounding pharmacy application for Primera Professional Pharmacy.

Second: Krystal Freitas

Action: Passed unanimously.

C. Town Total Compounding Center – Woodbury, NY

Joseph Navarra, Owner and Pharmacist, and Justin Tan, Managing Pharmacist, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge provided background on the application and questioned the business model and Mr. Tan's pharmacist experience.

Board discussion ensued.

Dave Wuest questioned their business model which may not comply with Nevada law, so he recommends that Mr. Navarra might want to contact Board staff to confirm.

Board Action:

Motion: Rolf Zakariassen moved to approve the out-of-state compounding pharmacy application for Town Total Compounding Center.

Second: Jade Jacobo

Action: Passed unanimously.

14. Application for Pharmacist Registration by Reciprocation NRS 639.134) – Appearance (**FOR POSSIBLE ACTION**)

James Arnett

James Arnett appeared and was sworn in by President Park prior to answering questions and offering testimony.

Dave Wuest provided background on the application and questioned Mr. Arnett on his disclosure regarding diversion of controlled substances.

Mr. Arnett provided clarification on the events that occurred with his disclosures.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the pharmacist registration by reciprocation application for James Arnett.

Second: Krystal Freitas

Action: Passed unanimously.

8. Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

D. WP Pharma Labs, Inc. – Dallas, TX

Matthew Watkins, Director of Quality, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge provided background on the application and questioned the business model, Ms. May's pharmacist experience, and their policies and procedures.

Mr. Watkins answered Mr. Dodge's questions.

Mr. Dodge has concerns regarding their peptide compounding. If the Board goes forward with approving, he recommends WP Pharma Labs provide information on the sources of where they are receiving their peptides.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the out-of-state compounding pharmacy application for WP Pharma Labs, Inc. pending positive inspection at the company's expense.

Second: Krystal Freitas

Action: Passed unanimously.

16. Application for Physician Assistant -Prescribe/Controlled Substance Registration – Appearance **(FOR POSSIBLE ACTION)**

Aaron Kuehl

Aaron Kuehl appeared and was sworn in by President Park prior to answering questions and offering testimony.

Dave Wuest questioned Mr. Kuehl about his disclosure regarding diversion of controlled substances, resisting an officer, and entering the Professional Recovery Network (PRN) Program in Nevada.

Mr. Keuhl provided background on the events that occurred with his disclosures and why he is looking to go back into the medical field.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the application for physician assistance - prescribe/controlled substance for Aaron Kuehl with conditions that he must comply with the remainder of his Nevada Board of Medical Examiners Agreement.

Second: President Park

Action: Passed unanimously.

15. Petition for Reinstatement of Controlled Substance Registration – Appearance. **(FOR POSSIBLE ACTION)**

Ronald Smith

The Board returned back to Ronald Smith's application.

Brett Kandt presented documentation to the Board for Ronald Smith: 1) a letter from North Carolina Medical Board entered a Partial Relief of Consent Order Obligations; 2) Judgement in a Criminal Case for Case Number: 2:19-cr-00154-RFB-VCF; and 3) North Carolina Medical Board Partial Relief of Consent Order Obligations.

Mr. Kandt commented that Mr. Smith's Nevada medical license is active and unrestricted.

Mr. Smith provided background on the events that occurred and the practice that he intends to do if his controlled substance registration is reinstated.

Board discussion ensued.

Board Action:

Motion: Richard Tomasso approved the controlled substance application for Ronald Smith with condition that he comply with the remainder of his Nevada PRN Agreement.

Second: Jade Jacobo

Action: Passed unanimously.

Richard Tomasso and Wayne Mitchell were excused from the hearing at 1:30 PM.

Wayne Mitchell returned to the meeting at 1:36 PM.

10. Application for Out-of-State Outsourcing Facility (NRS 639.100) – Appearance (**FOR POSSIBLE ACTION**)

C. PQ Pharmacy – Brooksville, FL

Angela Kassay (Vice President), Cari Smith (Quality Manager), Doug Sway (Pharmacist), and Hale Dimetry (Chief Operating Officer and Managing Pharmacist) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge questioned the business model, their FDA inspection, and their policies and procedures.

PQ Pharmacy answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the out-of-state outsourcing facility for PQ Pharmacy.

Second: Krystal Freitas

Action: Passed unanimously.

A. BPI Labs, LLC – Largo, FL

This matter was continued to a future Board meeting.

DRAFT

D. STERRX, LLC – Plattsburgh, NY

This application was withdrawn.

22. Applications for Out-of-State Wholesalers License (NRS 639.233) Appearance **(FOR POSSIBLE ACTION)**

STERRX, LLC – Plattsburgh, NY – Background Check Not Required - VAWD-Accredited (NAC 639.593(7)(c))

This application was withdrawn.

8. Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

E. 1st Choice Pharmacy – Holiday, FL

This matter was continued to a future Board meeting.

9. Application for Out-of-State Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

Seven Hills Pharmacy, LLC – Sharonville, OH

There was no representative present on behalf of Seven Hills Pharmacy, LLC.

This matter will be continued to a future Board meeting.

23. Public Comment September 7, 2023, 1:48 PM

There was no public comment.

22. Date and Location of Next Scheduled Board Meeting:

October 11-12, 2023 – Las Vegas, NV

23. Adjournment

DRAFT

4

4A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG ☐ Ownership Change* ■ Name Change* ☐ Location Change*	* If making a change, provide current license number: M P01610	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: HealthDyne Pharmacy

MDEG Physical Address: 500 Eagles Landing Drive, Suite B

City: Lakeland State: FL Zip: 33810

Mailing Address (if different from physical address): 500 Eagles Landing Drive

City: Lakeland, State: FL Zip: 33810

Telephone: 888-479-2000 Website: www.welldyne.com

Email: administration@welldyne.com

Name of MDEG Administrator (NAC 639.694): Joseph Michael Fleischman

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions ☐ Pharmacies[a] ☐ Practitioners[a] ☐ Hospitals/Clinics[a] ☐ Clinics[a] ☐ Wholesalers[a] ☐ Other business entities (specify)[a]:	☐ Medical Gases** ☐ Respiratory Equipment** ☐ Life-sustaining equipment** ☐ Parenteral and Enteral Equipment** ☐ Assistive Equipment ☒ Diabetic Supplies ☐ Orthotics and Prosthetics ☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription. [a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954): Name: Joseph M. Fleischman Telephone: 888.479.2000

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9:00 a.m. to 5:00 p.m.	■ Tue: 9:00 a.m. to 5:00 p.m.	■ Wed: 9:00 a.m. to 5:00 p.m.	■ Thurs: 9:00 a.m. to 5:00 p.m.	■ Fri: 9:00 a.m. to 5:00 p.m.
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Florida - 101969800
Medicare Part B - 1093974982

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): WD Wolverine Holdings, LLC

Corporation/Organization Name: WellDyneRx, LLC

Mailing Address: 500 Eagles Landing Drive

City: Lakeland State: FL Zip: 33810

Telephone: 888.479.2000 Email: administration@welldyne.com

Contact Person Name: Phillip P. Bisesi

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Phillip P. Bisesi

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

06.06.2023

Date

Board Use Only	Date Received: 6/12/23	Amount: $500 - CK - 902961 ✓ processed 6/12/23 LG

Wisconsin

WellDyneRx-FL

WellDyneRx-FL, a pharmacy located at 500 Eagles Landing Drive, Lakeland, FL 33810 Wisconsin License # 438-043 is owned by WellDyneRx, LLC. The Discipline was for WellDyneRx-FL's Wisconsin License #438-043.

WellDyneRx-FL is licensed in the State of Wisconsin as an out of state pharmacy. On May 6, 2014, a WellDyneRx-FL staff pharmacist attempted to transfer a refill prescription order of hydrochlorot 50mg tablets to another pharmacy via facsimile machine. WellDyneRx-FL did not require the pharmacist to contact the receiving pharmacist to verbally verify the prescription. WellDyneRx-FL voluntarily corrected the issue and the Wisconsin Pharmacy Examining Board required WellDyneRx-FL to pay a forfeiture in the amount of $2,500.00 and costs in the amount of $129.83.

WellDyneRx-FL regrets that this incident occurred, but WellDyneRx-FL has learned from the incident and has voluntarily implemented measures in an effort to mitigate future incidents. Specifically, this incident has suggested a need for WellDyneRx-FL to increase training of its pharmacy staff based on individual state laws and policies. As such, WellDyneRx-FL has developed independent compliance plans for each state through compliance and quality control committees.

In addition, said compliance and quality control committees are examining current training procedures for pharmacy staff. WellDyneRx-FL has required and will continue to require the retraining of individual pharmacy staff on compliance issues specific to each state in which WellDyneRx-FL operates.

WellDyneRx-FL strives to operate a fully compliant pharmacy operation. This incident suggested an area where WellDyneRx-FL can improve, and WellDyneRx-FL has implemented policies and procedures to mitigate similar future incidents.

Wisconsin Department of Safety and Professional Services
Division of Legal Services and Compliance
1400 E Washington Ave
PO Box 7190
Madison WI 53707-7190
RETURN SERVICE REQUESTED

Phone: 608-266-2112
Web: http://dsps.wi.gov
Email: dsps@wisconsin.gov

Scott Walker, Governor
Dave Ross, Secretary

Email: nilajah.hardin@wisconsin.gov
Direct Line: 608-267-7139
Facsimile: 608-266-2264

December 29, 2016

WELLDYNERX-FL
500 EAGLES LANDING DRIVE
LAKELAND, FL 33810

RE: Completion of Requirements; Final Decision and Order No. 0004736 ("Order")

Dear WellDyneRx-FL,

This letter confirms that you have paid the costs of the proceeding in the amount of $129.83 and forfeiture in the amount of $2,500.00, as ordered by the Pharmacy Examining Board on May 25, 2016. Therefore, all terms of the above Order have now been satisfied. Please feel free to contact me if you have any questions.

Sincerely,

Nilajah Hardin
Department Monitor
Division of Legal Services and Compliance

Cc:
Patrick J. Knight, Attorney
330 E Kilbourn Avenue, Suite 1170
Milwaukee, WI 53202

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
WELLDYNERX-FL, RESPONDENT.	:	0004736

Division of Legal Services and Compliance Case No. 14 PHM 085 and 14 PHM 136

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

WelldyneRx-FL
500 Eagles Landing Dr.
Lakeland, FL 33810

Wisconsin Pharmacy Examining Board
P.O. Box 8366
Madison, WI 53708-8366

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190
Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Respondent WelldyneRx-FL is licensed in the state of Wisconsin as an out-of-state pharmacy, having license number 438-043, first issued on March 30, 2009 and current through May 31, 2016. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 500 Eagles Landing Drive, Lakeland, Florida 33810.

2. On May 6, 2014, Respondent attempted to transfer a refill prescription order of hydrochlorot 50 mg tablets to a Fitchburg, Wisconsin pharmacy. The entire process was done via facsimile machine.

3. As a matter of policy, Respondent did not require a staff pharmacist to contact a receiving pharmacist to verbally verify the prescription order transfer. Respondent has voluntarily corrected the issue.

4. In resolution of this matter, Respondent consents to the entry of the following Conclusions of Law and Order.

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in the Findings of Fact, WelldyneRx-FL violated Wis. Admin. Code § Phar 7.055(1)(a), by failing to communicate directly between 2 pharmacists either by verbal transfer or by a computer system transfer.

3. Respondent, by violating Wis. Admin. Code § Phar 7.055(1)(a), engaged in unprofessional conduct as defined by Wis. Stat. § 450.10(1)(a)2., by violating a state rule which substantially relates to the practice of the licensee.

4. As a result of the above violations, WelldyneRx-FL is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

1. The attached Stipulation is accepted.

2. Respondent WelldyneRx-FL, license number 438-043, shall, within 90 days of the date of this Order, pay a FORFEITURE in the amount of $2,500.

3. Within ninety (90) days from the date of this Order, WelldyneRx-FL shall pay COSTS of this matter in the amount of $129.83.

4. Payment of costs and forfeiture (made payable to the Wisconsin Department of Safety and Professional Services) shall be sent by Respondent to the Department Monitor at the address below:

Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190, Madison, WI 53707-7190
Telephone (608) 267-3817; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

5. Case number 14PHM136 is closed for compliance gained.

6. Violation of any of the terms of this Order may be construed as conduct imperiling public health, safety and welfare and may result in a summary suspension of Respondent's license. The Board in its discretion may in the alternative impose additional conditions and limitations or other additional discipline for a violation of any of the terms of this Order. In the event Respondent fails to timely submit payment of costs or forfeiture as ordered, Respondent's license (no. 438-043) may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with payment of costs and forfeiture.

7. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by: _____ 5/25/16
A Member of the Board Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	STIPULATION
WELLDYNERX-FL, RESPONDENT.	:	0004736

Division of Legal Services and Compliance Case No. 14 PHM 085 and 14 PHM 136

Respondent WelldyneRx-FL and the Division of Legal Services and Compliance, Department of Safety and Professional Services stipulate as follows:

1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.

2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights:

- the right to a hearing on the allegations against Respondent, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
- the right to confront and cross-examine the witnesses against Respondent;
- the right to call witnesses on Respondent's behalf and to compel their attendance by subpoena;
- the right to testify on Respondent's own behalf;
- the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
- the right to petition for rehearing; and
- all other applicable rights afforded to Respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.

3. Respondent is aware of Respondent's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation. Respondent is represented by Attorney Patrick Knight.

4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining (Board). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

WellDyneRx-FL, Respondent
500 Eagles Landing Dr.
Lakeland, FL 33810
License no. 438-43

3/29/16
Date

Patrick J. Knight, Attorney for Respondent
Gimbel-Reilly-Guerin-Brown LLP
330 E Kilbourn Ave., Suite 1170
Milwaukee, WI 53202

3/30/16
Date

Sandra L. Nowack, Prosecuting Attorney
Attorney for the Division of Legal Services and Compliance
Wisconsin State Bar No. 1025643
Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190
Tel. (608) 266-8098

3/31/16
Date

FW: MDEG Application - MP01610 HealthDyne Pharmacy - Lakeland, FL [QBLLP-ACTIVE.FID42975033]

Veeder, Shaylynn L. <Shaylynn.Veeder@quarles.com>

Thu 7/6/2023 2:28 PM

To:Jessette Phaynarikone <jphaynarikone@pharmacy.nv.gov>
Cc:Vue, Janny V. <Janny.Vue@quarles.com>

3 attachments (522 KB)

WDRX FL - Nevada - MDEG - Administrator Application - Executed.pdf; FL - Certificate of Status - WellDyneRx, LLC - 2023.06.14.pdf; FL - HealthDyne Pharmacy - Online Verification.pdf;

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Jessette,

On behalf of the permit holder above, please find the following responses to your request below:

1. Proof of insurance – must be current and active

   We have requested this and will provide it once we receive it.

2. Certificate of Good Standing – can be obtained from the Secretary of State's Office in the State where the business is domiciled (must be dated within 1 year)

   Certificate of Good Standing attached.

3. MDEG Administrator Application - Please read the requirements for Administrator on application – NAC 639.694

   MDEG Administrator Application attached.

4. Copy of MDEG License – Out of state

   The Florida home permit verification is attached. Florida does not require a separate MDEG permit.

5. Personal History Record Application – must be completed by EACH shareholder/stockholder/owner/partner. (Owning more than 10% of the business or top 4 shareholders) - (wet signature required)

   There are no individual shareholders/owners. None of the officers have any ownership interest in the pharmacy.

If any additional information is needed for this application, please let me know.

WellDyneRx, LLC
FEIN: 84-1515837

Officer List:

Name	Title
Stephen M. Saft	Chief Executive Officer & Treasurer
David A. Skomo	Chief Operating Officer
Phillip P. Bisesi	Senior Vice President & Secretary

State of Florida
Department of State

I certify from the records of this office that WELLDYNERX, LLC is a limited liability company organized under the laws of the State of Florida, filed on February 14, 2017, effective August 26, 1999.

The document number of this limited liability company is L17000032307.

I further certify that said limited liability company has paid all fees due this office through December 31, 2023, that its most recent annual report was filed on January 27, 2023, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourteenth day of June, 2023

Secretary of State

Tracking Number: 5141926852CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Department of Health

WellDyneRx, LLC HealthDyne Pharmacy

License Number: PH23389

Data As Of 7/6/2023

Profession	Pharmacy	
License	PH23389	
License Status	CLEAR/	
Qualifications	Community Pharmacy	Schedule II & III
License Expiration Date	2/28/2025	
License Original Issue Date	05/21/2008	
Address of Record	500 EAGLES LANDING DRIVE Suite B LAKELAND, FL 33810	
Discipline on File	No	
Public Complaint	No	

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW0974863	05-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-10-2023

WELLDYNERX LLC
DBA HEALTHDYNE PHARMACY
500 EAGLES LANDING DR
LAKELAND, FL 338102899

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW0974863	05-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-10-2023

WELLDYNERX LLC
DBA HEALTHDYNE PHARMACY
500 EAGLES LANDING DR
LAKELAND, FL 338102899

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW0974863	05-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-10-2023

WELLDYNERX LLC
DBA HEALTHDYNE PHARMACY
500 EAGLES LANDING DR
LAKELAND, FL 338102899

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 2/16/2024 | 2/21/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Lockton Companies 8110 E Union Avenue Suite 100 Denver CO 80237 (303) 414-6000	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED 1477414 WellDyneRX, LLC 500 Eagles Landing Drive Lakeland, FL 33810	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Arch Specialty Insurance Company — 21199 INSURER B : Zurich American Insurance Company — 16535 INSURER C : ACE American Insurance Company — 22667 INSURER D : Berkley Insurance Company — 32603 INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 14497788 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:	N	N	FLP006017706	2/16/2023	2/16/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 100,000 $ 5,000 $ 1,000,000 $ 3,000,000 $ 3,000,000 $
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY	N	N	FLP006017706	2/16/2023	2/16/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ XXXXXXX $ XXXXXXX $ XXXXXXX $ XXXXXXX
A A	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [X] CLAIMS-MADE [ ] DED [ ] RETENTION $	N	N	FLP006017706 Prof.Liab.RetroDate:2/16/20	2/16/2023	2/16/2024	EACH OCCURRENCE AGGREGATE $	$ 10,000,000 $ 10,000,000 $ XXXXXXX
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [N] N/A If yes, describe under DESCRIPTION OF OPERATIONS below		N	WC014390906	2/16/2023	2/16/2024	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
A C D	Pharmacy Prof. Liab. PBM E&O Liab. Crime	N	N	FLP006017706 MPO14114300200 BCCR4500242326	2/16/2023 2/16/2023 2/16/2023	2/16/2024 2/16/2024 2/16/2024	$1M/$3M Retro Date: 2/16/2020 Limit: $3M/Ret $250K Limit: $2M per Occ.	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

14497788
For Information Only

CANCELLATION See Attachment

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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Excess Liability Schedule

Carrier	Policy Number	Limit
Lloyd's of London	MC-FAL-1000459	$25,000,000
Lloyd's of London	B0180PC2309645	$30,000,000

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

NAC 639.694

1. **Each medical products provider or medical products wholesaler shall employ an administrator at all times. The administrator must:**
   a. Be a natural person;
   b. Have a high school diploma or its equivalent;
   c. Have:
      i. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
      ii. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
   d. Be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
   e. Be approved by the Board.
2. The administrator shall ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.
3. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after the beginning of the employment.
4. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

NAC 639.6946

1. Except as otherwise provided in NAC 639.6945, a medical products provider shall:
   a. Provide services for all medical products sold, leased or otherwise provided by the medical products provider, including, without limitation, set up, repair and maintenance.
   b. Employ an administrator and other employees sufficient to provide the services described in paragraph (a).

NAC 639.6957

1. A medical products wholesaler shall:
   a. Employ a facility administrator and other employees sufficient to operate, set up, repair, maintain and service all medical products sold, leased or otherwise provided by the medical products wholesaler.

Please mail this completed application and all other required documents with your MDEG and/or Wholesaler Application to the address indicated above.

If you have any questions, please contact the Nevada State Board of Pharmacy at 775-850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG HealthDyne Pharmacy MDEG License # (if applicable) MP01610

Physical Address 500 Eagles Landing Drive, Suite B

City Lakeland State Florida Zip 33810

Mailing Address (if different from physical address) 500 Eagles Landing Drive

City Lakeland State FL Zip 33810

Telephone 888-479-2000 Website www.welldyne.com

Licensing Company Email administration@welldyne.com

Section 2: Personal information

First Joseph Middle Michael Last Fleischman

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 500 Eagles Landing Drive

City Lakeland State FL Zip 33810

Telephone [redacted] Email jfleischman@welldyne.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No	
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?			N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nova Southeasern University		1995 - 1999	
Address	**City**	**State**	**Zip**
3301 College Avenue	Davie	FL	33314
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of South Florida		1990 - 1995	
Address	**City**	**State**	**Zip**
4202 South Fowler Avenue	Tampa	FL	33620
Diploma/Degree obtained, if any			
BS in Biology			

School Name		From - To (MM/YY – MM/YY)	
Bloomingdale Senior High		1987 - 1989	
Address	**City**	**State**	**Zip**
1700 Bloomingdale Avenue	Valrico	FL	33596
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2012 - present	[redacted] Hollington Oaks Place	Brandon	FL	33511
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
WellDyneRx, LLC			
Business Address	**City**	**State**	**Zip**
500 Eagles Landing Drive	Lakeland	FL	33810
Phone	**Title**	**Number of Employed Hours**	
863.583.6063	Pharmacist in Charge		
Description of Duties			
I have been the pharmaicst in charge since 11/2017 working a minimum of 40hr per week.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Joseph Plew — Original Signature (electronic, copies or stamps not accepted)

6-9-23 — Date

I, Joseph M. Fleischman, certify that as the MDEG Administrator for

HealthDyne Pharmacy,

that I (initial that you have read and meet the following requirements):

1. JMF Have a high school diploma or its equivalent;
2. JMF Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JMF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JMF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph M. Fleischman

Print Name (First, Last)

Joseph Fl

Original Signature (electronic, copies or stamps not accepted)

6-9-23

Date

Board Use Only	Date Received:

4B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG ■ Ownership Change* ☐ Name Change* ☐ Location Change*	* If making a change, provide current license number: M MP03103	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9) ■ Partnership (complete sections 1, 2, 3, 4, 7, 9) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Prism Medical Products, LLC

MDEG Physical Address: 112 Church Street, Suite 101

City: Elkin State: NC Zip: 28621

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Email: compliance@prism-medical.com

Name of MDEG Administrator (NAC 639.694): Christopher Cartwright

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions ☐ Pharmacies[a] ☐ Practitioners[a] ☐ Hospitals/Clinics[a] ☐ Clinics[a] ☐ Wholesalers[a] ☐ Other business entities (specify)[a]:	☐ Medical Gases** ☐ Respiratory Equipment** ☐ Life-sustaining equipment** ☐ Parenteral and Enteral Equipment** ☐ Assistive Equipment ☐ Diabetic Supplies ☐ Orthotics and Prosthetics ■ Others: See Attached Document
This application is ONLY required if MDEG products will be sold to patients by prescription. [a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954): Name: N/A Telephone: N/A

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8am - 6pm	■ Tue: 8am - 6pm	■ Wed: 8am - 6pm	■ Thurs: 8am - 6pm	■ Fri: 8am - 6pm
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed for major holidays		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
CMS PTAN for Corporate Office: 5823260001
CMS PTAN for Las Vegas, NV Office Only: 5823260002
Please see attached for additional numbers

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: Prism Medical Products, LLC - See attached documents

Mailing Address: P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 x.4373 Email: compliance@prism-medical.com

Contact Person Name: Elizabeth Hyde

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Cartwright

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7/20/23

Date

Board Use Only	Date Received: 7/25/23	Amount: 500 - CK - 022372

PRISM
HOME MEDICAL SUPPLY SPECIALISTS

P. O. BOX 476
ELKIN, NC 28621
PHONE: 1-888-244-6421
FAX: 1-800-975-6321
WWW.PRISM-MEDICAL.COM

July 17, 2023

Nevada State Board of Pharmacy 985
Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

Type of MDEG Products being Sold:

Prism Medical Products, L.L.C. is a DME provider based out of North Carolina that specializes in providing Ostomy Supplies, Surgical Dressings, Urological Supplies, limited Compression Garments, and Breast Pumps to patients via a shipping courier, e.g., FedEx, and accepts assignment for health plan reimbursement.

If you have any questions, please let us know.

ELIZABETH HYDE
ADMINISTRATIVE COMPLIANCE COORDINATOR
COMPLIANCE & GOVERNMENT AFFAIRS

Office (336) 258-4373
Fax (855) 496-2996
elizabethw@prism-medical.com

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Prism Medical Products, LLC Information Sheet

TRADITIONAL STATE MEDICAID ENROLLMENTS

AK: 1652871 (eff. 09/01/2016)

AL: 125216 (eff. 02/03/2007)

AR: 238670741 (eff. 01/15/2020)

AZ: 900533 (eff. 11/01/2013)

CA: 1548367063 (eff. 02/07/2017)

CT: 1548367063 (eff. 11/01/2016)

CO: 1548367063 (eff. 08/03/2018)

DC: 089550700 (eff. 02/26/2013)

DE: 200141712 (eff. 01/19/2016)

FL: 112645100 (eff. 12/31/2020)

GA: 003101519A (eff. 02/01/2011)

IA: 1548367063 (eff. 10/01/2013)

ID: 1548367063 (eff. 04/10/2014)

IL: 753221011001 (eff. 03/07/2012)

IN: 201002170A (eff. 11/01/2011)

KS: 30003958520001 **(Primary)** (eff. 06/30/2017)

KS: 30003958520002 **(MCOs Only)** (eff. 12/30/2020)

KY: 7100723680 (eff. 03/01/2021)

LA: 2137671 (eff. 02/01/2011)

MA: 110112813A (eff. 05/20/2016)

MD: 551509200 (eff. 01/01/2012)

ME: 1548367063 (eff. 10/01/2015)

MI: 1548367063 (eff. 03/13/2012)

MN: 1548367063 (eff. 06/06/2016)

MO: 620007567 (eff. 07/01/2013)

MS: 009376349 - FFS
: 009450798 - CHIP
(eff. 02/07/2011)

MT: 1548367063 (eff. 08/15/2018)

NC: 7704585 (eff. 02/01/2007)

NE: 10026550601 (eff. 04/12/2016)

NH: 3127231 (eff. 01/27/2021)

NJ: 0766011 (eff. 06/11/2021)

NM: 51225514 (eff. 02/11/2014)

NV: 100541636 (eff. 06/18/2014)

NY: 03581275 (eff. 09/01/2017)

OH: 0060286 (eff. 02/01/2011)

OK: 200243820A (eff. 01/31/2011)

OR: 500671501 (eff. 05/12/2014)

PA: 102564320-0002 (Promise ID) (eff. 05/01/2011)

RI: 1548367063 (eff. 05/23/2016)

SC: DM1293 (eff. 07/01/2006)

SD: 2022288 (eff. 1/21/2021)

TN: 1508032 (eff. 02/03/2007)

TX: (a.k.a 'TPI') 205277101 Traditional Medicaid (eff. 07/13/2008)

205277103 CSHCN (eff. 07/13/2008)

UT: 1548367063 (eff. 06/10/2015)

VA: 30015257160001 (eff. 06/03/2008)

VT: 1027114 (eff. 04/22/2016)

WA: 1548367063 (eff. 01/07/2014)

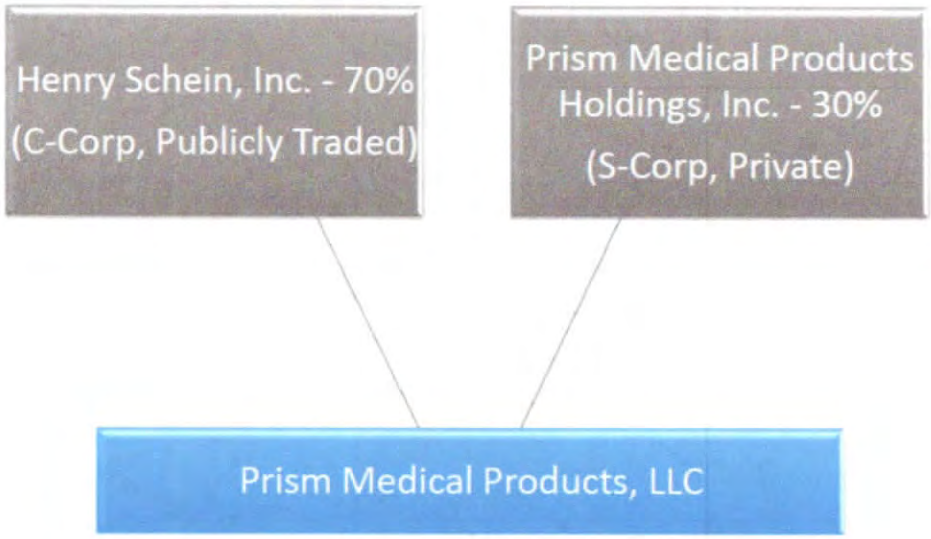
WI: 100152285 (eff. 01/01/2021)

WV: 888 (eff. 06/08/2012)

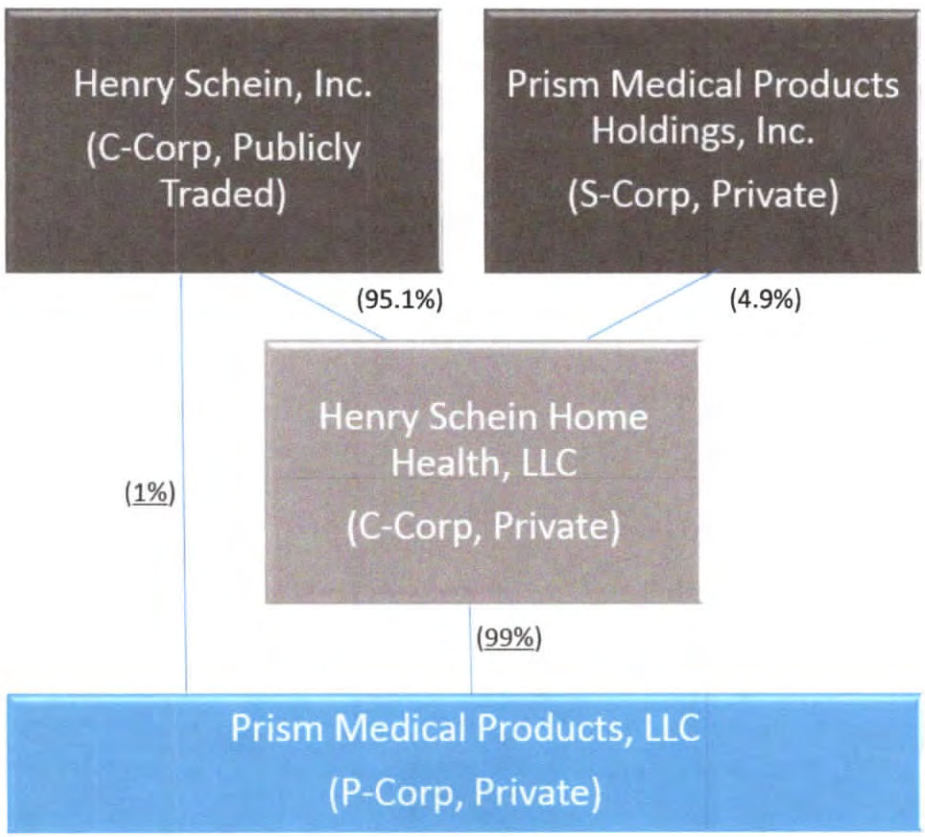
WY: 1548367063 (eff. 10/01/2016)

Prism Pre/Post Closing Information

Pre-Closing Structure



Post-Closing Structure



Address Information

Prism Medical Products, LLC
All demographic and contact information remains the same for the Elkin, NC location.

Parent Level Company
Henry Schein Home Health, L.L.C.
135 Duryea Rd.,
Melville NY 11747

Henry Schein, Inc.
135 Duryea Rd.,
Melville NY 11747

Grandparent Level Company
Prism Medical Products Holdings, Inc.
112 Church Street, Suite 102
Elkin, NC 28621

Henry Schein, Inc.
135 Duryea Rd.,
Melville NY 11747

Prism Medical Products, LLC

Prism Medical Products, LLC Officers/Board/Directors:

Prism Medical Products Holdings, Inc Representatives:

- Christopher Cartwright, President
- Kenneth Reel, Vice President

Henry Schein, Inc Representatives:

- Eileen Rosenbaum, Vice President
- Brad Connett, Senior Vice President
- Walter Siegel, SVP & General Council
- Michael Ettinger, EVP, Corporate & Legal Affairs

Henry Schein Home Health, LLC: 99% Direct Ownership

Directors

- Walter Siegel, SVP & General Council
- Michael Ettinger, EVP, Corporate & Legal Affairs
- Ronald South, SVP, CFO
- Brad Connett, SVP,
- Christopher Cartwright, VP

Officers

- Walter Siegel, SVP & General Council
- Michael Ettinger, EVP, Corporate & Legal Affairs
- Ronald South, SVP, CFO
- Brad Connett, SVP,
- Christopher Cartwright, VP
- Bob Ponzo, VP Tax
- Michael Amodio, VP and Treasurer

Henry Schein, Inc.: 1% Direct Ownership

Henry Schein is a publicly traded company with over 19,000 employees worldwide. Henry Schein does not have a traditional organizational chart. Provided below is a list of the Board of Directors and Executive Management. Please contact us if you require additional information.

Board of Directors

- Stanley M. Bergman, Chairman of the Board and Chief Executive Officer
- Mohamad Ali, Former Chief Executive Officer, IDG, Inc.
- James P. Breslawski, Vice Chairman of the Board and President
- Deborah Derby, President & CEO, Carrols Restaurant Group, Inc.
- Joseph L. Herring, Former Chief Executive Officer Covance, Inc.
- Kurt P. Kuehn, Former Chief Financial Officer, United Parcel Service, Inc.
- Philip A. Laskawy, Lead Director, Henry Schein, Inc.; and Retired Chairman, Ernst & Young, LLP (now known as EY LLP)
- Anne H. Margulies, Former Vice President and Chief Information Officer, Harvard University
- Mark E. Mlotek, Executive Vice President, Chief Strategic Officer
- Steven Paladino, Former Executive Vice President, Chief Financial Officer, Henry Schein, Inc.
- Carol Raphael, National Advisor, Manatt Health Solutions; and Former President and Chief Executive Officer, Visiting Nurse Service of New York
- Scott Serota, Former President and Chief Executive Officer of Blue Cross Blue Shield Association
- Bradley T. Sheares, Ph.D., Former Chief Executive Officer, Reliant Pharmaceuticals, Inc.; and Former President of U.S. Human Health, Merck & Co.
- Reed V. Tuckson, M.D., FACP, Managing Director of Tuckson Health Connections, LLC, and Founder, Black Coalition Against COVID-19

Executive Management

- Stanley M. Bergman, Chairman of the Board and Chief Executive Officer
- Andrea Albertini, Chief Executive Officer, International Distribution Group
- Leigh Benowitz, Senior Vice President and Chief Global Digital Transformation Officer
- James P. Breslawski, Vice Chairman of the Board and President
- David Brous, Chief Executive Officer, Strategic Business Group
- Trinh Clark, Senior Vice President and Chief Global Customer Experience Officer
- Brad Connett, Chief Executive Officer, North America Distribution Group
- Michael S. Ettinger, Executive Vice President and Chief Operating Officer
- Lorelei McGlynn, Senior Vice President, Chief Human Resources Officer
- Mark E. Mlotek, Executive Vice President, Chief Strategic Officer, Member of the Board of Directors
- James Mullins, Senior Vice President, Global Supply Chain
- Kelly Murphy, Senior Vice President and General Counsel
- Christopher Pendergast, Senior Vice President and Chief Technology Officer
- Michael Racioppi, Senior Vice President, Chief Merchandising Officer
- Walter Siegel, Senior Vice President and Chief Legal Officer
- Ronald N. South, Senior Vice President, Chief Financial Officer
- René Willi, Ph.D., Chief Executive Officer, Global Oral Reconstruction Group

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PRISM MEDICAL PRODUCTS, L.L.C." IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PRISM MEDICAL PRODUCTS, L.L.C." WAS FORMED ON THE THIRTY-FIRST DAY OF DECEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4587530 8300

SR# 20233022349

Authentication: 203769831

Date: 07-18-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HENRY SCHEIN HOME HEALTH, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HENRY SCHEIN HOME HEALTH, LLC" WAS FORMED ON THE NINTH DAY OF JUNE, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

7507294 8300

SR# 20233022350

Authentication: 203769832

Date: 07-18-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HENRY SCHEIN, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HENRY SCHEIN, INC." WAS INCORPORATED ON THE TWENTY-THIRD DAY OF DECEMBER, A.D. 1992.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2320192 8300

SR# 20233023629

Authentication: 203770874

Date: 07-18-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

NORTH CAROLINA BOARD OF PHARMACY

Facility: Prism Medical Products, LLC
Address: 112 Church St., Suite 101 P.O. Box 476
Elkin, NC 28621
Permit Type: DME
Permit #: 02866
Re-Issue Date: 11/23/2022
Expiration Date: 12/31/2023
Person In Charge: Christopher Jon Cartwright

NC Law requires notification of address change within 30 days.

PLEASE NOTIFY BOARD OF NAME AND/OR ADDRESS CHANGE

REFER TO YOUR LICENSE NUMBER IN ANY COMMUNICATION

Permit #: 02866

NORTH CAROLINA BOARD OF PHARMACY

Device & Medical Equipment

2023

This is to certify that

Prism Medical Products, LLC

doing business as

Prism Medical Products, LLC

112 Church St., Suite 101 P.O. Box 476 Elkin, NC 28621 Surry

Has been renewed for the year ending December 31st 2023.

Christopher Jon Cartwright

11/23/2022
Re-Issued

PRESIDENT

EXECUTIVE DIRECTOR

NC Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
06/01/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE		NAIC #
Prism Medical Products P O Box 476 112 Church Street, Suite 101 Elkin NC 28621 USA	INSURER A:	QBE Specialty Insurance Company	11515
	INSURER B:	Liberty Mutual Fire Ins Co	23035
	INSURER C:	ProAssurance Specialty Insurance Company	17400
	INSURER D:	Liberty Insurance Corporation	42404
	INSURER E:		
	INSURER F:		

COVERAGES **CERTIFICATE NUMBER:** 570099690193 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [ ] PRO-JECT [X] LOC OTHER:			TB2621093363033	06/01/2023	06/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $100,000 $5,000 $1,000,000 $2,000,000 Excluded
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			AS2-621-093363-043	06/01/2023	06/01/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
D	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED RETENTION			TH7621093363073	06/01/2023	06/01/2024	EACH OCCURRENCE AGGREGATE	$2,000,000 $2,000,000
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		WA762D093363013 AOS	06/01/2023	06/01/2024	X PER STATUTE [ ] OTH-ER	
D				WC7621093363023 WI	06/01/2023	06/01/2024	E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000
C	Products Liability			N23NY380024 Products Liability Claims	06/01/2023	06/01/2024	Per Occurrence Aggregate	$3,000,000 $3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Prism Medical Products, LLC
P O Box 476,112 Church Street, Suite 101
Elkin NC 28621 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier :

Certificate No : 570099690193

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AGENCY CUSTOMER ID: 570000025511
LOC #:

ADDITIONAL REMARKS SCHEDULE

Page _ of _

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Prism Medical Products
POLICY NUMBER: See Certificate Number: 570099690193	
CARRIER: See Certificate Number: 570099690193 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Locations

PRISM MEDICAL PRODUCTS - OFFICE LOCATIONS:
112 Church Street, Suite 101, Elkin, NC 28621
2445 Directors Row, Ste G, Indianapolis, IN 46241
4705 N Sonora Ave # 110, Fresno, CA 93722
119 W Main Street, Elkin, NC 28621
4900 Outland Center Drive, Ste 103, Memphis, TN 38118
416 Oakland Drive, Elkin, NC 28621
900 Albany Shaker Road Ste 1, Latham, NY 12110
3190 100th Street, Urbandale, IA 50322
2700 Commerce Square East. Irondale, AL 35210
6345 S Pecos Road #203-205, Las Vegas, NV 89120
111 Market Street Apt 203, Elkin, NC 28621
1421 Champion Drive Suite 100, Carrollton, TX 75006
12019 NE 99th Street Suite 1720, Vancouver, WA 98682
118 Circle Court, Elkin, NC 28621
197 Piedmont Blvd., Suite 212, Rock Hill, SC 29732
7003 Presidents Drive, Orlando, FL 32809
7060 103rd Street Ste 107, Jacksonville, FL 32210
1919 N. Bridge Street Suite 240; Elkin, NC 28621.
2800 Percy Machin Drive, Ste. 112, North Little Rock, AR 72114
1605 North Bridge Street; Elkin, NC 28621

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Prism Medical Products, LLC — MDEG License # (if applicable): MP03103

Physical Address: 112 Church Street, Suite 101

City: Elkin — State: NC — Zip: 28621

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin — State: NC — Zip: 28621

Telephone: (888) 244-6421 — Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: Christopher — Middle: Jon — Last: Cartwright

Alias(es, nicknames, name changes, etc.): Chris

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin — State: NC — Zip: 28621

Telephone: (888) 244-6421 x.4373 — Email: chris@prism-medical.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wingate University		1996-2000	
Address	**City**	**State**	**Zip**
315 E. Wilson Street	Wingate	NC	28174
Diploma/Degree obtained, if any			
B.S.			

School Name		From - To (MM/YY – MM/YY)	
Oviedo High School		1992-1996	
Address	**City**	**State**	**Zip**
601 King Street	Oviedo	FL	32765
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016 - Present	[redacted]Colonial Lane	State Road	NC	28676
2010 - 2016	[redacted]Carter Mill Road	Elkin	NC	28621

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Prism Medical Products, LLC			08/2006 - Present	
Business Address		**City**	**State**	**Zip**
112 Church Street, Suite 101		Elkin	NC	28621
Phone	**Title**		**Number of Employed Hours**	
(888) 244-6421	President		36,000+ Hours	
Description of Duties				
Owner, Executive				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

PRISM
HOME MEDICAL SUPPLY SPECIALISTS

P. O. Box 476
Elkin, NC 28621
Phone: 1-888-244-6421
Fax: 1-800-975-6321
www.prism-medical.com

July 26th, 2023

VIA NOTIFICATION EMAIL

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, Nevada 89521
pharmacy@pharmacy.nv.gov
jphaynarikone@pharmacy.nv.gov

RE: MDEG Licensed Entity: Prism Medical Products, LLC
Additional Information Request for Permit No. MP03103 – Administrator Application: Christopher Cartwright

To whom it may concern,

We received an email requesting a more detailed description of Christopher Cartwrights "Description of Duties" on page 4, section 7 of the Administrator Application. Christopher is an owner of Prism Medical Products, LLC and acts as the President. His duties as President include but are not limited to establishing and carrying out organizational or departmental procedures, goals, and policies, e.g., fiscal, operational, logistics, sales, business development, etc. Managing general activities associated with providing services and overseeing Prism's day-to-day operations.

Please reach out with any additional questions.

Thank you,

Elizabeth Hyde

ELIZABETH HYDE
ADMINISTRATIVE COMPLIANCE COORDINATOR
COMPLIANCE & GOVERNMENT AFFAIRS
Office (336) 258-4373
Fax (855) 496-2996
elizabethw@prism-medical.com

THIS MESSAGE IS INTENDED FOR THE USE OF THE PERSON OR ENTITY WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT ISPRIVILIGED AND CONFIDENTIAL, THIS DISCLOSURE OF WHICH IS GOVERNED BY APPLICABLE LAW. IF THE READER OF THIS MESSAGE IS NOTTHE INTENDED RECIPIENT OR THE EMPLOYEE OR AGENT RESPONSIBLE TO DELIVER IT TO THE INTENDED RECIPIENT, YOU ARE HEREBYNOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS INFORMATION IS **STRICTLY PROHIBITED**. IF YOU HAVE RECEIVEDTHIS MESSAGE IN ERROR, PLEASE NOTIFY US IMMEDIATELY AND DESTROY THE RELATED MESSAGE.
CONFIDENTIALITY NOTICE
HEALTH CARE INFORMATION IS PERSONAL AND SENSITIVE INFORMATION RELATED TO A PERSON'S HEALTH. IT IS BEING SENT TO YOU AFTER APPROPRIATEAUTHORIZATION FROM THE PATIENT OR UNDER CIRCUMSTANCES THAT DOESN'T REQUIRE PATIENT AUTHORIZATION. YOU, THE RECIPIENT, ARE OBLIGATED TO MAINTAIN IT IN A SAFE,SECURE, CONFIDENTIAL, MANNER. RE-DISCLOSURE WITHOUT ADDITIONAL PATIENT CONSENT OR AS PERMITTED BY LAW IS PROHIBITED. UNAUTHORIZED RE-DISCLOSURE OR FAILURETO MAINTAIN CONFIDENTIALITY COULD SUBJECT YOU TO PENALTIES UNDER FEDERAL AND STATE LAW

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case # N/A		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/20/23
Date

I, Christopher Cartwright, **certify that as the MDEG Administrator for**

Prism Medical Products, LLC,

that I (initial that you have read and meet the following requirements):

1. CC Have a high school diploma or its equivalent;
2. CC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Cartwright
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/20/23
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prism Medical Products, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP03103

Physical Address: 112 Church Street, Suite 101

City: Elkin State: NC Zip: 28621

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: Christopher Middle: Jon Last: Cartwright

Alias(es, nicknames, name changes, etc.): Chris

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin State: NC Zip: 28621

Telephone: 888-244-6421 x.4373 Email: chris@prism-medical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wingate University		1996-2000	
Address	**City**	**State**	**Zip**
315 E. Wilson Street	Wingate	NC	28174
Diploma/Degree obtained, if any			
B.S.			

School Name		From - To (MM/YY – MM/YY)	
Oviedo High School		1992-1996	
Address	**City**	**State**	**Zip**
601 King Street	Oviedo	FL	32765
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016 - Present	[redacted] Colonial Lane	State Road	NC	28676
2010 - 2016	[redacted] Carter Mill Road	Elkin	NC	28621

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Prism Medical Products, LLC	08/2006 - Present

Business Address	City	State	Zip
112 Church Street, Suite 101	Elkin	NC	28621

Phone	Title
(888) 244-6421	President

Description of Duties

Executive Duties, Planning, Daily Oversight

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/20/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Cartwright

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/20/23

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Surry

I, Christopher Cartwright, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/20/23

Date

Subscribed and Sworn to before me this 20 day of July 2023.

Elizabeth L. Hyde

Notary Public Signature

Elizabeth L. Hyde NOTARY PUBLIC SURRY COUNTY, NC

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prism Medical Products, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP03103

Physical Address: 112 Church Street, Suite 101

City: Elkin State: NC Zip: 28621

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: Kenneth Middle: Herbert Last: Reel, Jr.

Alias(es, nicknames, name changes, etc.): Ken

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin State: NC Zip: 28621

Telephone: 888-244-6421 x.4373 Email: ken@prism-medical.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nova Southeastern School of Law		08/2001 - 05/2004	
Address	**City**	**State**	**Zip**
3300 S University Drive	Fort Lauderdale	FL	33328
Diploma/Degree obtained, if any			
Juris Doctor			
School Name		**From - To (MM/YY – MM/YY)**	
University of Florida		01/1999 12/2000	
Address	**City**	**State**	**Zip**
Museum Road 7 Reitz Union Drive	Gainsville	FL	32611
Diploma/Degree obtained, if any			
B.A Degree			
School Name		**From - To (MM/YY – MM/YY)**	
Valencia Community College		06/1998 - 12/1998	
Address	**City**	**State**	**Zip**
1800 S Kirkman Road	Orlando	FL	32811
Diploma/Degree obtained, if any			
A.A. Degree			
School Name		**From - To (MM/YY – MM/YY)**	
University of Central Florida		08/1996 - 05/1998	
Address	**City**	**State**	**Zip**
4000 Central Florida Blvd	Orlando	FL	32816
Diploma/Degree obtained, if any			
Transfer			
School Name		**From - To (MM/YY – MM/YY**	
Oviedo High School		1992-1996	
Address	**City**	**State**	**Zip**
601 King Street	Oviedo	FL	32765
Diploma/Degree obtained, if any			
Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2019 - Present	[redacted]Queens Road W.	Charlotte	NC	28209
04/2014 - 12/2018	[redacted]dlewood Circle	Charlotte	NC	28209
04/2011 - 03/2014	[redacted] Red Oak Lane	Winston-Salem	NC	27106
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Prism Medical Products, LLC			01/2009 - Present	
Business Address	**City**		**State**	**Zip**
112 Church Street, Suite 101	Elkin		NC	28621
Phone	**Title**			
(888) 244-6421	Vice President			
Description of Duties				
Executive Duties, Company Oversight, Legal, Compliance HR, Sales				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/21/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kenneth Reel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7.21.23

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Surry

I, Kenneth Reel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-21-23

Date

Subscribed and Sworn to before me this 21 day of July 2023

Elizabeth L. Hyde

Notary Public Signature

Elizabeth L. Hyde NOTARY PUBLIC SURRY COUNTY, NC

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prism Medical Products, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP03103

Physical Address: 112 Church Street, Suite 101

City: Elkin State: NC Zip: 28621

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: James Middle: Robert Last: St. Cyr

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin State: NC Zip: 28621

Telephone: 888-244-6421 x.4373 Email: james@prism-medical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wingate University		1998-2002	
Address	**City**	**State**	**Zip**
315 E. Wilson Street	Wingate	NC	28174
Diploma/Degree obtained, if any			
B.S. Business Marketing			

School Name		From - To (MM/YY – MM/YY)	
Milford High School		1994-1998	
Address	**City**	**State**	**Zip**
100 West Street	Milford	NH	03055
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2013 - Present	[redacted] Laurel Hill Lane	State Road	NC	28676
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Prism Medical Products, LLC			05/2010 - Present	
Business Address	**City**		**State**	**Zip**
112 Church Street, Suite 101	Elkin		NC	28621
Phone	**Title**			
(888) 244-6421	President			
Description of Duties				
Executive Duties, Company Oversight, Operations, IT				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/20/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James St. Cyr

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/20/23

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Surry

I, James St. Cyr, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/20/23

Date

Subscribed and Sworn to before me this 20 day of July 2023.

Elizabeth L. Hyde

Notary Public Signature

Elizabeth L. Hyde
NOTARY PUBLIC
SURRY COUNTY, NC

(Seal)

PRISM
HOME MEDICAL SUPPLY SPECIALISTS

P. O. BOX 476
ELKIN, NC 28621
PHONE: 1-888-244-6421
FAX: 1-800-975-6321
WWW.PRISM-MEDICAL.COM

Change of Ownership Application Introduction & Index

Prism Medical Products, LLC is entering into a Contribution and Exchange Agreement between Henry Schein Home Health, LLC and Henry Schein, Inc. **The effective date of the proposed transaction is projected to be on or about August 7, 2023**. Prism Medical Products, LLC's tax classification is a partnership. This partnership is between two corporations, one partner is publicly traded and one non-public. The partnership section of the application asks for Personal History Records for each partner. We included Personal History Records for each managing employee. Mr. Christopher Cartwright, Mr. Kenneth Reel, and Mr. James St. Cyr will remain as managing employees at the Operating Entity as well as partial owners of Prism Medical Products Holdings, Inc., a grandparent-level owner.

For the publicly traded partner, Henry Schein, Inc., we provided a list of Directors and Management and the Certificate of Good Standing as requested on the publicly traded page of the application. We did not complete the application publicly and non-publicly traded corporation pages as a result of guidance from the Board that only one of the four ownership type sections should be completed. We did put N/A on Sections 5 and 6, even though they both apply to the owning partners; however, the ownership type of the entity being issued a license (Prism Medical Products, LLC) is a partnership. We hope that the information provided in this application will satisfy the Board's requirement.

Prism Medical Products, LLC has been licensed by Nevada Board of Pharmacy since 2014. Henry Schein, Inc. holds 11 Nevada Board of Pharmacy permits. Both entities have been previously vetted by Nevada Board of Pharmacy. Both entities have also conducted MDEG business transactions within Nevada, as appropriately licensed. As our original notice indicated, this ownership adjustment does not affect the daily management of Prism Medical Products, LLC. If additional information is required, please request via email to: compliance@prism-medical.com. Regards,
Lucy Ketner
Associate Vice President, Compliance & Government Affairs
(336) 258-4314

Index:

Check for all THREE Applications, p. 3
Original Notification, p. 4-5
Application for License MP03103 (Elkin, NC), p. 6-9
Application Supporting Documentation:
- Type of MDEG Products being Sold, p. 10
- Traditional State Medicaid Enrollments, p.11
- Pre-Closing/Post-Closing Structure, p. 12
- Ownership information with Addresses/Board of Directors/Officers, p. 13-15
- Secretary of State:
  - Prism Medical Products, LLC, p.16
  - Henry Schein Home Health, LLC, p. 17
  - Henry Schein, Inc, p. 18
- Prism, LLC-2023 NC BOP License, p. 19
- Certificate of Insurance, p. 20-21

Administrator Application, p. 22-27
Application for License MP01223 (Las Vegas, NV), p. 28-31
Application Supporting Documentation:
- Type of MDEG Products being Sold, p. 32
- Traditional State Medicaid Enrollments, p.33
- Pre-Closing/Post-Closing Structure, p. 34
- Ownership information with Addresses/Board of Directors/Officers, p. 35-37
- Secretary of State:

- Prism Medical Products, LLC, p.38
- Henry Schein Home Health, LLC, p. 39
- Henry Schein, Inc, p. 40

- Prism, LLC-2023 NV BOP License, p. 41
  - NV BOP 2022Inspection Report, p. 42-44
- Certificate of Insurance, p. 45-46

Administrator Application, p. 47-52
Application for License MP01354 (Fresno, CA), p. 53-56
Application Supporting Documentation:

- Type of MDEG Products being Sold, p. 57
- Traditional State Medicaid Enrollments, p.58
- Pre-Closing/Post-Closing Structure, p. 59
- Ownership information with Addresses/Board of Directors/Officers, p. 60-62
- Secretary of State:
  - Prism Medical Products, LLC, p.63
  - Henry Schein Home Health, LLC, p. 64
  - Henry Schein, Inc, p. 65
- Prism, LLC-2024 CA DPH License, p. 66
- Certificate of Insurance, p. 67-68

Administrator Application, p. 69-74

***PLEASE FIND ONE SET OF PERSONAL HISTORY RECORDS FOR ALL THREE APPLICATIONS FOR THE FOLLOWING:**

- Christopher Cartwright
- Kenneth Reel
- James St. Cyr

4C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG ■ Ownership Change* ☐ Name Change* ☐ Location Change*	* If making a change, provide current license number: M MP01354	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9) ■ Partnership (complete sections 1, 2, 3, 4, 7, 9) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Prism Medical Products, LLC

MDEG Physical Address: 4705 N. Sonora Ave., Suite 110

City: Fresno State: CA Zip: 93722

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Email: compliance@prism-medical.com

Name of MDEG Administrator (NAC 639.694): Daniel Aguirre, Shipping Coordinator

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions ☐ Pharmacies[a] ☐ Practitioners[a] ☐ Hospitals/Clinics[a] ☐ Clinics[a] ☐ Wholesalers[a] ☐ Other business entities (specify)[a]:	☐ Medical Gases** ☐ Respiratory Equipment** ☐ Life-sustaining equipment** ☐ Parenteral and Enteral Equipment** ☐ Assistive Equipment ☐ Diabetic Supplies ☐ Orthotics and Prosthetics ■ Others: See Attached
This application is ONLY required if MDEG products will be sold to patients by prescription. [a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954): Name: _____ Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8am - 6pm	■ Tue: 8am - 6pm	■ Wed: 8am - 6pm	■ Thurs: 8am - 6pm	■ Fri: 8am - 6pm
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed for major holidays		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
CMS PTAN for Corporate Office: 5823260001
CMS PTAN for Las Vegas, NV Office Only: 5823260002
Please see attached for additional numbers

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Partnership

Partnership Name: Prism Medical Products, LLC - See attached documents

Mailing Address: P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 x.4373 Email: compliance@prism-medical.com

Contact Person Name: Elizabeth Hyde

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Cartwright

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7/20/23

Date

Board Use Only	Date Received: 7/25/23	Amount: 500-CK-022372

PRISM
HOME MEDICAL SUPPLY SPECIALISTS

P. O. BOX 476
ELKIN, NC 28621
PHONE: 1-888-244-6421
FAX: 1-800-975-6321
WWW.PRISM-MEDICAL.COM

July 17, 2023

Nevada State Board of Pharmacy 985
Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

Type of MDEG Products being Sold:

Prism Medical Products, L.L.C. is a DME provider based out of North Carolina that specializes in providing Ostomy Supplies, Surgical Dressings, Urological Supplies, limited Compression Garments, and Breast Pumps to patients via a shipping courier, e.g., FedEx, and accepts assignment for health plan reimbursement.

If you have any questions, please let us know.

ELIZABETH HYDE
ADMINISTRATIVE COMPLIANCE COORDINATOR
COMPLIANCE & GOVERNMENT AFFAIRS

Office (336) 258-4373
Fax (855) 496-2996
elizabethw@prism-medical.com

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Prism Medical Products, LLC Information Sheet

TRADITIONAL STATE MEDICAID ENROLLMENTS

AK: 1652871 (eff. 09/01/2016)

AL: 125216 (eff. 02/03/2007)

AR: 238670741 (eff. 01/15/2020)

AZ: 900533 (eff. 11/01/2013)

CA: 1548367063 (eff. 02/07/2017)

CT: 1548367063 (eff. 11/01/2016)

CO: 1548367063 (eff. 08/03/2018)

DC: 089550700 (eff. 02/26/2013)

DE: 200141712 (eff. 01/19/2016)

FL: 112645100 (eff. 12/31/2020)

GA: 003101519A (eff. 02/01/2011)

IA: 1548367063 (eff. 10/01/2013)

ID: 1548367063 (eff. 04/10/2014)

IL: 753221011001 (eff. 03/07/2012)

IN: 201002170A (eff. 11/01/2011)

KS: 30003958520001 **(Primary)** (eff. 06/30/2017)

KS: 30003958520002 **(MCOs Only)** (eff. 12/30/2020)

KY: 7100723680 (eff. 03/01/2021)

LA: 2137671 (eff. 02/01/2011)

MA: 110112813A (eff. 05/20/2016)

MD: 551509200 (eff. 01/01/2012)

ME: 1548367063 (eff. 10/01/2015)

MI: 1548367063 (eff. 03/13/2012)

MN: 1548367063 (eff. 06/06/2016)

MO: 620007567 (eff. 07/01/2013)

MS: 009376349 - FFS : 009450798 - CHIP (eff. 02/07/2011)

MT: 1548367063 (eff. 08/15/2018)

NC: 7704585 (eff. 02/01/2007)

NE: 10026550601 (eff. 04/12/2016)

NH: 3127231 (eff. 01/27/2021)

NJ: 0766011 (eff. 06/11/2021)

NM: 51225514 (eff. 02/11/2014)

NV: 100541636 (eff. 06/18/2014)

NY: 03581275 (eff. 09/01/2017)

OH: 0060286 (eff. 02/01/2011)

OK: 200243820A (eff. 01/31/2011)

OR: 500671501 (eff. 05/12/2014)

PA: 102564320-0002 (Promise ID) (eff. 05/01/2011)

RI: 1548367063 (eff. 05/23/2016)

SC: DM1293 (eff. 07/01/2006)

SD: 2022288 (eff. 1/21/2021)

TN: 1508032 (eff. 02/03/2007)

TX: (a.k.a 'TPI') 205277101 Traditional Medicaid (eff. 07/13/2008)

205277103 CSHCN (eff. 07/13/2008)

UT: 1548367063 (eff. 06/10/2015)

VA: 30015257160001 (eff. 06/03/2008)

VT: 1027114 (eff. 04/22/2016)

WA: 1548367063 (eff. 01/07/2014)

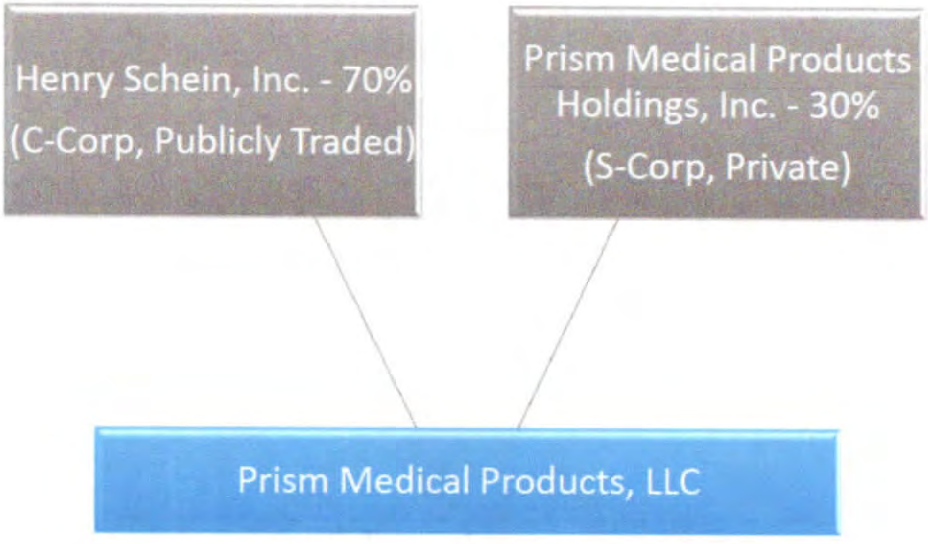
WI: 100152285 (eff. 01/01/2021)

WV: 888 (eff. 06/08/2012)

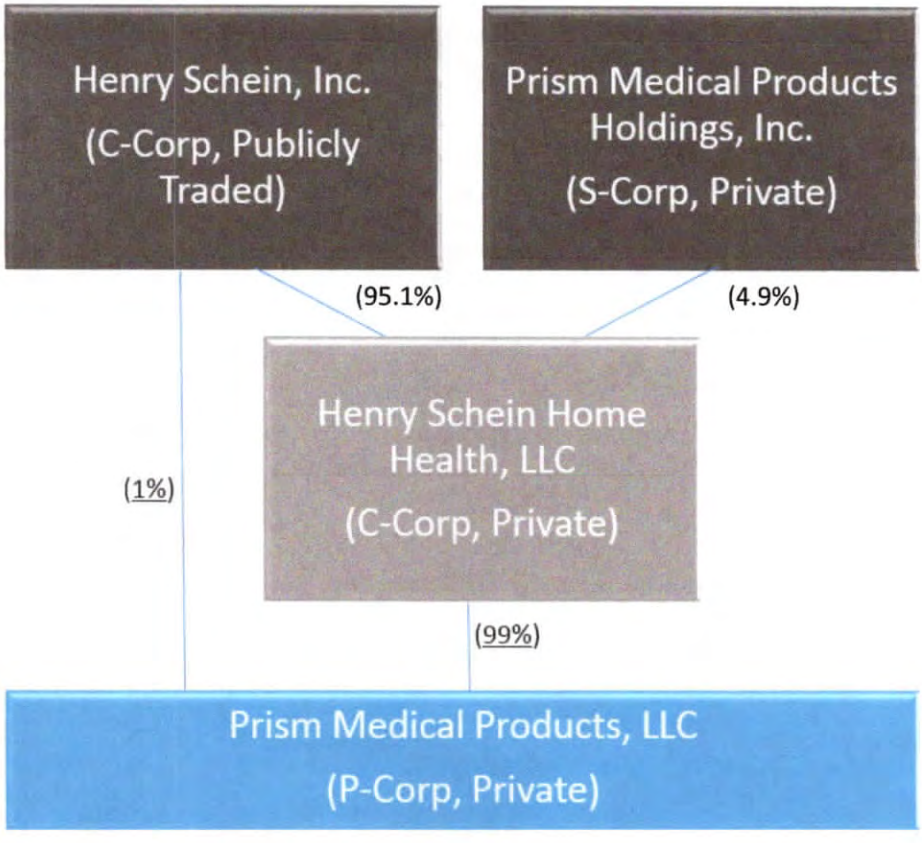
WY: 1548367063 (eff. 10/01/2016)

Prism Pre/Post Closing Information

Pre-Closing Structure



Post-Closing Structure



Address Information

Prism Medical Products, LLC
All demographic and contact information remains the same for the Elkin, NC location.

Parent Level Company
Henry Schein Home Health, L.L.C.
135 Duryea Rd.,
Melville NY 11747

Henry Schein, Inc.
135 Duryea Rd.,
Melville NY 11747

Grandparent Level Company
Prism Medical Products Holdings, Inc.
112 Church Street, Suite 102
Elkin, NC 28621

Henry Schein, Inc.
135 Duryea Rd.,
Melville NY 11747

Prism Medical Products, LLC

Prism Medical Products, LLC Officers/Board/Directors:

Prism Medical Products Holdings, Inc Representatives:

- Christopher Cartwright, President
- Kenneth Reel, Vice President

Henry Schein, Inc Representatives:

- Eileen Rosenbaum, Vice President
- Brad Connett, Senior Vice President
- Walter Siegel, SVP & General Council
- Michael Ettinger, EVP, Corporate & Legal Affairs

Henry Schein Home Health, LLC: 99% Direct Ownership

Directors

- Walter Siegel, SVP & General Council
- Michael Ettinger, EVP, Corporate & Legal Affairs
- Ronald South, SVP, CFO
- Brad Connett, SVP,
- Christopher Cartwright, VP

Officers

- Walter Siegel, SVP & General Council
- Michael Ettinger, EVP, Corporate & Legal Affairs
- Ronald South, SVP, CFO
- Brad Connett, SVP,
- Christopher Cartwright, VP
- Bob Ponzo, VP Tax
- Michael Amodio, VP and Treasurer

Henry Schein, Inc.: 1% Direct Ownership

Henry Schein is a publicly traded company with over 19,000 employees worldwide. Henry Schein does not have a traditional organizational chart. Provided below is a list of the Board of Directors and Executive Management. Please contact us if you require additional information.

Board of Directors

- Stanley M. Bergman, Chairman of the Board and Chief Executive Officer
- Mohamad Ali, Former Chief Executive Officer, IDG, Inc.
- James P. Breslawski, Vice Chairman of the Board and President
- Deborah Derby, President & CEO, Carrols Restaurant Group, Inc.
- Joseph L. Herring, Former Chief Executive Officer Covance, Inc.
- Kurt P. Kuehn, Former Chief Financial Officer, United Parcel Service, Inc.
- Philip A. Laskawy, Lead Director, Henry Schein, Inc.; and Retired Chairman, Ernst & Young, LLP (now known as EY LLP)
- Anne H. Margulies, Former Vice President and Chief Information Officer, Harvard University
- Mark E. Mlotek, Executive Vice President, Chief Strategic Officer
- Steven Paladino, Former Executive Vice President, Chief Financial Officer, Henry Schein, Inc.
- Carol Raphael, National Advisor, Manatt Health Solutions; and Former President and Chief Executive Officer, Visiting Nurse Service of New York
- Scott Serota, Former President and Chief Executive Officer of Blue Cross Blue Shield Association
- Bradley T. Sheares, Ph.D., Former Chief Executive Officer, Reliant Pharmaceuticals, Inc.; and Former President of U.S. Human Health, Merck & Co.
- Reed V. Tuckson, M.D., FACP, Managing Director of Tuckson Health Connections, LLC, and Founder, Black Coalition Against COVID-19

Executive Management

- Stanley M. Bergman, Chairman of the Board and Chief Executive Officer
- Andrea Albertini, Chief Executive Officer, International Distribution Group
- Leigh Benowitz, Senior Vice President and Chief Global Digital Transformation Officer
- James P. Breslawski, Vice Chairman of the Board and President
- David Brous, Chief Executive Officer, Strategic Business Group
- Trinh Clark, Senior Vice President and Chief Global Customer Experience Officer
- Brad Connett, Chief Executive Officer, North America Distribution Group
- Michael S. Ettinger, Executive Vice President and Chief Operating Officer
- Lorelei McGlynn, Senior Vice President, Chief Human Resources Officer
- Mark E. Mlotek, Executive Vice President, Chief Strategic Officer, Member of the Board of Directors
- James Mullins, Senior Vice President, Global Supply Chain
- Kelly Murphy, Senior Vice President and General Counsel
- Christopher Pendergast, Senior Vice President and Chief Technology Officer
- Michael Racioppi, Senior Vice President, Chief Merchandising Officer
- Walter Siegel, Senior Vice President and Chief Legal Officer
- Ronald N. South, Senior Vice President, Chief Financial Officer
- René Willi, Ph.D., Chief Executive Officer, Global Oral Reconstruction Group

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PRISM MEDICAL PRODUCTS, L.L.C." IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PRISM MEDICAL PRODUCTS, L.L.C." WAS FORMED ON THE THIRTY-FIRST DAY OF DECEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4587530 8300

SR# 20233022349

Authentication: 203769831

Date: 07-18-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HENRY SCHEIN HOME HEALTH, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HENRY SCHEIN HOME HEALTH, LLC" WAS FORMED ON THE NINTH DAY OF JUNE, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

7507294 8300

SR# 20233022350

Authentication: 203769832

Date: 07-18-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HENRY SCHEIN, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HENRY SCHEIN, INC." WAS INCORPORATED ON THE TWENTY-THIRD DAY OF DECEMBER, A.D. 1992.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2320192 8300

SR# 20233023629

Authentication: 203770874

Date: 07-18-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

Prism Medical Products, LLC
4705 N. Sonora Avenue,
Suite #110
Fresno, CA 93722

LICENSE NUMBER: 75838
EXPIRATION DATE: 3/5/2024

The person named herein is licensed to operate a Home Medical Device Retail Facility through the expiration date of this license. This annual license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to Home Medical Device Retail Facilities.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 4/27/2023

OSP 07 102308

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/01/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Prism Medical Products P O Box 476 112 Church Street, Suite 101 Elkin NC 28621 USA	INSURER A: QBE Specialty Insurance Company	11515
	INSURER B: Liberty Mutual Fire Ins Co	23035
	INSURER C: ProAssurance Specialty Insurance Company	17400
	INSURER D: Liberty Insurance Corporation	42404
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570099690193 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY			TB2621093363033	06/01/2023	06/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	$5,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	POLICY PRO-JECT X LOC						PRODUCTS - COMP/OP AGG	Excluded
	OTHER:							
B	AUTOMOBILE LIABILITY			AS2-621-093363-043	06/01/2023	06/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
D	X UMBRELLA LIAB X OCCUR			TH7621093363073	06/01/2023	06/01/2024	EACH OCCURRENCE	$2,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$2,000,000
	DED RETENTION							
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			WA762D093363013 AOS	06/01/2023	06/01/2024	X PER STATUTE OTH-ER	
D	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH) N/A			WC7621093363023 WI	06/01/2023	06/01/2024	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000
C	Products Liability			N23NY380024 Products Liability Claims	06/01/2023	06/01/2024	Per Occurrence Aggregate	$3,000,000 $3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Prism Medical Products, LLC
P O Box 476,112 Church Street, Suite 101
Elkin NC 28621 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast Inc.

Holder Identifier :

Certificate No : 570099690193

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AGENCY CUSTOMER ID: 570000025511
LOC #:

ADDITIONAL REMARKS SCHEDULE

Page _ of _

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Prism Medical Products
POLICY NUMBER	
See Certificate Number: 570099690193	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570099690193	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Locations

PRISM MEDICAL PRODUCTS - OFFICE LOCATIONS:
112 Church Street, Suite 101, Elkin, NC 28621
2445 Directors Row, Ste G, Indianapolis, IN 46241
4705 N Sonora Ave # 110, Fresno, CA 93722
119 W Main Street, Elkin, NC 28621
4900 Outland Center Drive, Ste 103, Memphis, TN 38118
416 Oakland Drive, Elkin, NC 28621
900 Albany Shaker Road Ste 1, Latham, NY 12110
3190 100th Street, Urbandale, IA 50322
2700 Commerce Square East. Irondale, AL 35210
6345 S Pecos Road #203-205, Las Vegas, NV 89120
111 Market Street Apt 203, Elkin, NC 28621
1421 Champion Drive Suite 100, Carrollton, TX 75006
12019 NE 99th Street Suite 1720, Vancouver, WA 98682
118 Circle Court, Elkin, NC 28621
197 Piedmont Blvd., Suite 212, Rock Hill, SC 29732
7003 Presidents Drive, Orlando, FL 32809
7060 103rd Street Ste 107, Jacksonville, FL 32210
1919 N. Bridge Street Suite 240; Elkin, NC 28621.
2800 Percy Machin Drive, Ste. 112, North Little Rock, AR 72114
1605 North Bridge Street; Elkin, NC 28621

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Prism Medical Products, LLC — MDEG License # (if applicable): MP01354

Physical Address: 4705 N. Sonora Ave., Suite 110

City: Fresno — State: CA — Zip: 93722

Mailing Address (if different from physical address): PO Box 476

City: Elkin — State: NC — Zip: 28621

Telephone: (888) 244-6421 — Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: Daniel — Middle: Santiago — Last: Aguirre

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: PO Box [redacted]

City: Elkin — State: NC — Zip: 28621

Telephone: (888) 244-6421 x4373 — Email: daguirre@prism-medical.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Sanger High School		07/2006 - 05/2010	
Address	**City**	**State**	**Zip**
1045 N. Bethel Avenue	Sanger	CA	93657
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2021 - Present	[redacted]E. Bullard Avenue,[redacted]	Fresno	CA	93710
10/2005 - 11/2021	[redacted]S. Preuss Avenue	Fresno	CA	93727
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Prism Medical Products, LLC			
Business Address	**City**	**State**	**Zip**
4705 N. Sonora Ave., Suite 110	Fresno	CA	93722
Phone	**Title**		**Number of Employed Hours**
(888) 244-6421	Shipping Coordinator		6,500+ Hours
Description of Duties			
Coordinate Accounts, Product Knowledge, Shipping and Receiving, Delegate tasks to team members, Completing Orders, Logistics			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case # N/A		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/19/23

Date

I, Daniel Aguirre, **certify that as the MDEG Administrator for**

Prism Medical Products, LLC,

that I (initial that you have read and meet the following requirements):

1. DA Have a high school diploma or its equivalent;
2. DA Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DA Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DA Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel Aguirre
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/19/23
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prism Medical Products, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP03103

Physical Address: 112 Church Street, Suite 101

City: Elkin State: NC Zip: 28621

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: Christopher Middle: Jon Last: Cartwright

Alias(es, nicknames, name changes, etc.): Chris

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin State: NC Zip: 28621

Telephone: 888-244-6421 x.4373 Email: chris@prism-medical.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wingate University		1996-2000	
Address	**City**	**State**	**Zip**
315 E. Wilson Street	Wingate	NC	28174
Diploma/Degree obtained, if any			
B.S.			

School Name		From - To (MM/YY – MM/YY)	
Oviedo High School		1992-1996	
Address	**City**	**State**	**Zip**
601 King Street	Oviedo	FL	32765
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016 - Present	[redacted] Colonial Lane	State Road	NC	28676
2010 - 2016	[redacted] Carter Mill Road	Elkin	NC	28621

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Prism Medical Products, LLC			08/2006 - Present	
Business Address	**City**		**State**	**Zip**
112 Church Street, Suite 101	Elkin		NC	28621
Phone	**Title**			
(888) 244-6421	President			
Description of Duties				
Executive Duties, Planning, Daily Oversight				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/20/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Cartwright

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/20/23

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Surry

I, Christopher Cartwright, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/20/23

Date

Subscribed and Sworn to before me this 20 day of July 2023.

Elizabeth L. Hyde

Notary Public Signature

Elizabeth L. Hyde NOTARY PUBLIC SURRY COUNTY, NC

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prism Medical Products, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP03103

Physical Address: 112 Church Street, Suite 101

City: Elkin State: NC Zip: 28621

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: Kenneth Middle: Herbert Last: Reel, Jr.

Alias(es, nicknames, name changes, etc.): Ken

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin State: NC Zip: 28621

Telephone: 888-244-6421 x.4373 Email: ken@prism-medical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nova Southeastern School of Law		08/2001 - 05/2004	
Address	**City**	**State**	**Zip**
3300 S University Drive	Fort Lauderdale	FL	33328
Diploma/Degree obtained, if any			
Juris Doctor			
School Name		**From - To (MM/YY – MM/YY)**	
University of Florida		01/1999 12/2000	
Address	**City**	**State**	**Zip**
Museum Road 7 Reitz Union Drive	Gainsville	FL	32611
Diploma/Degree obtained, if any			
B.A Degree			
School Name		**From - To (MM/YY – MM/YY)**	
Valencia Community College		06/1998 - 12/1998	
Address	**City**	**State**	**Zip**
1800 S Kirkman Road	Orlando	FL	32811
Diploma/Degree obtained, if any			
A.A. Degree			
School Name		**From - To (MM/YY – MM/YY)**	
University of Central Florida		08/1996 - 05/1998	
Address	**City**	**State**	**Zip**
4000 Central Florida Blvd	Orlando	FL	32816
Diploma/Degree obtained, if any			
Transfer			
School Name		**From - To (MM/YY – MM/YY**	
Oviedo High School		1992-1996	
Address	**City**	**State**	**Zip**
601 King Street	Oviedo	FL	32765
Diploma/Degree obtained, if any			
Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2019 - Present	[redacted] Queens Road W.	Charlotte	NC	28209
04/2014 - 12/2018	[redacted] dlewood Circle	Charlotte	NC	28209
04/2011 - 03/2014	[redacted] Red Oak Lane	Winston-Salem	NC	27106
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Prism Medical Products, LLC	01/2009 - Present

Business Address	City	State	Zip
112 Church Street, Suite 101	Elkin	NC	28621

Phone	Title
(888) 244-6421	Vice President

Description of Duties

Executive Duties, Company Oversight, Legal, Compliance HR, Sales

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/21/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kenneth Reel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7.21.23

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Surry

I, Kenneth Reel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-21-23

Date

Subscribed and Sworn to before me this 21 day of July 2023

Elizabeth L. Hyde

Notary Public Signature

Elizabeth L. Hyde NOTARY PUBLIC SURRY COUNTY, NC

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prism Medical Products, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP03103

Physical Address: 112 Church Street, Suite 101

City: Elkin State: NC Zip: 28621

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: James Middle: Robert Last: St. Cyr

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin State: NC Zip: 28621

Telephone: 888-244-6421 x.4373 Email: james@prism-medical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wingate University		1998-2002	
Address	**City**	**State**	**Zip**
315 E. Wilson Street	Wingate	NC	28174
Diploma/Degree obtained, if any			
B.S. Business Marketing			
School Name		**From - To (MM/YY – MM/YY)**	
Milford High School		1994-1998	
Address	**City**	**State**	**Zip**
100 West Street	Milford	NH	03055
Diploma/Degree obtained, if any			
Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2013 - Present	[redacted]aurel Hill Lane	State Road	NC	28676
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Prism Medical Products, LLC			05/2010 - Present	
Business Address	**City**		**State**	**Zip**
112 Church Street, Suite 101	Elkin		NC	28621
Phone	**Title**			
(888) 244-6421	President			
Description of Duties				
Executive Duties, Company Oversight, Operations, IT				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/20/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James St. Cyr

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/20/23

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Surry

I, James St. Cyr, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/20/23

Date

Subscribed and Sworn to before me this 20 day of July 2023.

Elizabeth L. Hyde

Notary Public Signature

Elizabeth L. Hyde NOTARY PUBLIC SURRY COUNTY, NC

(Seal)

PRISM
HOME MEDICAL SUPPLY SPECIALISTS

P. O. BOX 476
ELKIN, NC 28621
PHONE: 1-888-244-6421
FAX: 1-800-975-6321
WWW.PRISM-MEDICAL.COM

Change of Ownership Application Introduction & Index

Prism Medical Products, LLC is entering into a Contribution and Exchange Agreement between Henry Schein Home Health, LLC and Henry Schein, Inc. **The effective date of the proposed transaction is projected to be on or about August 7, 2023**. Prism Medical Products, LLC's tax classification is a partnership. This partnership is between two corporations, one partner is publicly traded and one non-public. The partnership section of the application asks for Personal History Records for each partner. We included Personal History Records for each managing employee. Mr. Christopher Cartwright, Mr. Kenneth Reel, and Mr. James St. Cyr will remain as managing employees at the Operating Entity as well as partial owners of Prism Medical Products Holdings, Inc., a grandparent-level owner.

For the publicly traded partner, Henry Schein, Inc., we provided a list of Directors and Management and the Certificate of Good Standing as requested on the publicly traded page of the application. We did not complete the application publicly and non-publicly traded corporation pages as a result of guidance from the Board that only one of the four ownership type sections should be completed. We did put N/A on Sections 5 and 6, even though they both apply to the owning partners; however, the ownership type of the entity being issued a license (Prism Medical Products, LLC) is a partnership. We hope that the information provided in this application will satisfy the Board's requirement.

Prism Medical Products, LLC has been licensed by Nevada Board of Pharmacy since 2014. Henry Schein, Inc. holds 11 Nevada Board of Pharmacy permits. Both entities have been previously vetted by Nevada Board of Pharmacy. Both entities have also conducted MDEG business transactions within Nevada, as appropriately licensed. As our original notice indicated, this ownership adjustment does not affect the daily management of Prism Medical Products, LLC. If additional information is required, please request via email to: compliance@prism-medical.com. Regards,
Lucy Ketner
Associate Vice President, Compliance & Government Affairs
(336) 258-4314

Index:

Check for all THREE Applications, p. 3
Original Notification, p. 4-5
Application for License MP03103 (Elkin, NC), p. 6-9
Application Supporting Documentation:
- Type of MDEG Products being Sold, p. 10
- Traditional State Medicaid Enrollments, p.11
- Pre-Closing/Post-Closing Structure, p. 12
- Ownership information with Addresses/Board of Directors/Officers, p. 13-15
- Secretary of State:
  - Prism Medical Products, LLC, p.16
  - Henry Schein Home Health, LLC, p. 17
  - Henry Schein, Inc, p. 18
- Prism, LLC-2023 NC BOP License, p. 19
- Certificate of Insurance, p. 20-21

Administrator Application, p. 22-27
Application for License MP01223 (Las Vegas, NV), p. 28-31
Application Supporting Documentation:
- Type of MDEG Products being Sold, p. 32
- Traditional State Medicaid Enrollments, p.33
- Pre-Closing/Post-Closing Structure, p. 34
- Ownership information with Addresses/Board of Directors/Officers, p. 35-37
- Secretary of State:

  - Prism Medical Products, LLC, p.38
  - Henry Schein Home Health, LLC, p. 39
  - Henry Schein, Inc, p. 40
- Prism, LLC-2023 NV BOP License, p. 41
  - NV BOP 2022Inspection Report, p. 42-44
- Certificate of Insurance, p. 45-46

Administrator Application, p. 47-52

Application for License MP01354 (Fresno, CA), p. 53-56

Application Supporting Documentation:

- Type of MDEG Products being Sold, p. 57
- Traditional State Medicaid Enrollments, p.58
- Pre-Closing/Post-Closing Structure, p. 59
- Ownership information with Addresses/Board of Directors/Officers, p. 60-62
- Secretary of State:
  - Prism Medical Products, LLC, p.63
  - Henry Schein Home Health, LLC, p. 64
  - Henry Schein, Inc, p. 65
- Prism, LLC-2024 CA DPH License, p. 66
- Certificate of Insurance, p. 67-68

Administrator Application, p. 69-74

***PLEASE FIND ONE SET OF PERSONAL HISTORY RECORDS FOR ALL THREE APPLICATIONS FOR THE FOLLOWING:**

- Christopher Cartwright
- Kenneth Reel
- James St. Cyr

4D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	☑ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Sunrise Respiratory Care, Inc.

MDEG Physical Address: 1481 Langley Ave Irvine MDE

City: Irvine State: CA Zip: 92614

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 949 398-6555 Website: www.sunriseresp.com

Email: management@sunriseresp.com

Name of MDEG Administrator (NAC 639.694): Oscar Munoz

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	■ Medical Gases**
☐ Pharmacies[a]	■ Respiratory Equipment**
☐ Practitioners[a]	■ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	■ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: craig sherman
	Telephone: 702.419.5736

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8:30-5:00	■ Tue: 8:30-5:00	■ Wed: 8:30-5:00	■ Thurs: 8:30-5:00	■ Fri: 8:30-5:00
■ Sat: 8:30-5:00	■ Sun: 8:30-5:00	■ Holidays: 8:30-5:00		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare PTAN: 6667640001
MediCal: 800659606
NPI: 1255632394

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: No owner has any licensure in the state of Nevada Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California (also registered in Nevada)

Parent Company (if any): _____

Corporation/Organization Name: Sunrise Respiratory Care, Inc.

Mailing Address: 1881 Langley Ave

City: Irvine State: CA Zip: 92614

Telephone: 949 398 6555 Email: Nevada@sunriseresp.com

Contact Person Name: Oscar Munoz

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Eilbert

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7/17/2023

Date

Board Use Only	Date Received: 7/31/23	Amount: 500-CK-5117

Jessette Phaynarikone

From: Michael Eilbert <meilbert@sunriseresp.com>
Sent: Thursday, August 24, 2023 2:52 PM
To: Jessette Phaynarikone
Cc: omunoz.src@gmail.com
Subject: Re: MDEG App - Sunrise Respiratory Care, Inc - Irvine CA
Attachments: Administrator App - Oscar Munoz.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Nevada Contact: (page 1, section 1)
Craig Sherman
(702) 419-5736

List of Officers and Directors:

Michael Eilbert President/CFO 50% ownership
Oscar Munoz President/CEO 50% ownership

Administrator application is attached but wet signed copy is coming via US mail

Thank you Jessette,

Michael Eilbert

On Mon, Jul 31, 2023 at 10:57 AM Jessette Phaynarikone <jphaynarikone@pharmacy.nv.gov> wrote:

Good morning,

I am in receipt of your MDEG Application for **Sunrise Respiratory Care, Inc – Irvine, CA**. Upon review we need the following information below.

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	SUNRISE RESPIRATORY CARE, INC.
Entity No.:	3317090
Registration Date:	09/01/2010
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of July 17, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 130109725

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

Sunrise Respiratory Care Inc
1881 Langley Ave
Irvine, Ca 92614

LICENSE NUMBER: 116854
EXPIRATION DATE: 10/25/2023

The person named herein is licensed to operate a Home Medical Device Retail Facility through the expiration date of this license. This annual license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to Home Medical Device Retail Facilities.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

SUNRRES-01 CMEKSAVANH

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 7/14/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER License # 0C36861
Irvine-Alliant Insurance Services, Inc.
18100 Von Karman Ave 10th Fl
Irvine, CA 92612

CONTACT NAME: Carla Meksavanh
PHONE (A/C, No, Ext): (619) 361-5582 FAX (A/C, No):
E-MAIL ADDRESS: Carla.Meksavanh@alliant.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Massachusetts Bay Insurance Company	22306
INSURER B : Allmerica Financial Benefit Insurance Company	41840
INSURER C : Hanover Insurance Company	22292
INSURER D : Hanover American Insurance Company	36064
INSURER E :	
INSURER F :	

INSURED
Sunrise Respiratory Care, Inc.
1881 Langley Ave
Irvine, CA 92614

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY							
	CLAIMS-MADE X OCCUR			LD3-H656305-04	7/11/2023	7/11/2024	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:						PROFESSIONAL LI	$ Included
B	AUTOMOBILE LIABILITY							
	X ANY AUTO			AWF-H683755-02	7/11/2023	7/11/2024	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per person)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
C	X UMBRELLA LIAB X OCCUR							
	EXCESS LIAB CLAIMS-MADE			UH3-H656307-04	7/11/2023	7/11/2024	EACH OCCURRENCE	$ 2,000,000
	DED X RETENTION $ 0						AGGREGATE	$
							General Agg	$ 2,000,000
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						X PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N / A		WM3-H943412-03	7/11/2023	7/11/2024	E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
A	Professional Liab			LD3-H656305-04	7/11/2023	7/11/2024	Ea Occ/Agg $1M	3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Proof of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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To whom it may concern.

We have a MDEG administrator who will be taking on this responsibility for Sunrise Respiratory Care in Nevada. This individual is already registered as a MDEG administrator and has requested to transfer his existing administrator status from his present employer to Sunrise Respiratory when the application for MDEG is complete.

Thank you

Michael Eilbert

meilbert@sunriseresp.com

949 945-3230

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/ Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Sunrise Respiratory Care, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 1881 Langley Ave

City: Irvine State: CA Zip: 92614

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 9493986555 Website: www.sunriseresp.com

Licensing Company Email: management@sunriseresp.com

Section 2: Personal Information

First: Oscar Middle: Last: Munoz

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Stageline Dr

City: Laguna Hills State: CA Zip: 92653

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Long Beach Paramedical		9/1990 - 5/1992	
Address	**City**	**State**	**Zip**
3745 Long Beach Blvd	Long Beach	CA	90807
Diploma/Degree obtained, if any			
Respiratory Therapy			
School Name		**From - To (MM/YY – MM/YY)**	
Fountain Valley High School		9/1979 - 6/1983	
Address	**City**	**State**	**Zip**
	Fountain Valley	CA	92708
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2021	[redacted] Stageline Dr	Laguna Hills	CA	92653
From - To (MM/YY – MM/YY)	Address	City	State	Zip
2003 -2021	[redacted] Aurora Way	Mission Viejo	CA	92691
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Sunrise Respiratory Care			2010 - present
Business Address	**City**	**State**	**Zip**
1881 Langley Ave	Irvine	CA	92614
Phone	**Title**		
949 290-6364	CEO, President, Director		
Description of Duties			
Overall operational management, supervision of respiratory services and sales force. Recruitment. Daily oversight.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

CIVIL CODE § 1189

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California)

County of Orange)

On June 18, 2025 before me, John Alan Tackman, Notary Public
Date *Here Insert Name and Title of the Officer*

Personally appeared Oscar Munoz
Name(s) of Signer(s)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(~~ies~~), and that by his/her/their signature(~~s~~) on the instrument the person(~~s~~), or the entity upon behalf of which the person(~~s~~) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

JOHN ALAN TACKMAN
COMM. #2426991
Notary Public - California
Orange County
My Comm. Expires Nov. 17, 2026

Signature John Alan Tackman
Signature of Notary Public

Place Notory Seal *Above*

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document Acknowledgment Document Date June 18, 2025

Number of Pages Multiple Signer(s) Other Than Named Above —

Capacity(ies) Claimed by Signer(s)

Signer's Name	Signer's Name
☐ Corporate Officer—Title(s)	☐ Corporate Officer—Title(s)
☐ Partner ☐ Limited ☐ General	☐ Partner ☐ Limited ☐ General
☐ Individual ☐ Attorney in Fact	☐ Individual ☐ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator	☐ Trustee ☐ Guardian or Conservator
☐ Other	☐ Other
Signer Is Representing	Signer Is Representing

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Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Oscar Munoz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-18-23

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of ORANGE

I, John Alan Tackman, Notary Public, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

July 18, 2023

Date

Subscribed and Sworn to before me this 18 day of July.

Notary Public Signature

JOHN ALAN TACKMAN
COMM. #2426991
Notary Public - California
Orange County
My Comm. Expires Nov. 17, 2026

NRO1 NRO1

(Seal)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Orange County		
Reason/Charge				
Small Claims Business Dispute				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Horizon Medical			Lawsuit	
Name of Business/Industry/Entity				
Sunrise Respiratory Care				

Provide explanation below:

Small claims action. Uncontested. Debt paid.

Original Signature (electronic, copies or stamps not accepted)

7/13/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		County of San Bernardino		
Reason/Charge				
Wage and Hour Payroll Claim				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Armando Flores			Lawsuit	
Name of Business/Industry/Entity				
Sunrise Respiratory Care				

Provide explanation below:

Employee made wage and hour claim under California PAGA act. Settled without judgment.

Original Signature (electronic, copies or stamps not accepted)

7/13/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Orange County		
Reason/Charge				
Employment Practice Liability Claim				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Jennica Lindqvist			Lawsuit	
Name of Business/Industry/Entity				
Sunrise Respiratory Care				

Provide explanation below:

Employee made claim of wrongful termination by employer. Settled without judgment.

Original Signature (electronic, copies or stamps not accepted)

7/13/23
Date

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Sunrise Respiratory Care, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 1881 Langley Ave

City: Irvine State: CA Zip: 92614

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 9493986555 Website: www.sunriseresp.com

Licensing Company Email: management@sunriseresp.com

Section 2: Personal Information

First: Michael Middle: Last: Eilbert

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]oble Champions Way

City: Bartonville State: TX Zip: 76226

Telephone: [redacted] Email: meilbert@sunriseresp.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
USC Keck School of Medicine		9/1991-5/1995	
Address	**City**	**State**	**Zip**
1975 Zonal Ave	Los Angeles	CA	90033
Diploma/Degree obtained, if any			
MD			
School Name		From - To (MM/YY – MM/YY)	
University of California at Berkeley		9/1987-5/1991	
Address	**City**	**State**	**Zip**
Sather Hall	Berkeley	CA	94720
Diploma/Degree obtained, if any			
BA			
School Name		From - To (MM/YY – MM/YY)	
Fountain Valley High School		9/1983 - 6/1987	
Address	**City**	**State**	**Zip**
17816 Bushard S	Fountain Valley	CA	92708Sather
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2020 - Present	[redacted] Noble Champions Way	Bartonville	TX	76226
2015 - 2020	[redacted] Mahogany Run	Coto De Caza	CA	92679
2012 - 2015	[redacted] Prairestone Dr	Laguna Hills	CA	92653
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Sunrise Respiratory Care			2010 - present
Business Address	**City**	**State**	**Zip**
1881 Langley Ave	Irvine	CA	92614
Phone	**Title**		
949 290-6364	CFO, controller		

Description of Duties

Financial management and reporting, insurance, licensure

Business Name			From - To (MM/YY – MM/YY)
Pacific Hospitalist Associates			3/1999 - present
Business Address	**City**	**State**	**Zip**
361 Hospital Rd ste 521	Newport Beach	CA	92663
Phone	**Title**		
	MD and administrative		

Description of Duties

Provide patient care services at hospital. Various administrative and financial tasks

Business Name			From - To (MM/YY – MM/YY)
Michael J Eilbert MD			2009 - present
Business Address	**City**	**State**	**Zip**
963 Noble Champions Way	Bartonville	CA	76226
Phone	**Title**		
	CEO		

Description of Duties

Provide Medical-Legal Review and consultation. Expert Witness work

Business Name			From - To (MM/YY – MM/YY)
Pacific Hospitalist Insurance Group			2017 - present
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Oversee captive insurance for medical group

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2013		CA		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Orange County		
Reason/Charge				
Employment Practice Liability Claim				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Jennica Lindqvist			Lawsuit	
Name of Business/Industry/Entity				
Sunrise Respiratory Care				

Provide explanation below:

Employee made claim of wrongful termination by employer. Settled without judgment.

Original Signature (electronic, copies or stamps not accepted)

7/13/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2021		CA		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		County of San Bernardino		
Reason/Charge				
Wage and Hour Payroll Claim				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Armando Flores			Lawsuit	
Name of Business/Industry/Entity				
Sunrise Respiratory Care				

Provide explanation below:

Employee made wage and hour claim under California PAGA act. Settled without judgment.

Original Signature (electronic, copies or stamps not accepted)

7/13/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2013		CA		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Orange County		
Reason/Charge				
Small Claims Business Dispute				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Horizon Medical		Lawsuit		
Name of Business/Industry/Entity				
Sunrise Respiratory Care				

Provide explanation below:

Small claims action. Uncontested. Debt paid.

Original Signature (electronic, copies or stamps not accepted)

7/13/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Eilbert

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/17/23

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

See Attached Notary Document

(Seal)

CALIFORNIA JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document, to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF CALIFORNIA }

COUNTY OF Orange }

Subscribed and sworn to (or affirmed) before me on this 24th day of July, 2023
Date *Month* *Year*

by Michael Eilbert,

Name of Signer

proved to me on the basis of satisfactory evidence to be the person who appeared before me.

Signature: _____
Signature of Notary Public

TORU HORIMACHI
Notary Public - California
Orange County
Commission # 2387012
My Comm. Expires Jan 11, 2026

Seal
Place Notary Seal Above

---------- **OPTIONAL** ----------

Though this section is optional, completing this information can deter alteration of the document or fraudulent attachment of this form to an unintended document.

Description of Attached Document
Title or Type of Document: Personal History Application

Document Date: _____

Number of Pages: _____

Signer(s) Other Than Named Above: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Sunrise Respiratory Care MDEG License # (if applicable) _____

Physical Address 1881 Langley Ave

City Irvine State CA Zip 92614

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 949 398-6555 Website www.sunriseresp.com

Licensing Company Email management@sunriseresp.com

Section 2: Personal Information

First Oscar Middle _____ Last Munoz

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Stage line Dr.

City Laguna Hills State CA Zip 92653

Telephone [redacted] Email _____

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Fountain Valley High School		09/79 - 05/83	
Address	**City**	**State**	**Zip**
17816 Bushard St.	Fountain Valley	CA	92708
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Orange Coast College		09/85 - 06/86	
Address	**City**	**State**	**Zip**
2701 Fairview Rd.	Costa Mesa	CA	92626
Diploma/Degree obtained, if any			
General Education			

School Name		From - To (MM/YY – MM/YY)	
California ParaMedical College		06/90 - 09/92	
Address	**City**	**State**	**Zip**
3745 Long Beach Blvd.	Long Beach	CA	90807
Diploma/Degree obtained, if any			
Respiratory Therapist			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/20 - 08/23	[redacted] Stageline Dr.	Laguna Hills	CA	92653
06/02 - 10/20	[redacted] Aurora Way	Mission Viejo	CA	92691
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Sunrise Respiratory Care, Inc.		10/2010-08/2023	
Business Address	**City**	**State**	**Zip**
1881 Langley Ave.	Irvine.	CA	92614
Phone	**Title**	**Number of Employed Hours**	
(949) 398-6555	President / CEO	27,000 hours	
Description of Duties			
Administration and clerical duties to hospitals, and administer medical equipment.			

Business Name		From - To (MM/YY – MM/YY)	
Choice one Medical		02/03 - 11/09	
Business Address	**City**	**State**	**Zip**
Forbes Rd.	Laguna Niguel	CA	
Phone	**Title**	**Number of Employed Hours**	
	Director of Respiratory		
Description of Duties			
oversee all Respiratory Therapists and deliver ~~equi~~ Respiratory equipment.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8-23-23
Date

I, Oscar Munoz, **certify that as the MDEG Administrator for**

Sunrise Respiratory care, Inc.,

that I (initial that you have read and meet the following requirements):

1. ___ Have a high school diploma or its equivalent;
2. ___ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ___ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ___ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Oscar, Munoz
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/23/2023
Date

Board Use Only	Date Received: 8/28/23

4E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located? ☐ Nevada ☒ Out-of-State

[a]Is the business also a wholesaler? (NRS 639.016) ☐ Yes ☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☒ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: VasoCare, LLC

MDEG Physical Address: 6554 Florida Blvd Suite 123

City: Baton Rouge State: LA Zip: 70806

Mailing Address (if different from physical address): P.O. Box 14933

City: Baton Rouge State: LA Zip: 70898

Telephone: 225-924-0444 Website: www.vasocare.com

Email: john@vasocare.com

Name of MDEG Administrator (NAC 639.694): John Berges

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☒ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☒ Others: TENS and Pneumatic Compression Devices
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: John Berges
	Telephone: 225-978-6696

Check the Days the Business will be Opened and provide the Hours of Operation				
☑ Mon: 8-4	☑ Tue: 8-4	☑ Wed: 8-4	☑ Thurs: 8-4	☑ Fri: 8-4
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
NPI - 1720256662
PTA - 6106920001

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: Louisiana

Parent Company (if any):

Corporation Name: VasoCARE, LLC

Mailing Address: P.O. Box 14933

City: Baton Rouge State: LA Zip: 70898

Telephone: 225-924-0444 Email: john@vasocare.com

Contact Person Name: John Berges

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Louisiana

Parent Company (if any):

Corporation/Organization Name: VasoCARE, LLC

Mailing Address: P.O. Box 14933

City: Baton Rouge State: LA Zip: 70898

Telephone: 2259240444 Email: john@vasocare.com

Contact Person Name: John Berges

Section 7: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: John Berges

Business Name: VasoCARE, LLC

Business Address: 6554 Florida Blvd, Suite 123

City: Baton Rouge State: LA Zip: 70806

Telephone: 225-924-0444 Email: john@vasocare.com

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John J. Berges

Print Name of Authorized Person Submitting Application

John J Berges

Original signature of Authorized Person (copies or stamps not accepted)

7182023

Date

Board Use Only	Date Received: 7/20/23	Amount: 500-cc

State of Louisiana
Secretary of State

COMMERCIAL DIVISION
225.925.4704

Fax Numbers
225.932.5317 (Admin. Services)
225.932.5314 (Corporations)
225.932.5318 (UCC)

Name	Type	City	Status
VASOCARE, LLC	Limited Liability Company	BATON ROUGE	Active

Previous Names

Business: VASOCARE, LLC
Charter Number: 36636741K
Registration Date: 1/16/2008
Domicile Address
6554 FLORIDA BLVD
SUITE 123
BATON ROUGE, LA 70806
Mailing Address
PO BOX 14933
BATON ROUGE, LA 70898

Status

Status: **Active**
Annual Report Status: **In Good Standing**
File Date: 1/16/2008
Last Report Filed: 12/27/2022
Type: Limited Liability Company

Registered Agent(s)

Agent: CORPORATION SERVICE COMPANY
Address 1: 501 LOUISIANA AVENUE
City, State, Zip: BATON ROUGE, LA 70802
Appointment Date: 1/23/2018

Officer(s)

Additional Officers: No

Officer: JOHN J. BERGES
Title: Member
Address 1: 6554 FLORIDA BLVD
Address 2: SUITE 123
City, State, Zip: BATON ROUGE, LA 70806

Amendments on File (2)

Description	Date
Domestic LLC Agent/Domicile Change	2/17/2011
Domestic LLC Agent/Domicile Change	1/23/2018

Print

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 2/1/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER: VGM Insurance Services, Inc. 1111 W. San Marnan Dr. Waterloo IA 50701	CONTACT NAME: Ben Deutsch PHONE (A/C, No, Ext): (844) 346-3951 FAX (A/C, No): E-MAIL ADDRESS: Ben.Deutsch@vgm.com
INSURED: Vasocare LLC 6554 Florida Blvd Ste 123 Baton Rouge LA 70806	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: BENCHMARK INSURANCE COMPANY — 41394 INSURER B: HARTFORD STEAM BOILER INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR X Professional Liability GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY [ ] PRO-JECT [ ] LOC OTHER:			D1022 G3666-16	02/7/2023	02/7/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 100,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 3,000,000
	AUTOMOBILE LIABILITY ANY AUTO ALL OWNED AUTOS HIRED AUTOS SCHEDULED AUTOS NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
	UMBRELLA LIAB [ ] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [ ] N/A If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
B	Cyber Liability			CYD1022 G3666-16	02/7/2023	02/7/2024	Aggregate	100,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Blue Cross Blue Shield of Louisiana
5525 Reitz Ave
Baton Rouge LA 70809

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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LOUISIANA BOARD of PHARMACY The Louisiana Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, and further, performs daily updates to the website. Therefore, the website is a secure and primary source for credential verification, as authentic as a direct inquiry to the Board.

Lookup Detail View

Name and Address

Name	PublicAddress
VasoCARE	6554 Florida Blvd Ste 123 Baton Rouge, LA 70806-4474

Credential Information

License	License Type	Issue Date	Expiration Date	Status
DME.000440	Durable Medical Equipment (DME) Provider	09/26/2013	08/31/2023	Active; within renewal cycle

verified 7.20.23

CDS Schedules and Restrictions

I	II	II-N	III	III-N	IV	V	Restrictions	Alternative Privileges

Generated on: 7/19/2023 8:04:37 AM

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.922.0852 ~ Email: info@pharmacy.la.gov

Application for Renewal of Durable Medical Equipment (DME) Permit For 2023-2024

Please complete, date and sign this application; send with fee, payable to "Louisiana Board of Pharmacy," to the address noted above, between July 1 and August 31, 2023. The total fee due with this application, if submitted timely, is **$200**. An incomplete application, including one without any required attachments, will be returned to the applicant. An application hand-delivered, postmarked, or placed with a mail carrier on or after *September 1, 2023* shall require additional fees and procedures.

① pharmacy.la.gov
② Verify on Look up Licensee
③ Permit #

Section 1 – Company Information

DME Permit No. 000440

Legal Name of Organization VasoCARE

Business Name [*d/b/a*] VasoCARE, LLC

National Provider Identifier (NPI) No. 1720256662

Medicare Provider No. 6106920001

Louisiana Medicaid Provider No. 1372676

Owner's Managing Officer (OMO) John Berges
(Must sign application form below.)

Section 2 – Disciplinary Actions

Since the last renewal (*OR if this is the first renewal, then since the initial issuance of the DME permit*), has the firm identified above:

- or any of its owners or employees, been convicted of fraud by any local, state, or federal court with respect to Medicare, Medicaid, or any other insurance or third party benefits program?

  ☐ Yes ■ No

- had an application for a permit denied in any other jurisdiction, OR had an existing permit in any other jurisdiction sanctioned or disciplined by any local, state, or federal licensing authority

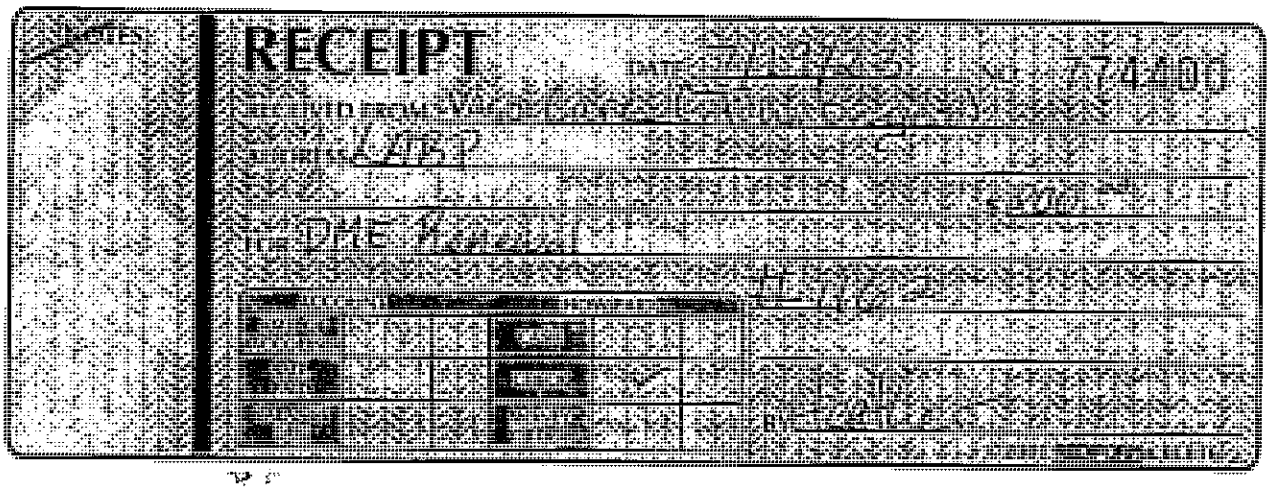
  ☐ Yes ■ No

An affirmative reply to either one of these questions requires two attachments: (1) your personal letter of explanation as well as (2) a certified copy of the judgment or other documents from the court or government agency.

Section 3 – Attestation

On behalf of the entity identified above, I certify I am the Owner's Managing Officer, and submit this application for the renewal of the DME permit identified above. I understand and agree this permit authorizes our firm to procure, possess and provide DME, legend devices and /or medical gases. Further, I understand and agree this permit does NOT authorize the procurement, possession, dispensing, or distribution of any legend drugs or controlled substances.

Signature of OMO John A Berges **Date** 7/19/2023


RECEIPT

y," to the
ed timely,
applicant.
ill require

Section 1 – Company Information

DME Permit No. 000440

Legal Name of Organization VasoCARE

Business Name [*d/b/a*] VasoCARE, LLC

National Provider Identifier (NPI) No. 1720256662

Medicare Provider No. 6106920001

Louisiana Medicaid Provider No. 1372676

Owner's Managing Officer (OMO) John Berges
(Must sign application form below.)

Section 2 – Disciplinary Actions

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- or any of its owners or employees, been convicted of fraud by any local, state, or federal court with respect to Medicare, Medicaid, or any other insurance or third party benefits program?

  ☐ Yes ■ No

- had an application for a permit denied in any other jurisdiction, OR had an existing permit in any other jurisdiction sanctioned or disciplined by any local, state, or federal licensing authority

  ☐ Yes ■ No

An affirmative reply to either one of these questions requires two attachments: (1) your personal letter of explanation as well as (2) a certified copy of the judgment or other documents from the court or government agency.

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Signature of OMO John A Berges **Date** 7/19/2023

John Berges
VasoCARE LLC
6554 Florida Blvd., Suite 123
Baton Rouge, LA 70806

May 18, 2023

RE: Accreditation Award

Dear John Berges,

The Healthcare Quality Association on Accreditation is pleased to inform you that VasoCARE LLC meets the DME accreditation requirements under section 1834(a)(20) of the Social Security Act (SSA) and the federal regulations at 42 CFR 424.58. HQAA has based this finding on a review of your application and an onsite survey conducted April 27, 2023.

This three-year accreditation award applies to the following VasoCARE LLC location through May 2, 2026:

6554 Florida Blvd., Suite 123
Baton Rouge, LA 70806
NPI # 1720256662

Please maintain a copy of your current equipment list with this letter. We look forward to working with you as you serve your customers throughout your service area. If you have any questions, please contact us.

Sincerely,

Rhonda Pearce
Executive Director

Award of Accreditation

For DMEPOS Products & Services
Awarded to

VasoCARE LLC
Baton Rouge, LA
HQAA ID # UFJDRI6D9

On this day of

May 2, 2023

For the dedicated commitment of demonstrating high standards of quality in business and patient care.

HQAA
HEALTHCARE QUALITY ASSOCIATION ON ACCREDITATION

President, CEO Signature
or Executive Director Signature

HQAA
ACCREDITED

This accreditation award is in effect for three years from the above date.

4/26/23, 1:40 PM CMSEquipmentList

Fax 800-851-2804

HQAA | HEALTHCARE QUALITY ASSOCIATION ON ACCREDITATION

WWW.HQAA.ORG CALL: 866.909.4722

Please fill in the following for:

VasoCARE LLC
6554 Florida Blvd., Suite 123
Baton Rouge LA 70806

Last Updated 9/30/2022

Corporate/Warehouse

This location is a Subcontractor, and solely provides delivery and education for DME companies DI

☐ This location does not supply ANY equipment and solely provides administrative support to the company NOPROC

Non-Medicare - Uncategorized Product NOPRON

☐ This location is a Warehouse/Storage location and does not dispense equipment items directly to patients NOPROW

Mobility Assistive Equipment

☐ Power Operated Vehicles (Scooters) M03
☐ Wheelchairs-Standard Manual M06
☐ Wheelchairs-Standard Manual Related Accessories and Repairs M06A
☐ Wheelchairs-Standard Power M07
☐ Wheelchairs-Standard Power Related Accessories and Repairs M07A
☐ Wheelchairs-Complex Rehabilitative Manual Wheelchairs M08
☐ Wheelchairs-Complex Rehabilitative Manual Wheelchairs Related Accessories M08A
☐ Wheelchairs-Complex Rehabilitative Power Wheelchairs M09
☐ Wheelchairs-Complex Rehabilitative Power Wheelchairs Related Accessories M09A
☐ Wheelchair Seating/Cushions M10

Respiratory Equipment

☐ Continuous Positive Airway Pressure (CPAP) Devices and/or Supplies R01
☐ High Frequency Chest Wall Oscillation (HFCWO) Devices and/or Supplies R02
☐ Intermittent Positive Pressure Breathing (IPPB) Devices R04
☐ Intrapulmonary Percussive Ventilation Devices R05
☐ Mechanical In-Exsufflation Devices R06
☐ Nebulizer Equipment and/or Supplies R07
☐ Oxygen Equipment R08
☐ Oxygen Supplies R08A
☐ Respiratory Assist Devices R09
☐ Respiratory Suction Pumps R10
☐ Ventilators: all types - not CPAP or RAD R12

Durable Medical Equipment

- [ ] Automatic External Defibrillators (AEDs) and/or Supplies DM01
- [ ] Commodes/Urinals/Bedpans DM02
- [ ] Continuous Passive Motion (CPM) Devices DM03
- [ ] Contracture Treatment Devices: Dynamic Splint DM04
- [ ] Blood Glucose Monitors and/or Supplies (non-mail order) DM05
- [ ] Blood Glucose Monitors and/or Supplies (mail order) DM06
- [ ] Gastric Suction Pumps DM07
- [ ] Heat & Cold Applications DM08
- [ ] Hospital Beds-Electric DM09
- [ ] Hospital Beds-Manual DM10
- [ ] Infrared Heating Pad Systems and/or Supplies DM11
- [ ] External Infusion Pumps DM12
- [ ] External Ambulatory Insulin Pump DM13
- [ ] Implanted Infusion Pumps and/or Supplies DM14
- [ ] Negative Pressure Wound Therapy Pumps and/or Supplies DM15
- [x] Neuromuscular Electrical Stimulators (NMES) and/or Supplies DM16
- [ ] Osteogenesis Stimulators DM17
- [x] Pneumatic Compression Devices and/or Supplies DM18
- [ ] Speech Generating Devices DM19
- [ ] Pressure Reducing Beds/Mattresses/Overlays/Pads - New DM20
- [ ] Traction Equipment DM21
- [ ] Transcutaneous Electrical Nerve Stimulators (TENS) and/or Supplies DM22
- [ ] Ultraviolet Light Devices and/or Supplies DM23
- [ ] External Infusion Supplies DM24
- [ ] External Ambulatory Insulin Supplies DM25
- [ ] Pressure Reducing Beds/Mattresses/Overlays/Pads - Used DM26
- [ ] Canes and Crutches M01
- [ ] Patient Lifts M02
- [ ] Seat Lift Mechanisms M04
- [ ] Walkers M05
- [ ] Ostomy Supplies PD06
- [ ] Tracheostomy Supplies PD08
- [ ] Urological Supplies PD09

Orthoses

- [ ] Orthoses: Custom Fabricated OR01
- [ ] Orthoses: Prefabricated (non-custom fabricated) OR02
- [ ] Orthoses: Off-The-Shelf OR03
- [ ] Penile Pumps OR04

Prosthetic Devices

- ☐ Breast Prostheses and Accessories PD01
- Cochlear Implants PD02
- ☐ Facial Prostheses PD03
- Neurostimulators and/or Supplies PD04
- Ocular Prostheses PD05
- Somatic Prostheses PD07
- ☐ Voice Prosthetics PD10
- ☐ Prosthetic Lenses: Conventional Eyeglasses PD11
- ☐ Prosthetic Lenses: Conventional Contact Lenses PD12
- Prosthetic Lenses: Prosthetic Cataract Lenses PD13
- ☐ Limb Prostheses PR01
- Eye Prostheses PR02

Enteral and Parenteral Nutrition

- ☐ Enteral Nutrients PE03
- ☐ Enteral Equipment and/or Supplies PE04
- ☐ Parenteral Nutrients (Requires State Pharmacy License) PE05
- ☐ Parenteral Equipment and/or Supplies PE06

Supplies

- ☐ Surgical Dressings S01
- ☐ Diabetic Shoes/Inserts, Off the Shelf S02
- ☐ Diabetic Shoes/Inserts, Custom S03

Submit Next page

Corey Carroll
HQAA 4/27/23

John J. Berges
VASoCal
4/27/2023

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site VasoCARE, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 6554 Florida Blvd, Suite 123

City Baton Rouge State LA Zip 70806

Mailing Address (if different from physical address) P. O. Box 14933

City Baton Rouge State LA Zip 70898

Telephone 225-924-0444 Website www.vasocare.com

Licensing Company Email john@vasocare.com

Section 2: Personal Information

First John Middle Joseph Last Berges

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address P.O. Box [redacted]

City Baton Rouge State LA Zip 70898

Telephone [redacted] Email john@vasocare.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern Mississippi		09/65-09/68	
Address	**City**	**State**	**Zip**
118 College Dr	Hattiesburg	MS	39406
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Holy Name of Mary High School		1961-1963	
Address	**City**	**State**	**Zip**
400 Verret St	Algiers	LA	70114
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2011- 07/23	[redacted]East Lake Terrace	Baon Rouge	LA	70817
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
VasoCARE, LLC			01/08-07/23
Business Address	**City**	**State**	**Zip**
6554 Florida Blvd, Suite 123	Baton Rouge	LA	70806
Phone	**Title**		
225-924-0444	President/Owner		
Description of Duties			
Home medical equipment - pneumatic compression devices for treating lymphedema and neuromuscular electrical stimulation for healing diabetic foot ulcers.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7-18-2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John J Berges

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 18, 2023

Date

Please have this section completed in the presence of a Notary Public.

State of Louisiana, ss. County of East Baton Rouge

I, John Joseph Berges, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

July 18- 2023

Date

Subscribed and Sworn to before me this 18th day of July, 2023

Notary Public Signature

MOHAMED MOUSSA
Notary Public
State of Louisiana
East Baton Rouge Parish
Notary ID # 131190
My Commission is for Life

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

NAC 639.694

1. **Each medical products provider or medical products wholesaler shall employ an administrator at all times. The administrator must:**
   a. Be a natural person;
   b. Have a high school diploma or its equivalent;
   c. Have:
      i. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
      ii. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
   d. Be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
   e. Be approved by the Board.
2. The administrator shall ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.
3. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after the beginning of the employment.
4. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

NAC 639.6946

1. Except as otherwise provided in NAC 639.6945, a medical products provider shall:
   a. Provide services for all medical products sold, leased or otherwise provided by the medical products provider, including, without limitation, set up, repair and maintenance.
   b. Employ an administrator and other employees sufficient to provide the services described in paragraph (a).

NAC 639.6957

1. A medical products wholesaler shall:
   a. Employ a facility administrator and other employees sufficient to operate, set up, repair, maintain and service all medical products sold, leased or otherwise provided by the medical products wholesaler.

Please mail this completed application and all other required documents with your MDEG and/or Wholesaler Application to the address indicated above.

If you have any questions, please contact the Nevada State Board of Pharmacy at 775-850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG VasoCARE, LLC John J. Berges MDEG License # (if applicable) _____

Physical Address 6554 Florida Blvd, Suite 123

City Baton Rouge State LA Zip 70806

Mailing Address (if different from physical address) P.O. Box 14933

City Baton Rouge State LA Zip 70898

Telephone 225-924-0444 Website www.vasocare.com

Licensing Company Email john@vasocare.com

Section 2: Personal Information

First John Middle J. Last Berges

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address P.O. Box [redacted]

City Baton Rouge State LA Zip 70898

Telephone [redacted] Email john@vasocare.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern Mississippi		09/65-09/68	
Address	**City**	**State**	**Zip**
118 College Dr.	Hattiesburg	MS	39406
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Holy Name of Mary High School		1961-1963	
Address	**City**	**State**	**Zip**
400 Verret	Algiers	LA	70114
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/11-07/23	[redacted] East Lake Terrace	Baton Rouge	LA	70817
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
VasoCARE, LLC		01/08-7/23	
Business Address	**City**	**State**	**Zip**
6554 Florida Blvd, Suite 123	Baton Rouge	LA	70806
Phone	**Title**	**Number of Employed Hours**	
225-924-0444	President/Owner	37,500	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7-18-2023
Date

I, John Berges, **certify that as the MDEG Administrator for**

VasoCARE, LLC,

that I (initial that you have read and meet the following requirements):

1. JJB Have a high school diploma or its equivalent;
2. JJB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JJB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JJB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John J Berges

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/18/2023

Date

Board Use Only	Date Received:

4F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: SunMed Group Holdings, LLC (dba AirLife)

Physical Address: 2710 Northridge Dr. NW, Suite A

City: Grand Rapids State: MI Zip: 49544

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-433-2797 Website: www.myairlife.com

Name of Designated Representative (DR): Rob Yamashita

Licensing Company Email: info@myairlife.com DR Email: ryamashita@myairlife.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: SunMed AP, LTD.
Address: 6-9 Zhufeng Rd, Qiannan Industrial Park City: Zhuhai City State: China Zip: 519170

Name: Well Lead Medical Co., Ltd.
Address: No. 47, Guomao Avenue South, Hualong City: Panyu, Guangzhou State: China Zip: 511434

Name: Plaxtron Industrial (M) Sdn. Bhd.
Address: Plot 28, Kawasan Perusahaan II City: Ipoh, Perak State: 30020 Zip: Malaysia

Name: Foxxmed Ltd.
Address: #60 Jianjin 2nd Rd, Dongshan Township City: Yilan County State: 269 Zip: Taiwan

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any):
Corporation/Organization Name: FH Sunrise Purchaser, Inc.
Mailing Address: 2710 Northridge Dr. NW, Suite A
City: Grand Rapids State: MI Zip: 49544
Telephone: 616-481-9115 Email: vdecker@myairlife.com
Contact Person Name: Valerie Decker

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

SunMed Group Holdings, LLC

Facility Name

Valerie A. Decker

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8/21/2023

Date

Board Use Only	Date Received: 8/23/23	Amount: 1000-CC ✓ 8/31/23

AirLife

September 19, 2023

RE: Nevada Temporary Wholesale License Application

Dear Nevada State Board of Pharmacy,

SunMed Group Holdings, LLC *dba* AirLife, on behalf of its subsidiary SunMed LLC, seeks a temporary license with the State of Nevada to distribute its medical devices to hospitals and medical facilities in Nevada.

AirLife has applied to obtain the "wholesaler license" for its subsidiary company SunMed LLC. This application is in the final stages of review with the Nevada State Board of Pharmacy, and we hope to have the approval in the upcoming weeks. We have ceased selling products into Nevada and did not contest and paid the $5,000 administrative fine based on case number 23-131-O (see FedEx tracking # 6843 5296 8680 for payment confirmation). In the meantime, we have a tremendous amount of demand from the local distribution channels in the State of Nevada. Any further disruption to the supply of our life-saving medical devices (which include resuscitation devices, endotracheal tubes, and oxygen administration supplies) into the State of Nevada could result in hospitals and clinicians being hindered in their ability to help their patients, the citizens of Nevada.

We are kindly asking for a temporary license so we can meet the Nevada medical community's demand for our life saving products. AirLife is committed to compliance with all state and federal regulations and laws, including Nevada's.

If you have questions, please feel free to contact me. Thank you.

Sincerely,

THANK CLEARSH APPROVED

9/25/23

Rob Yamashita

VP of Regulatory Affairs
269-873-0502
ryamashita@myairlife.com
2710 Northridge Dr. NW, Suite A I Grand Rapids, MI 49544 I USA

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

SUNMED HOLDINGS, LLC
2710 NORTHRIDGE DR.
SUITE A
GRAND RAPIDS, MI 49544

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

SUNMED HOLDINGS, LLC
2710 NORTHRIDGE DR.
SUITE A
GRAND RAPIDS, MI 49544

LICENSE NO.
5306006515

EXPIRATION DATE
06/18/2025

23229140858

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

SUNMED HOLDINGS, LLC
2710 NORTHRIDGE DR.
SUITE A
GRAND RAPIDS, MI 49544

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

SUNMED HOLDINGS, LLC
2710 NORTHRIDGE DR.
SUITE A
GRAND RAPIDS, MI 49544

LICENSE NO.
5306006515

EXPIRATION DATE
06/18/2025

23229140858

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

AirLife

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521
(775)850-1440

August 21, 2023

To Whom It May Concern,

Corresponding to the Wholesaler Applications for SunMed Group Holdings, LLC and Westmed, Inc, here is the required list of all the Officers and Directors:

Westmed, Inc.
Directors:

- Hendrik Struik
- Jon Singer

Officers:

- Hendrik Struik – Chief Executive Officer
- Jon Singer – Chief Financial Officer
- Caitlin Anderson – Chief Administrative Officer, General Counsel & Secretary

SunMed Group Holdings, LLC
Directors:

- Member-managed by FH Sunrise Purchaser, Inc.

Officers:

- Hendrik Struik – Chief Executive Officer
- Jon Singer – Chief Financial Officer
- Caitlin Anderson – Chief Administrative Officer, General Counsel & Secretary

Best Regards,

Valerie Decker

International Regulatory Specialist
AirLife | SunMed | Salter Labs | Westmed | Ventlab | Ethox

Toll Free 800.433.2797
T 616.259.8400
F 616.647.3430
www.myAirLife.com
2710 Northridge Dr NW, Ste. A
Grand Rapids, MI 49544

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SUNMED GROUP HOLDINGS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF AUGUST, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7571375 8300

SR# 20233282177

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203991346

Date: 08-17-23

Help (./help/index.html)

DRLM Home (mainMenu.htm) > View Your Registrations and Listings

Registration Information

Facility

Registration Number
1314417

FEI Number
1314417

Registration Status
Active

Registration Status Reason
TofO facility purchase

Initial Importer
Y

Facility Name
SUNMED HOLDINGS, LLC

Legal Name

Facility Address
2710 NORTHRIDGE DR NW STE A
GRAND RAPIDS, MICHIGAN, 49544, UNITED STATES

DUNS Number

Foreign Trade Zone
N

Facility URL
www.sun-med.com

Other Business Trade Name(s)
1. SunMed, LLC
2. Ventlab, LLC
3. Ethox Medical, LLC

Establishment located on a campus

Owner/Operator

Owner/Operator Number
10044795

Contact Name
ROB YAMASHITA

Business Name
SUNMED HOLDINGS, LLC (DBA VENTLAB, LLC, DBA ETHOX MEDICAL, LLC, DBA SUNMED, LLC)

Address

2710 NORTHRIDGE DRIVE NW, SUITE A
GRAND RAPIDS, MICHIGAN, 49544, UNITED STATES

Phone Number
01 - 616 - 2598373

Fax Number
01 - 616 - 6473430

E-mail ryamashita@sun-med.com

DUNS Number

Official Correspondent

Contact Name
ROB YAMASHITA

Business Name
SUNMED HOLDINGS, LLC (DBA VENTLAB, LLC, DBA ETHOX MEDICAL, LLC, DBA SUNMED, LLC)

Address
2710 NORTHRIDGE DRIVE NW, SUITE A
GRAND RAPIDS, MICHIGAN, 49544, UNITED STATES

Phone Number
01 - 616 - 2598373

Fax Number
01 - 616 - 6473430

E-mail ryamashita@sun-med.com

DUNS Number

Registration Status

Expiration Date
2023-12-31

PIN - PCN
50378620 - 23546981

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
SunMed Holdings, LLC
Business Trade Names:
(1) Ethox Medical, LLC (2) SunMed, LLC (3) Ventlab, LLC

2710 Northridge Dr NW Ste A
Grand Rapids, MI 49544
Registration Number: 1314417
FEI Number*: 1314417
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2023

Owner/Operator:
SunMed Holdings, LLC (Dba Ventlab, LLC, Dba Ethox Medical, L
2710 Northridge Drive NW, Suite A
Grand Rapids, MI US 49544
Owner/Operator Number: 10044795

Official Correspondent:
Rob Yamashita
2710 Northridge Drive NW, Suite A
Grand Rapids, MI 49544
Phone: 01-616-2598373

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Verified 8/31/23

Page Last Updated: 08/28/2023
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

12/31/2023

DATE (MM/DD/YYYY) 6/1/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Lockton Companies 3280 Peachtree Road NE, Suite #1000 Atlanta GA 30305 (404) 460-3600	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED 1493635 Salter Labs, LLC 272 E. Deerpath Rd Suite 302 Lake Forest IL 60045	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Great Northern Insurance Company — 20303 INSURER B : Federal Insurance Company — 20281 INSURER C : Chubb Indemnity Insurance Company — 12777 INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 18018543 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR X STOP GAP X $1,000,000 GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:	N	N	36057113	12/31/2022	12/31/2023	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ XXXXXXX $
A	AUTOMOBILE LIABILITY X ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY [ ]	N	N	73618786	12/31/2022	12/31/2023	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ 1,000,000 $ XXXXXXX $ XXXXXXX $ XXXXXXX $ XXXXXXX
B	X UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [X] RETENTION $ $0	N	N	78181821	12/31/2022	12/31/2023	EACH OCCURRENCE AGGREGATE [ ]	$ 10,000,000 $ 10,000,000 $ XXXXXXX
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A	N	71776686	12/31/2022	12/31/2023	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
B	Products/E&O-Claims Made	N	N	99497228	12/31/2022	12/31/2023	Occurrence Limit: $10,000,000 Deductible: 100,000 Aggregate: $10,000,000	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

18018543
For Informational Purposes Only

CANCELLATION See Attachments

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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VALUED CERTIFICATE HOLDER

To whom it may concern:

In our continuing effort to provide timely certificate delivery, Lockton Companies is transitioning to paperless delivery of Certificates of Insurance.

To ensure electronic delivery for future renewals of this certificate, we need your email address. Please contact us via the methods below, referencing Certificate Number that is listed in the Certificate Holder box just above the Certificate Holder Name or in middle section just below the Insured box towards the top **"CERTIFICATE NUMBER: ".**

- Email: **SE-EDelivery@lockton.com**
- **Include the Certificate ID number**
- **Subject line: TSU E-Delivery**

If you no longer need this certificate, please contact us at the email address above, reference the Certificate Holder ID number and use this subject line: "Certificate Removal"

The above inbox is for automating electronic delivery of certificates only. Please do NOT send future certificate requests to this inbox.

Thank you for your cooperation and willingness in reducing our environmental footprint.

Lockton Companies

Named Insureds

1. FH Sunrise Purchaser, Inc.
2. SunMed Group Holdings, LLC
3. SunMed Holdings, LLC
4. Omega Medical Products, LLC
5. Blue Jay Holding, LLC
6. SunMed, LLC
7. Bay Medical Products, LLC
8. Mainline Medical Products, LLC
9. Ventlab, LLC
10. VL International Limited
11. SunMed AP, LTD
12. Salter Labs, LLC
13. Salter Labs Texas, LLC
14. Ethox Medical, LLC
15. Salter Labs de Mexico S.A. de C.V.
16. Salter Labs UK Limited
17. Parker Medical, LLC
18. Westmed Holding Company
19. Westmed, Inc.
20. VBT, LLC
21. Westmed de Mexico S.A. de C.V
22. Cookgas, LLC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. SU 1196421

Application/License No. _____

SunMed Group Holdings, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2710 Northridge Dr. NW, Suite A, Grand Rapids, MI 49544 (Address of Applicant/Principal), as PRINCIPAL, and Arch Insurance Company (Surety Company), a corporation organized under the laws of the state of MO (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is Harborside 3, 210 Hudson Street, Suite 300, Jersey City, NJ 07311-1107 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 08/30/2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 30th day of August, 2023.

APPLICANT/PRINCIPAL
SunMed Group Holdings, LLC

Authorized Representative

SURETY COMPANY
Arch Insurance Company

Surety Company's Representative

Stephen A. Vann, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Ryan Norman

Witness Emma Bryant

Countersigned by:

N/A
Nevada Resident Agent

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated. Not valid for Note, Loan, Letter of Credit, Currency Rate, Interest Rate or Residential Value Guarantees.

POWER OF ATTORNEY

Know All Persons By These Presents:
That the Arch Insurance Company, a corporation organized and existing under the laws of the State of Missouri, having its principal administrative office in Jersey City, New Jersey (hereinafter referred to as the "Company") does hereby appoint:

Bradley Mapes, Oana Dimulescu, Sarah C. Belcastro and Stephen A. Vann of Atlanta, GA (EACH)

its true and lawful Attorney(s)in-Fact, to make, execute, seal, and deliver from the date of issuance of this power for and on its behalf as surety, and as its act and deed: Any and all bonds, undertakings, recognizances and other surety obligations, in the penal sum not exceeding One Hundred Fifty Million Dollars ($150,000,000.00). This authority does not permit the same obligation to be split into two or more bonds In order to bring each such bond within the dollar limit of authority as set forth herein.

The execution of such bonds, undertakings, recognizances and other surety obligations in pursuance of these presents shall be as binding upon the said Company as fully and amply to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at its principal administrative office in Jersey City, New Jersey.

This Power of Attorney is executed by authority of resolutions adopted by unanimous consent of the Board of Directors of the Company on August 31, 2022, true and accurate copies of which are hereinafter set forth and are hereby certified to by the undersigned Secretary as being in full force and effect:
"**VOTED**, That the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, or the Secretary shall have the power and authority to appoint agents and attorneys-in-fact, and to authorize them subject to the limitations set forth in their respective powers of attorney, to execute on behalf of the Company, and attach the seal of the Company thereto, bonds, undertakings, recognizances and other surety obligations obligatory in the nature thereof, and any such officers of the Company may appoint agents for acceptance of process."

This Power of Attorney is signed, sealed and certified by facsimile under and by authority of the following resolution adopted by the unanimous consent of the Board of Directors of the Company on August 31, 2022:

VOTED, That the signature of the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, and the signature of the Secretary, the seal of the Company, and certifications by the Secretary, may be affixed by facsimile on any power of attorney or bond executed pursuant to the resolution adopted by the Board of Directors on August 31, 2022, and any such power so executed, sealed and certified with respect to any bond or undertaking to which it is attached, shall continue to be valid and binding upon the Company. **In Testimony Whereof**, the Company has caused this instrument to be signed and its corporate seal to be affixed by their authorized officers, this **3rd day of January, 2023**.

Attested and Certified

Regan A. Shulman, Secretary

Arch Insurance Company

Stephen C. Ruschak, Executive Vice President

STATE OF PENNSYLVANIA SS
COUNTY OF PHILADELPHIA SS

I, **Michele Tripodi**, a Notary Public, do hereby certify that Regan A. Shulman and Stephen C. Ruschak personally known to me to be the same persons whose names are respectively as Secretary and Executive Vice President of the Arch Insurance Company, a Corporation organized and existing under the laws of the State of Missouri, subscribed to the foregoing instrument, appeared before me this day in person and severally acknowledged that they being thereunto duly authorized signed, sealed with the corporate seal and delivered the said instrument as the free and voluntary act of said corporation and as their own free and voluntary acts for the uses and purposes therein set forth.

Commonwealth of Pennsylvania - Notary Seal
MICHELE TRIPODI, Notary Public
Philadelphia County
My Commission Expires July 31, 2025
Commission Number 1168522

Michele Tripodi, Notary Public
My commission expires 07/31/2025

CERTIFICATION
I, **Regan A. Shulman**, Secretary of the Arch Insurance Company, do hereby certify that the attached **Power of Attorney dated January 3, 2023** on behalf of the person(s) as listed above is a true and correct copy and that the same has been in full force and effect since the date thereof and is in full force and effect on the date of this certificate; and I do further certify that the said Stephen C. Ruschak, who executed the Power of Attorney as Executive Vice President, was on the date of execution of the attached Power of Attorney the duly elected Executive Vice President of the Arch Insurance Company.
IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seal of the Arch Insurance Company on this **30th day of August, 2023**.

Regan A. Shulman, Secretary

This Power of Attorney limits the acts of those named therein to the bonds and undertakings specifically named therein and they have no authority to bind the Company except in the manner and to the extent herein stated.

PLEASE SEND ALL CLAIM INQUIRIES RELATING TO THIS BOND TO THE FOLLOWING ADDRESS:
Arch Insurance – Surety Division
3 Parkway, Suite 1500
Philadelphia, PA 19102

To verify the authenticity of this Power of Attorney, please contact Arch Insurance Company at SuretyAuthentic@archinsurance.com Please refer to the above named Attorney-in-Fact and the details of the bond to which the power is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: SunMed Group Holdings, LLC — MDEG License # (if applicable): 1314417

Physical Address: 2710 Nothridge Dr. NW, Suite A

City: Grand Rapids — State: MI — Zip: 49544

Mailing Address (if different from physical address):

City: — State: — Zip:

Telephone: 800-433-2797 — Website: www.myairlife.com

Licensing Company Email: info@myairlife.com

Section 2: Personal Information

First: Valerie — Middle: Ann — Last: Decker

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]N. White Rd.

City: Pierson — State: MI — Zip: 49339

Telephon[redacted] — Email: vdecker@myairlife.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Michigan State University		08/1997-0452001	
Address	City	State	Zip
426 Auditorium Road	East Lansing	MI	48824
Diploma/Degree obtained, if any			
Bachelor of Science in Physiology			
School Name		From - To (MM/YY – MM/YY)	
Lyman Briggs College		08/1997-05/2001	
Address	City	State	Zip
919 E Shaw Ln	East Lasning	MI	48825
Diploma/Degree obtained, if any			
Certificate of Science and Technology Studies			
School Name		From - To (MM/YY – MM/YY)	
Rockford Senior High School			
Address	City	State	Zip
4100 Kroes Street	Rockford	MI	49341
Diploma/Degree obtained, if any			
College Prep Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019-current	[redacted] N. White Rd.	Pierson	MI	49339
2018-2019	[redacted] N. Bossett Rd.	Ravenna	MI	49451
2015-2018	[redacted] Bridgeview Bay Lane	Norton Shores	MI	49441
2010-2015	[redacted] East Avery Ct. NW	Grand Rapids	MI	49534
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
SunMed Group Holdings, LLC			02/2022-current	
Business Address		**City**	**State**	**Zip**
2710 Northridge Dr. NW, Suite A		Grand Rapids	MI	49544
Phone	**Title**		**Number of Employed Hours**	
616-481-9115	International Regulatory Specialist		>3,000	
Description of Duties				
International registrations, product information requests, state licensing, regulatory impact assessments, etc.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) _____ Date _____

I, Valerie A. Decker, **certify that as the MDEG Administrator for**

SunMed Group Holdings, LLC,

that I (initial that you have read and meet the following requirements):

1. VAD Have a high school diploma or its equivalent;
2. VAD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. VAD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. VAD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Valerie A. Decker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/21/2023

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler SunMed Group Holdings LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2710 Northridge Drive NW - Suite A

City Grand Rapids State MI Zip 49544

Mailing Address (if different from physical address) N/A

City N/A State N/A Zip N/A

Telephone 616-259-8400 Website www.myairlife.com

Licensing Company Email info@myairlife.com

Section 2: Personal Information

First Robert Middle Akira Last Yamashita

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Northridge Drive NW - Suite[redacted]

City Grand Rapids State MI Zip 49544

Telephon[redacted] Email ryamashita@myairlife.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520; NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western Michigan University		09/99 - 06/04	
Address	**City**	**State**	**Zip**
1903 W. Michigan Ave	Kalamazoo	MI	49008
Diploma/Degree obtained, if any			
Bachelor's Degree, Computer Information Systems			

School Name		From - To (MM/YY – MM/YY)	
University Hill Secondary High School		09/92 - 06/96	
Address	**City**	**State**	**Zip**
3228 Ross Drive	Vancouver	BC	V6S 0C6
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2015 - 08/2023	[redacted] Royal Hannah Drive	Rockford	MI	49341
From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2007 - 04/2015	[redacted] Frontier Avenue	Portage	MI	49024
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
SunMed Group Holdings LLC			01/14 - 08/23	
Business Address		**City**	**State**	**Zip**
2710 Northridge Drive NW - Suite A		Grand Rapids	MI	49544
Phone	**Title**		**Number of Employed Hours**	
616-259-8400	VP of Regulatory Affairs		85,200	
Description of Duties				
Lead the Regulatory Affairs team.				

Business Name			From - To (MM/YY – MM/YY)	
Stryker Craniomaxillofacial (CMF)			01/09 - 12/13	
Business Address		**City**	**State**	**Zip**
750 Trade Centre Way		Portage	MI	49002
Phone	**Title**		**Number of Employed Hours**	
269-385-2600	Associate Manager, RAQA		43,800	
Description of Duties				
Lead US FDA Regulatory Affairs and Quality Assurance				

Business Name			From - To (MM/YY – MM/YY)	
Stryker Medical			01/04 - 12/08	
Business Address		**City**	**State**	**Zip**
3800 E. Centre Ave		Portage	MI	49002
Phone	**Title**		**Number of Employed Hours**	
269-329-2100	Sr. IT Helpdesk Lead		43,800	
Description of Duties				
Lead the IT Helpdesk and network infrastructure support.				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		N/A		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted) Date

I, Rob Yamashita, **certify that as the designated representative for**

SunMed Group Holdings LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RAY I am at least 21 years of age;
3. RAY I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RAY I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RAY I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RAY I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RAY I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Rob Yamashita
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

17 Aug 2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rob Yamashita

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

17 Aug 2023

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Kent

I, Kyle Griffin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

17 AUG 2023

Date

Subscribed and Sworn to before me this 17 day of August 2023.

Notary Public Signature

KYLE GRIFFIN
Notary Public - State of Michigan
County of Kent
My Commission Expires Apr 21, 2028
Acting in the County of Kent

(Seal)

AirLife

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

August 21, 2023

To Whom It May Concern,

Corresponding to the Wholesaler Application for SunMed Group Holdings, LLC, here is the required list of all persons employed at 2710 Northridge Dr. NW, Suite A, Grand Rapids, MI 49544:

Allen	Pamela	REGSPEC - Regulatory Specialist
Anderson	Abram Joel	DOCORD - Document Control Coordinator
Arnold	Julee	OPSPECAT - Operations Specialist- Catalog
Ashley	Debra	PRODUCT - Production
Awng	Zau Mun	WRHASSOC - Warehouse Associate
Ball	Lisa	SRDIRCON - Senior Director, Assistant Controller
Battista	Travis	NTWENG - Network Engineer
Bishop	Jara	SCHBYPLN - Supply Chain Buyer/Planner
Bliss	Kayla	LABLMGR - Labeling Manager
Bowden	Dylan	MRKGRDES - Marketing Graphic Designer
Brickley	Melissa	REGSPEC - Regulatory Specialist
Brock	Amanda	REC - Recruiter
Brown	Mark	MACHTECH - Machine Technician
Brown	Ethan	PRODTENG - Product Engineer
Burnis	Elizabeth M	WEBMGR - Web Manager
Bustraan	Michael Allyn	SHRESP - Shipping and Receiving Specialist
Calkins	Jennifer	WRHASSOC - Warehouse Associate
Calkins	Tyler James	WRHASSOC - Warehouse Associate
Carillo Sr	Javier	JANITOR - Janitor
Casey	Timothy	SLSPEC - Sales Specialist
Chen	Aron	SYSANLST - Systems Analyst

Toll Free 800.433.2797
T 616.259.8400
F 616.647.3430
www.myAirLife.com
2710 Northridge Dr NW, Ste. A
Grand Rapids, MI 49544

AirLife

Colclasure	Jesse Michael	ENGPM - Engineering Project Manager
Coleman	Sherin Marie	WRHASSOC - Warehouse Associate
Colon	Amy J	DIRQUALT - Director of Quality
Corea Flores	YeniFer E	WRHASSOC - Warehouse Associate
Cullimore	Cali	SRHRGEN - Senior Human Resources Generalist
Currier	Brad Dale	PURMGR - Purchasing Manager
Cwynar	Adam	PRDVLDEN - Product Validation Engineer
Dahmen	Leslie Ann	QALENG - Quality Engineer
Daly	Mark	REC - Recruiter
Danov	Timothy	DIRBANAL - Director of Business Analytics
Decker	Valerie	INTREGS - International Regulatory Specialist
DeYoung	Lily Michele	WRHASSOC - Warehouse Associate
Dyer	Lori Anne	SCHBYPLN - Supply Chain Buyer/Planner
Dykstra	Alaina	LDDSGNR - Lead Designer, Marketing Communications
Edwards	Evelyn Grace	SLSPEC - Sales Specialist
Eerdmans	Matthew	LABLCOOR - Labeling Coordinator
Feliciano Torres	Brenda Liz	WRHASSOC - Warehouse Associate
Filkins	Tammi	ARSUP - Accounts Receivable Supervisor
Flores	Graciela	WRHASSOC - Warehouse Associate
Foster	Angel K	WRHASSOC - Warehouse Associate
Fuller	Ashley	REC - Recruiter
Gerber	Ivy	DOCORD - Document Control Coordinator
Gills	Diane D	CSCRSPEC - Customer Care Specialist- Catalog
Glynn	Tim	PRODMGR - Project Manager
Goehle	Lorelee	DIRCLINC - Director Clinical
Golson	Stephen T	WRHASSOC - Warehouse Associate
Goorhouse	Sherri	QALSPECL - Quality Specialist- Labeling
Graham	Aubrey	MRKGRDES - Marketing Graphic Designer
Gray	Madelyn Margaret Jean	INTSLSPC - International Sales Specialist

AirLife

Griffin	Kyle	REGAFSPE - Regulatory Affairs Specialist
Hart	Andrea Elizabeth	MGRFPA - Manager of FP and A
Hartman	Tyler	INVMGR - Inventory Manager
Hernandez	Armando	FACMGR - Facilities Manager
Hernandez	Jasmine	WRHASSOC - Warehouse Associate
Herrera	Zoyla	SRPROJMN - Senior Project Manager
Hmun	Pa	WRHASSOC - Warehouse Associate
Hollins	Larry	WRHASSOC - Warehouse Associate
Holtrop	Jessica	REGSPEC - Regulatory Specialist
Ibarra	Erika	OPSINTSP - Operations Integration Specialist
Isham	John Ryan	WRHASSOC - Warehouse Associate
Jorden	Alexus	APSPCIAL - Accounts Payable Specialist
Joslyn	Chet	QALENG - Quality Engineer
Kemp	Andrew Chad Michael	WRHASSOC - Warehouse Associate
Kiel	Carsen Landry	MRKASSC - Marketing Associate
Kim	Niang San	QALCNTIN - Quality Control Inspector
King	Karyl	DIRPRJMG - Director of Project Management Office
Kooistra	Heather	QAPRMG - QA Program Manager, Sterility and Integration
Kornowicz	Daniel	INTRGDIR - International Regulatory Director
Kunjan	Christiane	SRREGAFS - Senior Regulatory Affairs Specialist
Kuzner	Alexander	PRODENG - Product Design Engineer
Labelle	Raelyn	ACCTMGR - Accounting Manager
Laskowski	Kimberly	ARSPCIAL - Accounts Receivable Specialist
Lasley	Donna	SRCYCCOU - Senior Cycle Counter
Learmont	Trevor	PRODTENG - Product Engineer
Lemus	Ofelia	WRHASSOC - Warehouse Associate
Lockwood	Holly	ASPRDMNG - Associate Product Manager
Loda	Kimberly Anna	PRODENG - Product Design Engineer
Loftus	Kevin James	WRHASSOC - Warehouse Associate

AirLife

Loftus	Paul	WRHASSOC - Warehouse Associate
Lopez	Richard	VIMPRMGR - Value Improvement Manager
Luehrs	Chelsea	LABLDSGN - Label Designer
Lyar	Mary	PRODUCT - Production
Lytle	Amber V	LABLSPEC - Labeling Specialist
MacK	Ryan	SRDIRSTO - Senior Director of Strategic Operations
Maier	Courtney	REC - Recruiter
Majors	Julie	HRGNLST - Human Resources Generalist
Manager	Test	HRMNG - Human Resources Manager
Martinez	Catalina	WRHASSOC - Warehouse Associate
May	Madelyn Dawn	STFACCT - Staff Accountant
McCarty	Dennis	MNGSUP - Manager, Supplier Management
McGrew	Kelli Jean	SRMCMT - Sr. Manager, Clinical Marketing & Training
Melendes	Stephanie	WRHASSOC - Warehouse Associate
Melendes-Carbajal	Anai	QALCNTIN - Quality Control Inspector
Mendoza	Maria	WRHASSOC - Warehouse Associate
Menzie	Samuel	ENGCOOP - Engineering Co-Op
Merlo	Cori Lynn	ARSPCIAL - Accounts Receivable Specialist
Moran	Treasa	CSCRSPEC - Customer Care Specialist- Catalog
Muchai	Esther	ITINTRN - IT Intern
Nhkum	Naw L	PRODUCT - Production
Noble	Reilly Ann	SLSPEC - Sales Specialist
Nowak	John	SRSYSAD - Senior System Administrator
Nugent	Matthew	ASALMNG - Associate Sales Manager
O'Donnell	Ryan	SRENGPM - Sr. Engineering Program Manager
Ojeda	Viridiana L	COMPLCOR - Complaint Coordinator
Oosting	Suellyn	DIROPS - Director of Operations
Osborn	Breanna	SUPQLENG - Supplier Quality Engineer
Parra	Gloria	QLSYSCRD - Quality Systems Coordinator

AirLife

Penate	Karla	PRODMGR - Project Manager
Perez	Lazaro	MKTPOJ - Marketing Project Manager
Perez-Gonzalez	Rene	INVCONRM - Inventory Control
Petre	Steven	ENGLABMG - Test Engineer Lab Manager
Petty	Jay	QLENGMGR - Quality Engineer Manager
Pi	Lem	WHSPEC - Warehouse Specialist
Praay	Keith	QLSYSCRD - Quality Systems Coordinator
Romero	Arturo M	ENGTECH - Engineering Technician
Rosso	Matthew	QALENG - Quality Engineer
Ryman	Chandler Jacob	PRDVLDEN - Product Validation Engineer
Sai	Austin	SRINTCOR - Senior International Coordinator
Sanchez-Valera	Aleli	ARSPCIAL - Accounts Receivable Specialist
Sar	Mary	LDWHASSC - Lead Warehouse Associate
Seyfried	Mark	SYSANLST - Systems Analyst
Simons	Leonard	DIREXPIN - Director, User Experience / Infrastructure
Slocum	Janis	WRHASSOC - Warehouse Associate
Smith	Hannah	ENGCOOP - Engineering Co-Op
Smith	Amanda	REC - Recruiter
Stein	Russell	QALENG - Quality Engineer
Stella	Joshua	ASSREGMN - Associate Regional Sales Manager
Stolarski	Ellen	ENGCOOP - Engineering Co-Op
Stout	Cayla	ENGCOOP - Engineering Co-Op
Suchanek	David	SRSQLENG - Sr Supplier Quality Engineer
Syverson	Erica	MRKGRDES - Marketing Graphic Designer
Talcott	Kathy	ASINTSLS - Associate International Sales Manager
Terkeurst	Alicia	APANLYST - Accounts Payable Analyst
Tibbe	Kasey Jo	APSPCIAL - Accounts Payable Specialist
Van Ni Lin	Andrew Li	SHRESR - Shipping and Receiving Senior
Van Vels	Matthew	CUSPMNG - Customer Support Manager

AirLife

VanDenHout	Julia Catherine	SLSPEC - Sales Specialist
Vela-Cruz	Henry	QCTL - Quality Control Team Lead
Villereal	Nathaniel Demetrius	DIRSTRSR - Director of Strategic Sourcing
Wah	Do Poe	PRODUCT - Production
Wah	Naing Naing C	PRODL - Production Lead
Walters	Marlie	DCOCONSP - Document Control Specialist
Ward	Anthony R	LDWHASSC - Lead Warehouse Associate
Weeks	Rogina N	ARSPCIAL - Accounts Receivable Specialist
Wegener	Martin	SRSHRELD - Sr. Shipping and Receiving Lead
Weitzmann	James	ITHLPDSK - IT Help Desk Specialist
Whipple	Linda	PRODSUP - Production Supervisor
Wisniewski	Brenda	MGREHSF - Manager of EHS & Facilities
Wroten Knowling	Tamykal	ARSPCIAL - Accounts Receivable Specialist
Zahkung	Cecilia J	PRODUCT - Production
Zapolnik	Michael	BUSSYSAN - Business System Analyst
Zaw	Su Mon	WARSR - Warehouse Senior
Zealhum	Cing M	WARSR - Warehouse Senior
Zunich	Gregory	DIRCONS - Director of Engineering, Consumables

Best Regards,

Valerie Decker

International Regulatory Specialist

AirLife | SunMed | Salter Labs | Westmed | Ventlab | Ethox

4G

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Almaject, Inc.

Physical Address: 44 Whippany Road, Suite 300

City: Morristown State: NJ Zip: 07960

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 973-796-3400 Website: www.alvogen.com

Name of Designated Representative (DR): Marylea Hutchason

Licensing Company Email: mary.hutchason@alvogen.com DR Email: mary.hutchason@alvogen.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer (Virtual)
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See attached List

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Alvogen Pharma US, Inc.

Corporation/Organization Name: Almaject, Inc.

Mailing Address: 44 Whippany Road, Suite 300

City: Morristown State: NJ Zip: 07960

Telephone: 973-796-3400 Email: mary.hutchason@alvogen.com

Contact Person Name: Mary Hutchason

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Application Attachment – Almaject Inc. – CMO's/Trading Partners

Gland Pharma Ltd
6-3-865/1/2, flat No.201
Greenland Apartments,
Ameerpet, Hyderabad -500016 Telangana

Pfizer (Pharmacia)
7000 Portage Road
Kalamazoo, MI 49001

3PL:
UPS Supply Chain Solutions
1860 Outer Loop
Louisville, KY 40219

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration See attached Proof of FDA Labeler Code 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Almaject, Inc.

Facility Name

Lisa Graver

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6.1.22

Date

Board Use Only	Date Received: _____	Amount: 1,000 CC

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0747858

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

44 WHIPPANY RD, STE 300 MORRISTOWN, NJ 07960-

Reg. No.
5005555

ALMAJECT
44 WHIPPANY RD, STE 300
MORRISTOWN, NJ 07960-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2024

Establishment Copy

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALMAJECT, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-NINTH DAY OF AUGUST, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6969743 8300

SR# 20233363973

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204055290

Date: 08-29-23

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through March 10, 2022

You have searched Finished drug products

Search Results: *'Almaject'*

Back to Search Page () | **Search Again ()**

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Name
caspofungin acetate	72611-700-01	5 mg/mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	ANDA207092	Almaject Inc.	72611-700	caspofungin acetate	CASPOFUNGIN ACETATE	HUMAN PRESCRI DRUG
Caspofungin Acetate	72611-702-01	7 mg/mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	ANDA207092	Almaject Inc.	72611-702	caspofungin acetate	CASPOFUNGIN ACETATE	HUMAN PRESCRI DRUG
Clindamycin Phosphate	72611-634-25	150 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	NDA050441	ALMAJECT, INC.	72611-634	clindamycin phosphate	CLINDAMYCIN PHOSPHATE	HUMAN PRESCRI DRUG
Clindamycin Phosphate	72611-639-25	150 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	NDA050441	ALMAJECT, INC.	72611-639	clindamycin phosphate	CLINDAMYCIN PHOSPHATE	HUMAN PRESCRI DRUG
Clindamycin Phosphate	72611-642-25	150 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	NDA050441	ALMAJECT, INC.	72611-642	clindamycin phosphate	CLINDAMYCIN PHOSPHATE	HUMAN PRESCRI DRUG

Verified 7/19/22 MS

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Name
Clindamycin Phosphate	72611-645-55	150 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	NDA050441	ALMAJECT, INC.	72611-645	clindamycin phosphate	CLINDAMYCIN PHOSPHATE	HUMAN PRESCRI DRUG
Dexrazoxane	72611-716-01	500 mg/50mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	ANDA207321	Almaject, Inc.	72611-716	Dexrazoxane for Injection	DEXRAZOXANE HYDROCHLORIDE	HUMAN PRESCRI DRUG
Ketorolac Tromethamine	72611-719-25	15 mg/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA204216	Almaject, Inc.	72611-719	ketorolac tromethamine	KETOROLAC TROMETHAMINE	HUMAN PRESCRI DRUG
Ketorolac Tromethamine	72611-722-25	30 mg/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA204216	Almaject, Inc.	72611-722	ketorolac tromethamine	KETOROLAC TROMETHAMINE	HUMAN PRESCRI DRUG
Ketorolac Tromethamine	72611-725-25	30 mg/mL	INJECTION, SOLUTION	INTRAMUSCULAR	ANDA204216	Almaject, Inc.	72611-725	ketorolac tromethamine	KETOROLAC TROMETHAMINE	HUMAN PRESCRI DRUG
labetalol hydrochloride	72611-734-01	5 mg/mL	INJECTION	INTRAVENOUS	ANDA090699	Almaject, Inc.	72611-734	labetalol hydrochloride	LABETALOL HYDROCHLORIDE	HUMAN PRESCRI DRUG
labetalol hydrochloride	72611-738-01	5 mg/mL	INJECTION	INTRAVENOUS	ANDA090699	Almaject, Inc.	72611-738	labetalol hydrochloride	LABETALOL HYDROCHLORIDE	HUMAN PRESCRI DRUG

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Name
melphalan hydrochloride	72611-779-02		KIT		ANDA204817	Almaject, Inc.	72611-779	melphalan hydrochloride		HUMAN PRESCRI DRUG
Metoprolol Tartrate	72611-740-10	1 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA204205	Almaject, Inc.	72611-740	metoprolol tartrate	METOPROLOL TARTRATE	HUMAN PRESCRI DRUG
midazolam	72611-741-25	1 mg/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA090696	Almaject, Inc.	72611-741	midazolam	MIDAZOLAM HYDROCHLORIDE	HUMAN PRESCRI DRUG
midazolam	72611-749-10	5 mg/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA090850	Almaject, Inc.	72611-749	midazolam	MIDAZOLAM HYDROCHLORIDE	HUMAN PRESCRI DRUG
Rocuronium Bromide	72611-756-10	10 mg/mL	INJECTION	INTRAVENOUS	ANDA205656	Almaject, Inc.	72611-756	rocuronium bromide	ROCURONIUM BROMIDE	HUMAN PRESCRI DRUG
Rocuronium Bromide	72611-757-10	10 mg/mL	INJECTION	INTRAVENOUS	ANDA205656	Almaject, Inc.	72611-757	rocuronium bromide	ROCURONIUM BROMIDE	HUMAN PRESCRI DRUG

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Name
Temsirolimus	72611-785-02		KIT		ANDA207383	Almaject, Inc.	72611-785	Temsirolimus Injection		HUMAN PRESCRI DRUG
Tranexamic Acid	72611-760-10	100 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA207239	Almaject, Inc.	72611-760	tranexamic acid	TRANEXAMIC ACID	HUMAN PRESCRI DRUG
Vancomycin Hydrochloride	72611-761-10	500 mg/10mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	ANDA205694	Almaject, Inc.	72611-761	vancomycin hydrochloride	VANCOMYCIN HYDROCHLORIDE	HUMAN PRESCRI DRUG
Vancomycin Hydrochloride	72611-765-10	1 g/20mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	ANDA205694	Almaject, Inc.	72611-765	vancomycin hydrochloride	VANCOMYCIN HYDROCHLORIDE	HUMAN PRESCRI DRUG

Showing 1 to 22 of 22 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Almaject Officers

Lisa Graver – CEO
44 Whippany Road
Suite 300
Morristown, NJ 07960
973-796-3400
Ownership: 0%

Andrea Sweet – Secretary
44 Whippany Road
Suite 300
Morristown, NJ 07960
973-796-3400
Ownership: 0%

Lumtunie Zaku – CFO/Treasurer
44 Whippany Road
Suite 300
Morristown, NJ 07960
973-796-3400
Ownership: 0%

Designated Representative:

Mary Hutchason– Office Manager
44 Whippany Road
Suite 300
Morristown, NJ 07960
973-796-3400

Application Attachment – Employee Roster

Johnson, Andrea
Gordon, Christine
David, Andrew D
Kushner, Phillip
Kraft, Kristine J.
Hutchason, Marylea
Ziegler, Linda
Keys-Lundy, Zakiyyah
Billemeyer, Carolyn
Spinelli, Leonard
Marchitelli, John
Shah, Kaushik
Watson, Raymond
Spears, Twonna L.
Cestaro, Frank
Miranda, Roberto
Ramirez, Myreen
Rosario, Lucy
Buenviaje, Agustin Abarquez
Zaku, Lumtunie
Ulit, Ithti T
Demera, Luis
Stedge, Barbara
Puzanova, Svetlana
Guarch, Elisabeth
Garbarini, John
Park, Peter J.
Lasser, Robert
Halpin, Janet
Wickware, Erin
Lucero-Urgilez, Yennifer
Mossa, Annemarie
Andre, Elvila
Smith, Emily
Zamor, Wendy
Said, Momina
Suchy, William
Nugent, Roxan A
Seymore, Taneka C
Karamched, Srinivasa C
Daniels, Neema
Pena, Wendy
Fecho Jr., Stephen J
Palmer, Joana
Bersey, Joshua A
Beal, Douglas L

Moss, Raymond
Scheideler, Gregg S
Anello, Natale F
Lorenz, Sean Joseph
Vitale, Sheryl
Sinha, Neela
Leonor, Christopher
Binaku, Shqipe
Wood, Kevin
Rehberger, Mary Beth
Lee, Evan
Deng, Li
Spruill, Natasha
White, James P.
Dixit, Karuna
Patel, Sonal
Terra, Joel
Penny, Keith B.
Oliveira, Damiana
Ellison, Paul
Sumler, Heather L.
Haddad, Ali
Vieru, Oleg
Zagmot, Robert J
Kirsch, Daniel
Marino, Mark
Patel, Neha
Graynor, Michael
Jackson, Leslie
Bailey, Anna Kay
Lepelis, Sara
Referente, Michael S
Guerrero, Pilar
Ludwig, Matthew B
Peele, Tonya
Lin, Howie
Williams, Aisha
Lee, Alyssa
Dinh, Daniel
Bianchini, Matthew W
Elvin, Lisa
Godek, Anna M
Beffert, Jordan
Knauer, Kristina
Ramkishun, Nadina
Oyebade, Joseph
Krishnaraj, Narmadha
Rosado, Nicholas

Luo, Min
Cakmak Yuce, Yekta
Singh, Harvinder
Hamlett, Kelvin Marcus
Graver, Lisa
Ore, Rita
Kusmick, Michael
Baker, Ivana
Vettoso, Brian
Kannan, Ravishankar
Hamblin, Stacey Sun

*** Effective 06/01/2022 this bond cancels and replaces The Hanover Insurance Company bond #1000977. ***

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 20BSBIW6143

Application/License No. _____

Alvogen, Inc. and entities on attached schedule (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 44 Whippany Road, Morristown, NJ 07960 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartf :d Plaza, Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 1, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of June, 2012.

APPLICANT/PRINCIPAL

Alv[illegible]

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Sandy McElhan[illegible]y, Attorney in Fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Marie Lett

Witness Andrea Allman

Countersigned by:

N/A

Nevada Resident Agent

Alvogen, Inc.
Pharmaceutical Wholesaler Surety Bond
Schedule of Applicant/Principal Names for bond 20BSBIW6143
as of 06/01/2022

Application/License No.:	Applicant/Principal Name	Address of Applicant/Principal
	Almatica Pharma, LLC	44 Whippany Road, Morristown, NJ 07960
	Almaject, Inc.	44 Whippany Road, Morristown, NJ 07960
	County Line Pharmaceuticals	44 Whippany Road, Morristown, NJ 07960
	Norwich Pharmaceuticals, Inc.	6826 State Highway 12, Norwich, NY 13815

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
or 888-266-3488 *or fax* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name:
Agency Code:

- [ ] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint Sandy M.

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument.
Bond No.
Naming
and Nev

in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 12228
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of _____.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

THE HARTFORD

SURETY BOND DIGITAL SEAL
The Hartford Financial Services Group, Inc.

To Our Valued Partners:

In efforts of continuing business during the pendency of the COVID-19 pandemic, The Hartford has authorized its Attorneys-in-Fact to affix the electronic corporate seal in a digital format, in lieu of its traditional raised seal to any bond document issued on its behalf by any such Attorney-in-Fact.

The Hartford agrees and affirms that the digital corporate seal affixed to any bond document is equivalent to its raised corporate seal had it been affixed to the bond document itself.

Effective this 30th day of March, 2020.

The Hartford

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

The Hartford Financial Services Group, Inc.
P.O Box 958461
Lake Mary, FL 32795

P: 888-656-0817
F: 877-257-2166

www.thehartford.com/bond
www.thehartford.com
www.facebook.com/thehartford
www.twitter.com/thehartford

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Almaject, Inc.

Physical Address 44 Whippany Road, Suite 300

City Morristown State NJ Zip 07960

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 973-796-3400 Website www.alvogen.com

Licensing Company Email mary.hutchason@alvogen.com

Section 2: Personal Information

First Marylea Middle _____ Last Hutchason

Alias(es, nick[redacted]changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Willet St.

City Clifton State NJ Zip 07013

Telephone 973-796-3403 Email mary.hutchason@alvogen.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Applicant's initials _____

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Nutley Senior HS			1974-1978
Address	**City**	**State**	**Zip**
	Nutley	NJ	
Diploma/Degree obtained, if any			
HS Diploma			

School Name			From - To (MM/YY – MM/YY)
Kaplan University			2010-2012
Address	**City**	**State**	**Zip**
Online University			
Diploma/Degree obtained, if any			
Assoc. Paralegal Studies			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1998 to Present	[redacted] Willet Street	Clifton	NJ	07013
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Almaject Inc.			From - To (MM/YY – MM/YY): 6/2014 to Present
Business Address: 44 Whippany Road, Suite 300	City: Morristown	State: NJ	Zip: 07960
Phone: 973-796-3412	Title: Exec. Assistant to CEO, Office Manager		Number of Employed Hours: 13,520 employed hours
Description of Duties: Exec. Assistant to CEO, Manage day to day operations at Office			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

MARYLEA HUTCHASON

[redacted]Willet Street
Clifton, NJ 07013

Home: [redacted] Cell: [redacted]

SUMMARY

Accomplished Executive Assistant with strong organizational, interpersonal, written and oral communication skills. Excellent organizer and planner possessing energy and flexibility for managing in a dynamic, ever-changing environment. Ability to absorb, organize, prioritize, and analyze data. Dedicated, self-starter, team player.

PROFESSIONAL EXPERIENCE

ALVOGEN, INC. Morristown, NJ 2014 – Present
Executive Assistant/Office Manager
Primary contact/liaison providing administrative support to the President, US

- Manage appointment calendars and mail, screen phone calls and emails. Arrange travel and prepare itineraries, coordinate meetings, complete expense reports in Concur.
- Preparation and distribution of meeting agendas, presentations and minutes
- Manage repository of documents for the Legal Department on SharePoint.
- Process invoices for timely payment and track all departmental expenses
- Office supply and inventory management
- Manage the day-to-day operations of the Morristown office.
- Responsible for ensuring that all records regarding the dispensing and distribution of, and recordkeeping relating to, prescription drugs are maintained in a secure and safe manner, with access to the information as needed.

ACTAVIS INC., Morristown, NJ 2008 – 2014
Executive Assistant
Primary contact/liaison providing administrative support to the Chief Legal Officer, VP Human Resources, Ethics and Compliance Officer, Americas and their subordinates. Recording secretary for Board of Directors Meetings and three sub-committees - Compensation, Benefits and Compliance.

- Manage appointment calendars and mail, screen phone calls and emails. Arrange travel and prepare itineraries, coordinate meetings, complete expense reports in Concur. Prepare presentations, set up department filing system, and complete special projects.
- Manage repository of documents relating to Board of Directors Meetings and sub-committees on SharePoint.
- Process and track all departmental budget expenses utilizing Serengeti Tracker, department billing system.
- Coordinate employee activities: Annual Kick-Off Meeting, Town Hall Meetings, Health & Wellness Events

BLACKROCK, Florham Park, NJ 2006 – 2008
Executive Assistant
Primary contact/liaison for the Account Management Group providing administrative support to Account Management Group - two Managing Directors, three Directors, and five Vice Presidents.

MARYLEA HUTCHASON

Page 2

Home: [redacted] Cell: [redacted]

- Managed appointment calendars and mail. Screened phone calls and emails. Arranged travel and prepared itineraries. Coordinated meetings, completed expense reports, prepared presentations, set up department filing system. Fulfilled ad hoc requests.
- Received code and coordinate payment of all invoices.
- Processed and tracked all expenses impacting department budget.

ALPHARMA, INC., Ft. Lee, NJ 2001 – 2006
Executive Assistant – Human Resources
Provided administrative support to the Executive Vice President of Human Resources, Vice President, Compensation & Benefits and Director of Communications. Primary contact/liaison for department. Served as back-up to CEO's Assistant.

- Managed appointment calendars, mail. Screened phone calls and email. Arranged travel and prepared itineraries, coordinated meetings, scheduled executive interviews. Completed expense reports, prepared presentations, and completed special projects.
- Designed and established systems and processes to organize office in all administrative areas.
- Processed and tracked all expenses impacting department budget.
- Prepared materials for department meetings and Compensation Committee of the Board of Directors. Formulated agendas, prepared presentations and acted as meeting secretary.

ADDITIONAL RELEVANT EXPERIENCE

FAULDING PHARMACEUTICALS, Paramus, NJ 2001
Human Resources Administrator

LECHTERS, INC., Harrison, NJ 1997 – 2001
Executive Assistant – Human Resources

LIZ CLAIBORNE, INC., North Bergen, NJ 1983 – 1997
Senior Administrative Assistant

EDUCATION

AAS, Paralegal Studies, Kaplan University, Ft. Lauderdale, FL

HONORS

President's List, Dean's List, GPA 3.95

TECHNICAL SKILLS

Microsoft Office (Word, Excel, PowerPoint, Outlook), Lotus Notes, Org. Plus for Windows, SharePoint, Serengeti Tracker, Speedwriting, Dictaphone

PROFESSIONAL DEVELOPMENT

Dale Carnegie Course

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials _____ 5

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

Applicant's initials _____

I, Marylea Hutchason, **certify that as the designated representative for**

Almaject, Inc.,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Marylea Hutchason

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5.31.22

Date

Applicant's initials

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Marylea Hutchason

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5·31·22

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Passaic

I, Marylea Hutchason, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5·31·22

Date

Subscribed and Sworn to before me this 31 day of May, 2022

Notary Public Signature

MARWA LABSIR
Notary Public, State of New Jersey
My Commission Expires 11/06/2024

(Seal)

Applicant's initials

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Almaject, Inc.

Physical Address: 44 Whippany Road, Suite 300

City: Morristown State: NJ Zip: 07960

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 973-796-3400 Website: www.alvogen.com

Licensing Company Email: mary.hutchason@alvogen.com

Section 2: Personal Information

First: Andrea Middle: Last: Sweet

Alias(es, nick[redacted] changes, etc.): Johnson

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted] Morgan Drive

City: Glastonbury State: CT Zip: 06033

Telephone: [redacted] Email: andrea.sweet@alvogen.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Applicant's initials AS

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: West Canada Valley			From - To (MM/YY – MM/YY): 1992 to 1996
Address: 5447 State Rt 28	City: Newport	State: NY	Zip: 13416
Diploma/Degree obtained, if any: HS diploma			
School Name: Boston University			From - To (MM/YY – MM/YY): 1996 to 2000
Address: 881 Commonwealth Ave	City: Boston	State: MA	Zip: 02215
Diploma/Degree obtained, if any: Bachelor's of Arts			
School Name: Western New England University			From - To (MM/YY – MM/YY): 2002-2005
Address: 1215 Wilbraham Rd	City: Springfield	State: MA	Zip: 01119
Diploma/Degree obtained, if any: JD and Law Degree			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/2016 to Present	[redacted]Morgan Drive	Glastonbury	CT	06033
8/2005 to 3/2016	[redacted]Evergreen Road	Vernon	CT	06066
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Almaject, Inc.			From - To (MM/YY – MM/YY): 3/2013 to Present	
Business Address: 44 Whippany Road, Suite 300	City: Morristown		State: NJ	Zip: 07960
Phone: 973-487-3978	Title: Secreatary			
Description of Duties: Vise President, Legal Affairs				

Business Name: Actavis			From - To (MM/YY – MM/YY): 12/2009 to 3/2013	
Business Address: 400 Interplace Parkway	City: Parsippany		State: NJ	Zip: 07054
Phone: 862-261-7000	Title: Senior Director of IP			
Description of Duties: Intellectual Property counsel				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/27/2022
Date

Applicant's initials AS

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrea Sweet

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 5/27/2022

Please have this section completed in the presence of a Notary Public.

State of NEW JERSEY, ss. County of MORRIS

I, Andrea Sweet, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 5/27/2022

Subscribed and Sworn to before me this 27th day of MAY 2022.

Notary Public Signature

Marylea Hutchason
NOTARY PUBLIC
State of New Jersey
ID # 2376861
My Commission Expires August 13, 2023

(Seal)

Applicant's initials AS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Almaject, Inc.

Physical Address 44 Whippany Road, Suite 300

City Morristown State NJ Zip 07960

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 973-796-3400 Website www.alvogen.com

Licensing Company Email mary.hutchason@alvogen.com

Section 2: Personal Information

First Lumtunie Middle _____ Last Zaku

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Lorraine Drive

City Pine Brook State NJ Zip 07058

Telephone [redacted] Email tunie.zaku@alvogen.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Applicant's initials TZ

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Boonton High School		1992 to 1996	
Address	**City**	**State**	**Zip**
	Boontoon	NJ	
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Seton Hall University		1996 to 1999	
Address	**City**	**State**	**Zip**
	Orange	NJ	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/2013 to Present	[redacted] Lorraine Drive	Pine Brook	NJ	07058
11/2002 to 6/2013	[redacted] Evergreen Drive	Lincoln Park	NJ	07035
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Almaject, Inc.			From - To (MM/YY – MM/YY): 2/2018 to Present
Business Address: 44 Whippany Road, Suite 300	City: Morristown	State: NJ	Zip: 07960
Phone: 973-487-3957	Title: Chief Financial Officer, Americas Region		
Description of Duties: CFO			

Business Name: Par Pharmaceutical Inc			From - To (MM/YY – MM/YY): 11/2006 to 2/2018
Business Address: 1 Ram Ridge Road	City: Chestnut Ridge	State: NY	Zip: 10977
Phone: 845-364-4780	Title: Generics Controller		
Description of Duties: Controller			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials TJ

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

Applicant's initials _____

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lumtunie Zaku

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/1/2022

Date

Please have this section completed in the presence of a Notary Public.

State of NEW JERSEY, ss. County of MORRIS

I, LUMTUNIE ZAKU, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/1/2022

Date

Subscribed and Sworn to before me this 1ST day of JUNE 2022.

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Almaject, Inc.

Physical Address 44 Whippany Road, Suite 300

City Morristown State NJ Zip 07960

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 973-796-3400 Website www.alvogen.com

Licensing Company Email mary.hutchason@alvogen.com

Section 2: Personal Information

First Lisa Middle _____ Last Graver

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] N Ft. Lauderdale Beach Blvd [redacted]

City Ft. Lauderdale State FL Zip 33304

Telephone 973-796-3423 Email lisa.graver@alvogen.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Applicant's initials _____

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
St. Francis High School			1986 to 1990	
Address		City	State	Zip
Diploma/Degree obtained, if any				
HS diploma				
School Name			From - To (MM/YY – MM/YY)	
Lakehead University			1990 to 1994	
Address		City	State	Zip
		Thunder Bay	Ontario	
Diploma/Degree obtained, if any				
Bachelor's in Biology				
School Name			From - To (MM/YY – MM/YY)	
Case Western University			1995 to 1998	
Address		City	State	Zip
Diploma/Degree obtained, if any				
JD and Law Degree				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/2021 to present	[redacted]N. Ft. Lauderdale Beach Blvd [redacted]	Ft. Lauderdale	FL	33304
From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020 to 5/2021	[redacted]Prospect Street, Apt [redacted]	Morristown	NJ	07960
From - To (MM/YY – MM/YY)	Address	City	State	Zip
2014 to 2020	[redacted] William Street, Apt [redacted]	New York	NY	10005
From - To (MM/YY – MM/YY)	Address	City	State	Zip
2009 to 2014	[redacted]loomfield Avenue	Essex Fells	NJ	07021
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials 

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Almaject, Inc.			From - To (MM/YY – MM/YY): 6/2010 to Present
Business Address: 44 Whippany Road, Suite 300	City: Morristown	State: NJ	Zip: 07960
Phone: 973-796-3423	Title: CEO		
Description of Duties: CEO			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Applicant's initials

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials 

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Applicant's initials 

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lisa Graver

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-1-22

Date

Please have this section completed in the presence of a Notary Public.

State of NEW JERSEY, ss. County of MORRIS

I, LISA GRAVER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-1-22

Date

Subscribed and Sworn to before me this 1ST day of JUNE 2022

Notary Public Signature

(Seal)

Applicant's initials

4H

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Altor BioScience, LLC

Physical Address: 9920 Jefferson Blvd, Suite 1

City: Culver City State: CA Zip: 90232

Mailing Address (if different from physical address): 9920 Jefferson Blvd, Suite 1

City: Culver City State: CA Zip: 90232

Telephone: 844-696-5235 Website: https://immunitybio.com/

Name of Designated Representative (DR): Jose Laureano Ramos

Licensing Company Email: AltorStateLicensing@immunitybio.com DR Email: daniel.laureano@immunitybio.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Biologics	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Distributors, Hospital Pharmacies, Physician Offices		☒ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been licensed with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No suppliers sold, dispensed or distributed within last year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ **City:** _____ **State:** _____ **Zip:** _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ **City:** _____ **State:** _____ **Zip:** _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): NantCell, Inc.

Corporation/Organization Name: Altor BioScience, LLC

Mailing Address: 9920 Jefferson Blvd, Suite 1

City: Culver City State: CA Zip: 90232

Telephone: 844-696-5235 Email: AltorStateLicensing@immunitybio.com

Contact Person Name: Jason Liljestrom

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Altor BioScience, LLC
Facility Name

Jason Liljestrom
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

June 2, 2023
Date

Board Use Only	Date Received: 7/10/23	Amount: CK - 1000 - 18806

TwoLabs PHARMA SERVICES

Altor BioScience CORPORATION

June 23, 2023

Via Fed Ex
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

To Whom It May Concern:

On behalf of Altor BioScience, LLC, attached is the Altor BioScience, LLC, application for a Wholesale License.

Altor BioScience, LLC is a biopharmaceutical company that researches, develops, and markets biopharmaceuticals products targeting immunotherapeutic agents for the treatment of cancer, viral infections, inflammatory, and autoimmune diseases.

Altor BioScience, LLC is a virtual manufacturer, whose products are manufactured by a contract manufacturer and distributed by a third-party logistics provider, who meets licensure requirements to ship pharmaceutical products into your state. At no time is commercial product manufactured at, stored at, or distributed from Altor BioScience, LLC's office. Altor BioScience, LLC's product, Anktiva, is not a controlled substance. Accordingly, Altor BioScience, LLC is not required to obtain a DEA registration.

According to the California 2023 Lawbook for Pharmacy, statute 4160, Altor BioScience, LLC is exempt from the requirement of licensure in their home state of CA. The lawbook can be found at www.pharmacy.ca.gov/laws_regs/lawbook.pdf. Statue 4160 starts on page 204 and the reference to (h) as presented with this letter can be found directly on page 207. I hope this narrative is helpful as you review Altor BioScience, LLC's application. If you have a question regarding this application, please contact me at (614) 204-1718 or via email at sherri.kolath@twolabs.com. Please also address all written communication to me. My address is: Sherri Kolath/Two Labs, 2788 Barharbor Court, Lewis Center, OH 43035.

Thank you in advance for your consideration.

Sherri J Kolath

Sherri Kolath
Licensing Analyst

responsible manager, and shall on the same form propose another designated representative-3PL to take over as the responsible manager. The proposed replacement responsible manager shall be subject to approval by the board. If disapproved, the third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a responsible manager is approved by the board.

(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(i) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. For purposes of retaining a temporary license, or for purposes of any disciplinary or license denial proceeding before the board, the temporary licenseholder shall not be deemed to have a vested property right or interest in the license.

4160.5. Nonprescription Diabetes Test Devices – Authorized Distributors Posted on Board Website

Within 30 days of the effective date of the act adding this section, a manufacturer of a nonprescription diabetes test device

June 15, 2023

Exemption from home state licensure:

Altor BioScience, LLC is a biopharmaceutical company that researches, develops, and markets biopharmaceuticals products targeting immunotherapeutic agents for the treatment of cancer, viral infections, inflammatory, and autoimmune diseases.

Altor BioScience, LLC is a "virtual manufacturer" whose products are manufactured by a contract manufacturer and distributed by a third-party logistics provider, who meets licensure requirements to ship pharmaceutical products into your state. At no time is commercial product manufactured at, stored at, or distributed from Altor BioScience, LLC's office. Altor BioScience, LLC's product, Anktiva, is not a controlled substance. Accordingly, Altor BioScience, LLC is not required to obtain a DEA registration. Altor BioScience, LLC does not distribute drugs or devices for any other manufacturer.

According to the California Pharmacy Law Book, statue 4160, Altor BioScience, LLC is exempt from the requirement of licensure and inspection in their home state of CA.

(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf

Statue 4160 starts on page 204 and the reference to (h) as presented above can be found directly on page 207.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALTOR BIOSCIENCE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTIETH DAY OF JANUARY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6414345 8300

SR# 20230200062

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202535119

Date: 01-20-23

Altor BioScience
CORPORATION

Description of Operations

Altor BioScience, LLC is a Virtual Manufacturer. Altor BioScience LLC's products are manufactured by contract manufacturers and will be distributed to Specialty Partners by their 3rd Party Logistics Provider, Integrated Commercialization Solutions, LLC. where their sales records are stored.

Contract Manufacturer Information:
Altor BioScience, LLC is using the following contract manufacturers to produce their products:

Ajinomoto Althea, Inc.
11040 Roselle Street
San Diego, CA 92121
FEIN Establishment Number: 3004575449
Contact Person: Bert Barbosa
Contact Phone Number: (858) 281-7490

Sharp Packaging Services, LLC
7451 Keebler Way
Allentown, PA 18106
FEIN Establishment Number: 3004161147
Contact Person: Barbara H. Ost
Contact Phone Number: (610) 366-8748

Ajinomoto Althea, Inc. manufactures Altor BioScience, LLC's finished products and Sharp Packaging Services, LLC packages the product. At no time does Ajinomoto Althea, Inc, or Sharp Packaging Services, LLC own the product, contract with Altor BioScience, LLC's customers, invoice, nor sell the Altor BioScience, LLC products. Altor BioScience, LLC products, are not Controlled Substances.

Third Party Logistic information:
For distribution into the commercial supply channel, Integrated Commercialization Solutions, LLC acts as Altor BioScience, LLC's Third-Party Logistics (3PL) provider to manage the storage and distribution of Altor BioScience, LLC's product to Specialty partners. Integrated Commercialization Solutions, LLC's address is:

420 International Blvd, Ste 500
Brooks, KY 40109
Contact Person: Jerry Schiller
Contact Phone Number: (502) 955-3650

Altor BioScience, LLC's normal business hours are 9:00 am – 5:00 pm Monday through Friday.

From: CDER Electronic Drug Registration and Listing <EDRLS@fda.hhs.gov>
Sent: Thursday, March 30, 2023 9:36 AM
To: Ecalnea, Curtis <curtis.ecalnea@twolabs.com>
Subject: RE: [EXTERNAL] Altor BioScience, LLC. Labeler Code (81481) Reactivation

[External]

The labeler code is now active:

NAME	DUNS	LABELER CODE	TYPE
Altor BioScience, LLC, an indirect wholly-owned subsidiary of ImmunityBio, Inc.	138254896	81481	NDC/NHRIC LABELER CODE RE(

Regards,
The DRLS Branch

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This e-mail message and any attachments contain confidential information. If you are not the intended recipient, you are hereby notified that disclosure, printing, copying, distribution, or the taking of any action in reliance on the contents of this electronic information is strictly prohibited. If you have received this e-mail message in error, please immediately notify the sender by reply message and then delete the electronic message and any attachments.

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√ verified
M.H 7/11/23

Altor BioScience
CORPORATION

Company Information

Company Name:	Altor BioScience, LLC
Licensing Email:	AltorStateLicensing@immunitybio.com
Address:	9920 Jefferson Blvd, Suite 1
City, State, Zip:	Culver City, CA 90232
Phone:	844-696-5235
Website:	https://immunitybio.com/
E-mail:	AltorStateLicensing@immunitybio.com
EIN:	30-0999738
State of Formation:	Delaware
Date Incorporated:	May 17, 2017

Ownership Information

Altor BioScience, LLC is a corporation 100% owned by NantCell, Inc. Their address is as follows: 2040 E. Mariposa Ave. El Segundo, CA 90245.

Officers

Richard Adcock, CEO and President
Business Address: 9920 Jefferson Blvd, Suite 1, Culver City, CA 90232
Phone: 844-696-5235

David Sachs, Chief Financial Officer
Business Address: 9920 Jefferson Blvd, Suite 1, Culver City, CA 90232
Phone: 844-696-5235

Jason Liljestrom, General Counsel
Business Address: 9920 Jefferson Blvd, Suite 1, Culver City, CA 90232
Phone: 844-696-5235

Privileged and confidential. Do not disclose without prior consent.

Altor BioScience
CORPORATION

Altor BioScience Employees

Officers / Designated Representative

1. Rich Adcock
2. David Sachs
3. Jason Liljestrom
4. Daniel Laureano

Commercial:

5. Helen Luu
7. Tracy Maines

Accounting / Finance

8. Irene Idnani

Quality:

10. Rick Lehman
11. Camille Denoga

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Altor BioScience, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 9920 Jefferson Blvd, Suite 1

City: Culver City State: CA Zip: 90232

Mailing Address (if different from physical address): 9920 Jefferson Blvd, Suite 1

City: Culver City State: CA Zip: 90232

Telephone: 844-696-5235 Website: https://immunitybio.com/

Licensing Company Email: AltorStateLicensing@immunitybio.com

Section 2: Personal Information

First: Jose Middle: Daniel Last: Laureano Ramos

Alias(es, nicknames, name changes, etc.): Daniel Laureano

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 9920 Jefferson Blvd, Suite 1

City: Culver City State: CA Zip: 90232

Telephone: 844-696-5235 Email: daniel.laureano@immunitybio.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		x

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
West Texas A&M University		07/14 - 05/19	
Address	**City**	**State**	**Zip**
2501 4th Ave	Canyon	TX	79016
Diploma/Degree obtained, if any			
Master of Business Administration (MBA)			
School Name		**From - To (MM/YY – MM/YY)**	
Polytechnic University of Puerto Rico		08/02 - 05/07	
Address	**City**	**State**	**Zip**
377 Av. Juan Ponce de León	Hato Rey	Puerto	00918
Diploma/Degree obtained, if any			
Bachelor of Science, Industrial Engineering			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/16 - Present	[redacted] West Hills Drive	Valencia	CA	91354
01/12 - 06/16	[redacted] Herrera St	Valencia	CA	91354
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Altor BioScience, LLC			02/18 - Present
Business Address	**City**	**State**	**Zip**
9920 Jefferson Blvd, Suite 1	Culver City	CA	90232
Phone	**Title**	**Number of Employed Hours**	
844-696-5235	Director, Supply Chain	10,920	

Description of Duties

Leading a team of 7 supply chain professionals in developing and managing End-to-End supply chain operations for two clinical stage manufacturing facilities, including material planning, logistics, and warehouse operations.

Business Name			From - To (MM/YY – MM/YY)
Shire			08/11 - 02/18
Business Address	**City**	**State**	**Zip**
1700 Rancho Conejo Blvd	Thousand Oaks	CA	91320-1424
Phone	**Title**	**Number of Employed Hours**	
(805) 375-6758	Supply Chain Global CI Lead, Supply Chain Facility Lead,	23,400	

Description of Duties

See Attached Resume

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		x
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

June 1st 2023
Date

I, Jose Laureano Ramos, **certify that as the designated representative for**

Altor BioScience, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DL I am at least 21 years of age;
3. DL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jose Laureano Ramos

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 1st 2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jose Laureano Ramos

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 1st 2023

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

SEE ATTACHED

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 1st day of June, 2023, by Jose Laureano Ramos,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.



(Seal)

Signature Gina J. Wells

Daniel Laureano

Valencia, California 91354 ▪ [redacted]
[redacted]
linkedin.com/in/daniel-laureano

Biotechnology Operations Management

Masterful supply chain & manufacturing professional with over 10 years of specialized experience leading and establishing planning & manufacturing strategies.

Biotechnology front-runner with expertise in all facets of production and material planning, material purchasing, and inventory management within a global specialty company. Skilled in collaborating with all levels of management to achieve production and operational objectives. Instrumental in establishing and improving processes, enhancing productivity, and implementing quality and safety solutions. Proficient in Sigma Six manufacturing and GMP and GDP specifications.

Areas of Expertise

- Production & Material Planning
- Lean / Six Sigma
- Warehouse Operations
- Manufacturing Operations
- Inventory Management
- GMP / GDP Compliance
- Operational Budgeting / Forecasting

Professional Experience

ImmunityBio, Inc | NantCell, Inc | Altor BioScience, LLC
Culver City, CA
Director, Supply Chain, February 2018 - Present
Leading a team of 7 supply chain professionals in developing and managing End-to-End supply chain operations for two clinical stage manufacturing facilities, including material planning, logistics, and warehouse operations.

- Designated Representative, Altor BioScience, LLC
- Design and developed Supply Chain organization structure and policies from the ground up.
- Successfully implemented distribution procedures for clinical products.
- Established a Material Requisition Plan, ensuring proper raw material inventory level is sustained at all times.
- Implemented procedures to execute routine supply chain operations, including: warehouse management, cold chain logistics, and procurement tasks.

Shire, Thousand Oaks, CA
Supply Chain Global CI Lead, June 2017 – February 2018
Dedicated to the development and fostering of a Lean culture which drives exceptional performance.

- Developed virtual Lean Management Systems that support future company growth.
- In charge of the development and execution of the Continuous Improvement strategy, focused on further advancing the CI culture in Global Operations.
- Provide Change Management support by influencing key stakeholders, team members & executive leadership in order to drive and enable positive change.

Shire, Thousand Oaks, CA
Supply Chain Facility Lead, January 2016 – June 2017

continued...

Manage a team of seven supply chain professionals in the lead planning function, including production and material planning, and inventory management.

- Maintain master production schedules based on regulatory license requirements, regional specifications, market demands, and material availability.
- Create long range capacity plans and strategies for inventory reduction of raw materials and finish products.
- Collaborated with Supplier Relation Management Team to meet comply with CMO terms.

Shire, Los Angeles, CA
Manufacturing Manager, Purification & Filling Department, August 2011 - December 2015
Guided almost 200 employees across various manufacturing departments to produce eleven different commodities. Established a work standard to meet production and budget goals.

- Reviewed and approved all documents as the subject matter expert for antihemophilic factor-method M (AHF-M) bulk and aseptic filling manufacturing operations, including SOP changes, non-conformance investigations, and validations.
- Reduced operational expenses from $1.24 million to $999 thousand while maintaining production outputs.
- Achieved Environmental Health and Safety Gold Level with a recordable injury rate of less than .01.
- Launch commercial production in the new Nano-Filtration Area.

Baxter, Irvine, CA
Manufacturing Superintendent, June 2010 - August 2011
Directed a high volume medical device operation of almost 300 employees and supervisors, successfully meeting manufacturing and quality commitments.

- Conducted daily meetings to review key process indicators and drive corrective actions for seven manufacturing lines.
- Administered the manufacturing system which consistently met and exceeded financial targets for 2011.

Shire, Los Angeles, CA
Supervisor II, March 2008 - June 2010
Ensured manufacturing operations were performed in a safe environment following the Global Supply Chain schedule, which complied with GMP and GDP specifications.

- Directed manufacturing operations using effective presentations.
- Guided multiple continuous enhancement activities to drive improvements on quality and safety.

Shire, Los Angeles, CA
Material Planner, July 2007 - March 2008
Completed forecasting, consumption, and inventory of raw materials activities across all manufacturing departments. Provided assessment and work status reports of raw material management for new manufacturing projects.

Education

Master of Business Administration (MBA), May 2019
West Texas A&M University, Canyon, TX
Bachelor of Science, Industrial Engineering, May 2007
Polytechnic University of Puerto Rico, Hato Rey, PR

NEVADA STATE BOARD OF PHARMACY
986 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 83BSBJA8963

Application/License No. _____

ALTOR BIOSCIENCE, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 9920 Jefferson Blvd, Suite 1 Culver City, CA 90232 (Address of Applicant/Principal), as PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 22, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of June, 2023.

APPLICANT/PRINCIPAL
ALTOR BIOSCIENCE, LLC

Authorized Representative

SURETY COMPANY
HARTFORD FIRE INSURANCE COMPANY

Surety Company's Representative

Derek J. Elston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Ann Formhals

Witness Chris Troha

Countersigned by:

N/A
Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5838**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: AON RISK SERVICES CENTRAL INC
Agency Code: 83-550003

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :

Corinne Chapman, Samantha Chierici, Kristin L. Hannigan, Jennifer L. Jakaitis, Nicholas Kertesz, Judith A. Lucky-Etimov, Roger Paraison, Tara A. Reimer, Christina L. Sandoval, Jean Torres, Susan A. Welsh, Sandra M. Winsted, Dartonya Wright of CHICAGO, Illinois

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of June 22nd, 2023.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

41

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Applied Medical Distribution Corporation

Physical Address: 9401 Toledo Way

City: Irvine State: CA Zip: 92618

Mailing Address (if different from physical address): 22872 Avenida Empresa

City: Rancho Santa Margarita State: CA Zip: 92688

Telephone: 949-713-8000 Website: www.appliedmedical.com

Name of Designated Representative (DR): Susan Ahlberg

Licensing Company Email: premarketregulatory@appliedme DR Email: sahlberg@appliedmedical.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Applied Medical Resources Corporation

Corporation/Organization Name: Applied Medical Distribution Corporation

Mailing Address: 28872 Avenida Empresa

City: Rancho Santa Margarita State: CA Zip: 92688

Telephone: 949-713-8000 Email: premarketregulatory@appliedmedical.com

Contact Person Name: Leilani Domingo

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%207-1-19.pdf		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Applied Medical Resources Corporation

Facility Name

Greg Vrablik

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

29 July 2022

Date

Board Use Only	Date Received: 8·3·22	Amount: 1000.00 CK· 122306

Applied Medical

Applied Medical Distribution Corporation (AMDC)
9401 Toledo Way
Irvine, CA 92681
List of all Officers, Directors, and Shareholders – 2022

Responses to Section 9 of the Nevada State Board of Pharmacy Wholesaler Application:

Directors:

- Nabil Hilal
- Susan Ahlberg
- Hany Louis

Officers:

- Susan Ahlberg, Chief Executive Officer
- Nabil Hilal, Senior Vice President
- Samir Tall, Chief Financial Officer and Secretary
- Hany Louis, Chief Accounting Officer

Shareholder:

- The sole shareholder of Applied Medical Distribution Corporation, a California corporation, is Applied Medical Resources Corporation, a California corporation

Sincerely,

Matthew C. Vogt
Corporate Counsel

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Applied Medical Resources Corp.
9401 Toledo Way
Irvine, CA 92618

LICENSE NUMBER: 56468
EXPIRATION DATE: 10/3/2024

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

OSP 07 102308

Printed: 9/1/2022

Nathalie Raad,
Applied Medical Resources Corp. - 56468
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	APPLIED MEDICAL DISTRIBUTION CORPORATION
Entity No.:	2114075
Registration Date:	07/10/1998
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of August 04, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 135404028

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
Applied Medical Distribution Center
9401 Toledo Way
Irvine, CA 92618
Registration Number: 3009051888
FEI Number*: 3009051888
Status: Active
Date Of Registration Status: 2023

Owner/Operator:
APPLIED MEDICAL RESOURCES
22872 AVENIDA EMPRESA
Rancho Santa Margarita, CA US 92688
Owner/Operator Number: 2027111

Official Correspondent:
Leilani Domingo
22872 AVENIDA EMPRESA
Rancho Santa Margarita, CA 92688
Phone: 949-7138317

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 07/24/2023
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
9/28/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Woodruff-Sawyer & Co. 2 Park Plaza, Suite 500 Irvine CA 92614	CONTACT NAME: Katharine Tiller PHONE (A/C, No, Ext): 949-435-7353 FAX (A/C, No): 949-476-3118 E-MAIL ADDRESS: ktiller@woodruffsawyer.com
INSURED APPLMED-01 Applied Medical Corporation 22872 Avenida Empresa Rancho Santa Margarita, CA 92688	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Federal Insurance Company — 20281 INSURER B : INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 700132976 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			36051683	10/1/2022	10/1/2023	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	POLICY PRO-JECT X LOC						PRODUCTS - COMP/OP AGG	$ Separate policy
	OTHER:							$
A	AUTOMOBILE LIABILITY			73600364	10/1/2022	10/1/2023	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
	X Comp Ded $1K X Coll Ded $1K						Physical Damage	$ ACV
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A (Mandatory In NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products Liability/Completed Ops Claims Made Retro Date: 3/1/1989			36051684	10/1/2022	10/1/2023	Each Occurrence Aggregate	$10,000,000 $10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Applied Medical Resources Corporation
Applied Medical Distribution Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688
USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

K. Tiller

© 1988-2015 ACORD CORPORATION. All rights reserved.

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual SURETY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8207861- 024079**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Alicia Dass; Andrew S. Holloway; Charles R. Shoemaker; Christina Parsons; Joan DeLuca; Karen Rhodes; Kelly Holtemann; Mark M. Munekawa; Nerissa S. Bartolome; Patrick R. Diebel; Peter Tam; Thomas E. Hughes; Valerie Takeuchi; Yvonne Roncagliolo; Zachary V. Overbay

all of the city of San Francisco state of CA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 21st day of April, 2022.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 21st day of April, 2022 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 25th day of July, 2022.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8207861- 024079**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Alicia Dass; Andrew S. Holloway; Charles R. Shoemaker; Christina Parsons; Joan DeLuca; Karen Rhodes; Kelly Holtemann; Mark M. Munekawa; Nerissa S. Bartolome; Patrick R. Diebel; Peter Tam; Thomas E. Hughes; Valerie Takeuchi; Yvonne Roncagliolo; Zachary V. Overbay

all of the city of San Francisco state of CA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 21st day of April, 2022.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 21st day of April, 2022 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 25th day of July, 2022.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Applied Medical Distribution Corporation Employee List
As of September 30, 2022

Team Member Name	Location
Amado, Jake R.	Irvine
Anaya, Victor M.	Irvine
Arce, Nelson N.	Irvine
Arce, Pablo F.	Irvine
Baez, Kimberly A.	Irvine
Boutcher Jr., Gilbert P.	Irvine
Cervantes, Tiffaney A.	Irvine
Contreras, George J.	Irvine
Doan, Cathalina M.	Irvine
Dominguez, Ivone	Irvine
Garcia, Anthony E.	Irvine
Gutierrez, Alicia	Irvine
Guzman-Martinez, Erika	Irvine
Hernandez, Maria G.	Irvine
Johnson, Eugene	Irvine
Juarez, Raul O.	Irvine
Lauderdale, Trenton D.	Irvine
Mercado, Juan C.	Irvine
Oehlers, Ross M.	Irvine
Punzo, Humberto	Irvine
Ramirez, Erika M.	Irvine
Roman, Rosa I.	Irvine
Romero, Alma D.	Irvine
Rosales Castellanos Jr., Rafael	Irvine
Sharp, Jenifer K.	Irvine
Ta, Trong D.	Irvine
Villalobos, Ruben	Irvine
Zaragoza-Huipe, Joselyn	Irvine

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Applied Medical Distribution Corporation

Physical Address: 9401 Toledo Way

City: Irvine State: CA Zip: 92618

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 949-713-8000 Website: www.appliedmedical.com

Licensing Company Email: PremarketRegulatory@appliedmedical.com

Section 2: Personal Information

First: Susan Middle: S Last: Ahlberg

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]Feldspar Way

City: Rancho Santa Margarita State: CA Zip: 92688

Telephone: [redacted] Email: sahlberg@appliedmedical.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: to:

Military Occupation/Specialty

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Applicant's initials: SA

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California Polytechnic State University		1986 to 1988	
Address	**City**	**State**	**Zip**
1 Grand Avenue	San Luis Obispo	CA	93407
Diploma/Degree obtained, if any			
BS - Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Allan Hancock College		1984 - 1986	
Address	**City**	**State**	**Zip**
800 S. College Drive	Santa Maria	CA	93455
Diploma/Degree obtained, if any			
AA			

School Name		From - To (MM/YY – MM/YY)	
Ernst Righetti High School		1980 - 1984	
Address	**City**	**State**	**Zip**
941 E Foster Road	Santa Maria	CA	93455
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2004 to Present	[redacted]Feldspar Way	Rancho Santa Margarita	CA	92688
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Applied Medical Distribution Corporation			From - To (MM/YY – MM/YY): 1996 to Present	
Business Address: 9401 Toledo Way	City: Irvine		State: CA	Zip: 92618
Phone: 949 713 8635	Title: Vice President Operations		Number of Employed Hours: More than 6000	
Description of Duties: Please see resume				
Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				
Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				
Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				
Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

June 23, 2022
Date

Applicant's initials _____

I, Susan Ahlberg, **certify that as the designated representative for**

Applied Medical Distribution Corporation,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Susan Ahlberg

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 23, 2022

Date

Applicant's initials

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Susan Ahlberg

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 23, 2022

Date

See Attached.

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

_____ _____

Original Signature **Date**

Subscribed and Sworn to before me this _____ day of _____.

_____

Notary Public Signature

(Seal)

Applicant's initials _____

CALIFORNIA ACKNOWLEDGMENT CIVIL CODE § 1189

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Orange }

On June 23, 2022 *Date* before me, Erika Mason, Notary Public *Here Insert Name and Title of the Officer*,

personally appeared Susan Shizuko Ahlberg *Name(s) of Signer(s)*,

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

ERIKA MASON
Notary Public - California
Orange County
Commission # 2362233
My Comm. Expires Jun 22, 2025

Place Notary Seal and/or Stamp Above

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature Erika Mason
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____	Signer's Name: _____
☐ Corporate Officer – Title(s): _____	☐ Corporate Officer – Title(s): _____
☐ Partner – ☐ Limited ☐ General	☐ Partner – ☐ Limited ☐ General
☐ Individual ☐ Attorney in Fact	☐ Individual ☐ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator	☐ Trustee ☐ Guardian or Conservator
☐ Other: _____	☐ Other: _____
Signer is Representing: _____	Signer is Representing: _____

©2019 National Notary Association

SUSAN AHLBERG

sahlberg@appliedmedical.com
[redacted]

EXPERIENCE

September 1996-Present Applied Medical Resources Corporation/Applied Medical Distribution Corporation

Finance Manager 1996

Director of Sales Operations 1998

Finance Controller 2000

Vice President of Operations 2008

Responsibilities:

- Manage organization operations by directing and coordinating activities consistent with established goals, objectives and policies in the areas of customer relations, travel, credit and collections, budgeting and forecasting, commissions and reporting
- Research and implement programs and processes to ensure optimum workflow operations
- Promote and support activities directed at global expansion
- Provide direction and structure for reporting departments
- Develop and create strategies and policies aligned with organizational goals
- Provide mentoring and guidance to direct reporting team and other team members

EDUCATION

California Polytechnic State University – San Luis Obispo, California
December 1988: Bachelor of Science in Business Administration with concentration in Accounting

Certified Public Accountant, State of California since 1993

PROFESSIONAL AFFILIATIONS

California Society of Certified Public Accountants

American Institute of Certified Public Accountants

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Applied Medical Distribution Corporation MDEG License # (if applicable) _____

Physical Address 9401 Toledo Way

City Irvine State CA Zip 92618

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 949-713-8000 Website www.appliedmedical.com

Licensing Company Email premarketregulatory@appliedmedical.com

Section 2: Personal Information

First Susan Middle S Last Ahlberg

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN _____ Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]Feldspar Way

City Rancho Santa Margarita State CA Zip 92688

Telephone 949-713-8635 Email sahlberg@appliedmedical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California Polytechnic State University		1986 to 1988	
Address	**City**	**State**	**Zip**
1 Grand Avenue	San Luis Obispo	CA	93407
Diploma/Degree obtained, if any			
BS - Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Allan Hancock College		1984 - 1986	
Address	**City**	**State**	**Zip**
800 S. College Drive	Santa Maria	CA	93455
Diploma/Degree obtained, if any			
AA			

School Name		From - To (MM/YY – MM/YY)	
Ernst Righetti High School			
Address	**City**	**State**	**Zip**
941 E Foster Road	Santa Maria	CA	93455
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2004 to Present	[redacted] Feldspar Way	Rancho Santa Margarita	CA	92688
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Applied Medical Distribution Corporation			1996 to Present
Business Address	**City**	**State**	**Zip**
9401 Toledo Way	Irvine	CA	92618
Phone	**Title**	**Number of Employed Hours**	
949-713-8635	Vice President Operations	More than 1500	
Description of Duties			
See resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Susan Ahlberg, **certify that as the MDEG Administrator for**

Applied Medical Distribution Corporation,

that I (initial that you have read and meet the following requirements):

1. SA Have a high school diploma or its equivalent;
2. SA Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SA Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SA Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Susan Ahlberg
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

October 28, 2022
Date

Board Use Only	Date Received: 11-2-22

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 070215997

Application/License No. _____

Applied Medical Distribution Corporation (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 9401 Toledo Way, Irvine, CA 92618 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 255 California Street, Suite 950, San Francisco, CA 94111 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 21st, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25th day of July, 2022.

APPLICANT/PRINCIPAL

Applied Medical Distribution Corporation

Authorized Representative

SURETY COMPANY

Liberty Mutual Insurance Company

Surety Company's Representative

Kelly Holtemann, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness James Moore

Witness Taylor Holtemann

Countersigned by:

Mark Masami Munekawa
Nevada Resident Agent
Non-Resident Producer License #546936
Woodruff-Sawyer & Co., NV Non-Res. Lic. #1838
50 California Street, 12th Floor
San Francisco, CA 94111/(415) 391-2141

Posted February 20, 2020

RIDER

This Rider to be attached to and form part of Nevada State Board of Pharmacy

Bond Number _____

on behalf of Applied Medical Distribution Corporation

in favor of State of Nevada and to the Nevada State Board of Pharmacy

issued by Liberty Mutual Insurance Company

issued on the 21st day of July, 2022 , 19--

IT IS HEREBY UNDERSTOOD AND AGREED, That

Add additional locations:

1. 355 Satellite Boulevard, Suite 175, Suwanee, GA 30024
2. 45 Turner Drive, Middletown, NY 10940

PROVIDED, HOWEVER, that all other terms and conditions of the attached bond are to remain unchanged.

Signed, sealed and dated this 25th day of July, 2022 19--

Applied Medical Distribution Corporation

Principal

By: _____

Liberty Mutual Insurance Company

Surety

By: _____

Kelly Holtemann, Attorney-in-Fact

4J

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: BioHorizons Implant Systems Inc.

Physical Address: 2300 Riverchase Center

City: Birmingham State: Alabama Zip: 35244

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 205-967-7880 Website: https://www.biohorizons.com/

Name of Designated Representative (DR): Jared Cooper

Licensing Company Email: regulatory@biohorizons.com DR Email: jcooper@biohorizons.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Dental implant systems & associated instrumentation (Class I & II devices); biologics distributor	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Government		■ Others: biologics distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: ACE Surgical Supply Co., Inc.
Address: 1034 Pearl St. City: Brockton State: MA Zip: 02301
Name: Collagen Matrix, Inc. (CMI)
Address: 509 Commerce St. City: Franklin Lakes State: NJ Zip: 07417
Name: Medtronic Osteotech, Inc.
Address: 51 James Way City: Eatontown State: NJ Zip: 07724
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): BioHorizons, Inc.
Corporation/Organization Name: BioHorizons Implant Systems Inc.
Mailing Address: 2300 Riverchase Center
City: Birmingham State: AL Zip: 35244
Telephone: 205-967-7880 Email: regulatory@biohorizons.com
Contact Person Name: Jared Cooper

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

BioHorizons Implant Systems Inc.

Facility Name

Jared Cooper

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

08/24/2023

Date

Board Use Only	Date Received: 8/28/23	Amount: 1000-CK-10029206

BIOHORIZONS
INNOVATION • SERVICE

08/24/2023

RE: Nevada State Board of Pharmacy Wholesaler Application & Supporting Documentation

We, **BioHorizons Implant Systems Inc.**, located at **2300 Riverchase Center, Birmingham, Alabama, 35244, USA**, received a "Notice of Nevada Wholesale Licensure Requirement" (See Wholesale Application - Attachment 1) via U.S. Mail. Per the notice, BioHorizons received the notification "*because our organization submitted a marketing code of conduct but does not hold a current Nevada Wholesaler license.*" Per the notice: *"Should your company be engaged in the business of wholesale distribution or furnishing items covered by NRS 639.233 , you are required to obtain a Nevada Wholesaler license."*

BioHorizons Implant Systems Inc. is an out-of-state manufacturer of legend medical devices (i.e., dental implant systems and associated dental instruments) and a distributor of a biologics portfolio (i.e., hard and soft biologic products from other manufacturers) utilized during temporary or definitive restorations of dental implants. Our medical devices/products are not directly sold to consumers but sold and shipped only to licensed practitioners of dentistry for use in their office or private practice. We have an FDA Establishment Registration (Reg. No. 1060818) but are not required to maintain a license from the Alabama Board of Pharmacy. The Alabama Board of Pharmacy communicated via letter, after review of our renewal application for licensure (i.e., 29-NOV-2021), that "*...the determination has been made that no licensure is required for your business.*"

BioHorizons Implant Systems Inc. does not manufacture, store, or distribute "drugs," "medicine," or "controlled substances" (*NRS 639.007* & *NRS 453.081*). Our products are not processed or dispensed via a pharmacy *(NRS 454.0094)*. Our legend medical devices do not clearly fall within the supply channels or definitions as specified by the Nevada regulations. In the most simplistic process representation, BioHorizons supplies "dentists" or dental "practitioners" our products via their professional order of our products (i.e., dental implant systems and associated dental instruments which are legend medical devices or distributed biologic products). These products/orders are not processed from a physician of medicine, via a "prescription through a pharmacy," but rather directly to the dentist or dental practitioner.

Considering our business/product type (i.e., well established technology that is considered legend medical devices), we are not certain that BioHorizons Implant Systems Inc. would fall under the requirements to hold a Nevada Wholesaler license as per the Nevada regulations. We are

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submitting the appropriate documentation (Wholesaler Application, supporting application documentation, and payment) for consideration per the "Notice of Nevada Wholesale Licensure Requirement" and, to err on the side of caution, to meet the requirements of the referenced Nevada Revised Statue (NRS) 639.233.

Please confirm receipt of this application package and let us know if you require any additional information. Thank you for your assistance and we look forward to your response!

Best regards,

Jared Cooper
Director, Regulatory Affairs
BioHorizons Implant Systems Inc.

08/24/23
Date

2300 Riverchase Center • Birmingham, Alabama 35244 • corporate: 866.872.9785 or 205.967.7880 • fax: 205.870.0304
BioHorizons products are available in 90 countries throughout the world • www.biohorizons.com

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Section 9 – Attachment 8

BioHorizons FDA Establishment Registration (# 1060818) & Alabama BOP Decision Letter (No Licensure Required)

07/21/2023

To: Nevada State Board of Pharmacy

The BioHorizons Implant Systems Inc.'s FDA Establishment Registration (Reg. No. 1060818), as requested in Section 9 of the Wholesaler Application, can be found in Section 8 – Attachment 1 with this application.

Also, we've attached a letter from the Alabama Board of Pharmacy indicating that it was determined that no licensure is required for BioHorizons Implant Systems Inc. after review of our renewal application for licensure.

ALABAMA
BOARD OF PHARMACY

Donna C. Yeatman, R.Ph.
Executive Secretary

Location:
111 Village Street
Birmingham, AL 35242

(205) 981-2280
(205) 981-2330 Fax
www.albop.com

MEMBERS 2021

Brenda Denson, PharmD
President

Chris Phung, R.Ph.
Vice President

Robert Colburn, Jr., R.Ph.
Treasurer

Christy Garmon, PharmD

Gary Mount, PharmD

November 29, 2021

Biohorizons Implant Systems, Inc (194959)
Attn:Jared Cooper
2300 Riverchase Center
Birmingham, AL 35244

To Whom It May Concern:

This letter is to inform you of the decision made concerning your recent renewal application for licensure with the Alabama Board of Pharmacy. Applicants seeking licensure with this agency, for the purpose of supplying medical devices in the state of Alabama, are reviewed to determine whether the device(s):

1. Has/Have a drug component involved or imbedded in the device and/or
2. Must be dispensed through a pharmacy pursuant to a prescription.

The information you provided has been reviewed and the determination has been made that **no licensure is required** for your business. Again, this decision is based on information you provided during the renewal process, and it is your responsibility to promptly notify this Board and seek licensure should your business model change to include any device meeting the above criteria.
Please note that your renewal fee is being refunded to credit card or account used to complete the transaction. If you have not received your credit in 30 days from the date above, please contact me at the email below.

Feel free to contact us with any questions or concerns.

Thank You,

Kim Pickett
Facilities Licensing Manager
kpickett@albop.com

Help (./help/index.html)

DRLM Home (mainMenu.htm)

✔ Facility

✔ Products Listing

Annual Registration Successful

Facility: BIOHORIZONS IMPLANT SYSTEMS, INC., BIRMINGHAM, Alabama, UNITED STATES

You have successfully updated your registration and listing information for 2023.

Your registration will be valid through Dec 31, 2023.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2023.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 9024113.

Facility Information

Registration Number:
1060818

Initial Importer:
Y

Facility Name:
BIOHORIZONS IMPLANT SYSTEMS, INC.

Legal Name:

Address:
2300 RIVERCHASE CENTER,
BIRMINGHAM, Alabama, 35244, UNITED STATES

DUNS Number:
987279910

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:
9024113

Contact Name:
Jared Cooper

Company:
BIOHORIZONS IMPLANT SYSTEMS, INC.

Address: **2300 RIVERCHASE CENTER, --**
Birmingham, ALABAMA, 35244, UNITED STATES

Telephone:
205 - 9867994

Fax:
-

E-mail: **jcooper@biohorizons.com**

DUNS Number:

Official Correspondent Information

Contact Name:
Jared Cooper

Company:
BIOHORIZONS IMPLANT SYSTEMS, INC.

Address: **2300 RIVERCHASE CENTER, --**
Birmingham, ALABAMA, 35244, UNITED STATES

Telephone:
205 - 9867994

Fax:
-

E-mail: **jcooper@biohorizons.com**

DUNS Number:

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
E284375		510(k) exempt	ELZ	CROWN, PREFORMED	Manufacturer
D072480		510(k) exempt	EHY	TRAY, IMPRESSION, PREFORMED	Manufacturer

D277547	K041938	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277548	K032351	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277540	K972313	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277541	K010458	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277542	K020133	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277543	K020645	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277544	K030463	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277545	K990277	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277546	K052419	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D334813	K182070	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277536	K042429	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D308069	K172576	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277537	K011675	DZL	SCREW, FIXATION, INTRAOSSEOUS	Manufacturer
D277536	K022790	DZL	SCREW, FIXATION, INTRAOSSEOUS	Manufacturer

D277539	K964330		DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D088039		510(k) exempt	NDP	Accessories, implant, dental, endosseous	Manufacturer Contract Manufacturer
D277530	K143022		DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277531	K151621		NHA	Abutment, implant, dental, endosseous	Manufacturer
D277532	K071638		NHA	Abutment, implant, dental, endosseous	Manufacturer
			DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	
D277533	K061567		NHA	Abutment, implant, dental, endosseous	Manufacturer
D277534	K053099		NHA	Abutment, implant, dental, endosseous	Manufacturer
D277535	K053152		DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D334811	K180998		NHA	Abutment, implant, dental, endosseous	Specification Developer
E260383		510(k) exempt	DZA	DRILL, DENTAL, INTRAORAL	Manufacturer
D353204	K021322		NHA	Abutment, implant, dental, endosseous	Contract Manufacturer
			DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	
E260382	K993493		DZL	SCREW, FIXATION, INTRAOSSEOUS	Manufacturer

E260381	K022795	NHA	Abutment, implant, dental, endosseous	Manufacturer
E260380	K960026	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277525	K103691	NHA	Abutment, implant, dental, endosseous	Manufacturer
D277527	K103291	NHA	Abutment, implant, dental, endosseous	Manufacturer
D277529	K121787	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277522	K081818	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D277523	K093321	NHA	Abutment, implant, dental, endosseous	Manufacturer
		DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	
D277524	K100985	NHA	Abutment, implant, dental, endosseous	Manufacturer
D353209	K050970	NHA	Abutment, implant, dental, endosseous	Manufacturer
		DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	
D353208	K040205	NHA	Abutment, implant, dental, endosseous	Contract Manufacturer
D353215	BK120048	ORG	Platelet and plasma separator for bone graft handling	Specification Developer Manufacturer
D353214	K111199	NHA	Abutment, implant, dental, endosseous	Contract Manufacturer

D353213	K103194	NHA	Abutment, implant, dental, endosseous	Contract Manufacturer
		DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	
D353211	K080598	NHA	Abutment, implant, dental, endosseous	Manufacturer
D353210	K070601	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D441978	K203252	NHA	Abutment, implant, dental, endosseous	Manufacturer
D276428	K073268	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D276429	K073282	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Manufacturer
D063291	K060267	LLZ	System, image processing, radiological	Manufacturer
D353217	K133613	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Contract Manufacturer
D353216	K130140	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	Contract Manufacturer

Imported Products and Manufacturers

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
W&H DENTALWERK BUERMOOS GMBH	53 IGNAZ-GLASER-STRASSE, BUERMOOS, Salzburg, 5111, AUSTRIA	EBW	Controller, foot, handpiece and cord	K052741

W&H DENTALWERK BUERMOOS GMBH	53 IGNAZ-GLASER-STRASSE, BUERMOOS, Salzburg, 5111, AUSTRIA	EBW	Controller, foot, handpiece and cord	K014068
W&H DENTALWERK BUERMOOS GMBH	53 IGNAZ-GLASER-STRASSE, BUERMOOS, Salzburg, 5111, AUSTRIA	EGS	Handpiece, contra- and right-angle attachment, dental	K011061
W&H DENTALWERK BUERMOOS GMBH	53 IGNAZ-GLASER-STRASSE, BUERMOOS, Salzburg, 5111, AUSTRIA	EKX	Handpiece, direct drive, ac-powered	K100600
JEIL MEDICAL CORPORATION	702,703,704,705,706,804,805,807,812,815-ho, 55, Digital-ro34-gil, Guro-gu, Seoul, Seoul, 08378, KOREA, SOUTH	DZL	SCREW, FIXATION, INTRAOSSEOUS	K050669
		JEY	PLATE, BONE	
OSSTELL AB	Stampgaten 14, GOTEBORG, Vastra Gotaland, 41101, SWEDEN	EKX	Handpiece, direct drive, ac-powered	K142358
OSSTELL AB	Stampgaten 14, GOTEBORG, Vastre Gotaland, 41101, SWEDEN	EKX	Handpiece, direct drive, ac-powered	K181888
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	K000100
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K032448
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K051636
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K073553
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K083496
		DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K090347

ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K103252
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K113779
		DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K133991
		DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K143337
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K151599
		DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K152509
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K153779
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NHA	Abutment, implant, dental, endosseous	K160784
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	DZE	IMPLANT, ENDOSSEOUS, ROOT-FORM	K193401
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	EMM	CHISEL, OSTEOTOME, SURGICAL	
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	EJL	BUR, DENTAL	

ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	NDP	Accessories, implant, dental, endosseous	
ALTATEC GMBH	MAYBACHSTRASSE 5, WIMSHEIM, Baden-Wurttemberg, D-71299, GERMANY	FSM	TRAY, SURGICAL, INSTRUMENT	
ELOS MEDTECH PINOL A/S	Engvej 33, Goerloese, Hovedstaden, DK3330, DENMARK	NDP	Accessories, implant, dental, endosseous	
W&H DENTALWERK BUERMOOS GMBH - SITE 2	WERNER-BADER-STRASSE 1, BUERMOOS, Salzburg, 5111, AUSTRIA	EKX	Handpiece, direct drive, ac-powered	K100600
W&H DENTALWERK BUERMOOS GMBH - SITE 2	WERNER-BADER-STRASSE 1, BUERMOOS, Salzburg, 5111, AUSTRIA	EBW	Controller, foot, handpiece and cord	K161957

Date of Initial Registration: 1996-01-04 10:17:05.0

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Section 9 – Attachment 1

List of Officers/Directors

07/21/2023

To: Nevada State Board of Pharmacy

Below is the list of Officers/Directors at BioHorizons Implant Systems Inc. as requested in Section 9 of the Wholesaler Application:

Title	Full Name	Personal/Primary Address	Telephone Number	Effective Date
Board Member / Officer	Roy Steven Boggan	[redacted] Legacy Drive, Birmingham, AL 35242	[redacted]	12/10/2010
Board Member / Officer	Jeffery Todd Strong	[redacted] Cedar Bark Lane, Birmingham, AL 35216	[redacted]	12/10/2010
Board Member / Officer	David Dutil	[redacted] Double Oak Lane, Birmingham, AL 35242	[redacted]	12/10/2010
Board Member / Officer	John Michael Mills, II	[redacted] Eagle Mountain Lane, Birmingham, AL 35242	[redacted]	08/31/2018

BIOHORIZONS
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Section 9 – Attachment 2

List of Corporation Shareholders & Percent Ownership

07/21/2023

To: Nevada State Board of Pharmacy

Below is the list of Corporation Shareholders and their percent ownership at BioHorizons Implant Systems Inc. as requested in Section 9 of the Wholesaler Application:

Full Name of Entity	Personal/Primary Address	Personal/Primary Address	EIN (NO SSN)	% Ownership	Effective Date
BioHorizons, Inc.	2300 Riverchase Center, Birmingham, AL 35244	205-967-7880	20-5912502	100	12/30/2013

BIOHORIZONS
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Section 9 – Attachment 3

Certificate of Good Standing

07/21/2023

To: Nevada State Board of Pharmacy

Attached is the Certificate of Good Standing (Ref. Authentication # 202884237 / Date: 03-10-23) for BioHorizons Implant Systems Inc., from the Secretary of State of the state of Delaware, as requested in Section 9 of the Wholesaler Application.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BIOHORIZONS IMPLANT SYSTEMS INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF MARCH, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BIOHORIZONS IMPLANT SYSTEMS INC." WAS INCORPORATED ON THE THIRD DAY OF NOVEMBER, A.D. 1995.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2558681 8300

SR# 20230938908

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202884237

Date: 03-10-23

BIOHORIZONS
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Section 9 – Attachment 10

BioHorizons Certificate of Liability Insurance

(Cert# 570100278664)

07/21/2023

To: Nevada State Board of Pharmacy

Attached is the BioHorizons Implant Systems Inc.'s Certificate of Liability Insurance (Certificate Number: 570100278664) as requested in Section 9 of the Wholesaler Application.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/27/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Northeast, Inc.
New York NY Office
One Liberty Plaza
165 Broadway, Suite 3201
New York NY 10006 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Berkshire Hathaway Specialty Ins Company	22276
INSURER B:	QBE Specialty Insurance Company	11515
INSURER C:	ProAssurance Specialty Insurance Company	17400
INSURER D:	Liberty Mutual Fire Ins Co	23035
INSURER E:		
INSURER F:		

INSURED
Henry Schein, Inc.,
Subsidiaries & Affiliates
135 Duryea Road
Melville NY 11747 USA

COVERAGES **CERTIFICATE NUMBER:** 570100278664 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS,

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
D	X COMMERCIAL GENERAL LIABILITY			TB2621093363033	06/01/2023	06/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	$5,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$1,000,000
	POLICY [ ] PRO-JECT [X] LOC						PRODUCTS - COMP/OP AGG	Excluded
	OTHER:							
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	
	ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE [ ] OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER (Mandatory in NH) N/A						E.L. EACH ACCIDENT	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	
							E.L. DISEASE-POLICY LIMIT	
c	Products Liability			N23NY380024 Claims Made	06/01/2023	06/01/2024	Each Occurrence	$1,000,000
							Aggregate	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno NV 89521 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier :

Certificate No : 570100278664

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AGENCY CUSTOMER ID: 570000025511

LOC #:

ACORD

ADDITIONAL REMARKS SCHEDULE

Page _ of _

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Henry Schein, Inc.,
POLICY NUMBER	
See Certificate Numbe 570100278664	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Numbe 570100278664	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

Named Insureds

Henry Schein, Inc.
Ace Surgical Supply Company, Inc.
All Star Orthodontics
BIOHORIZONS IMPLANT SYSTEMS, INC.
Camlog
Dental Instrument Sales & Service, LLC
Dentrix Dental Systems
Exan Enterprises
G.I.V. Inc.
General Injectibles & Vaccines, Inc.
HF Acquisition Co. LLC
Hand Piece Parts & Repair, Inc.
Henry Schein and Schvadent
Henry Schein Dental, Inc.
Henry Schein Global Sourcing, Inc.
Henry Schein Medical
Henry Schein Practice Solutions
Henry Schein, Supply
HealthFirst
Impromed, LLC.
Insource, Inc.
Ortho Organizers, Inc.
Ortho Technology, Inc.
RXWORKS, INC.
Southern Anesthesia & Surgical Inc.
The Custom Milling Center, Inc.
Zahn Dental Company, Inc.
Zahn/Darby Lab
Edge Endo
Henry Schein Professional Practice Transitions
North American Rescue LLC and NAR Medical Depot, LLC
NAR Training LLC
Lighthouse 360, Inc.
Hayes Handpiece Franchises, Inc.
Henry Schein One, LLC
US Endodontics
TDSC, Inc.
NAR Medical Depot LLC
Prism Medical Products - 12.31.20
Sesame Communications
eAssist Inc.
eAssist Publishing LLC
Midway Dental Supply LLC
Ace Southern Surgical Solutions

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 015220682

Application/License No. _____

BIOHORIZONS IMPLANT SYSTEMS, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2300 Riverchase Center Birmingham, AL 35244 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 11, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th day of July, 20 23.

APPLICANT/PRINCIPAL
BIOHORIZONS IMPLANT SYSTEMS, INC.

Authorized Representative

SURETY COMPANY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Sandra Diaz, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Grace Laterza

Witness Aklima Noorhassan

Countersigned by:

N/A
Nevada Resident Agent

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th day of July, 20 23.

APPLICANT/PRINCIPAL
BIOHORIZONS IMPLANT SYSTEMS, INC.

_____
Authorized Representative

SURETY COMPANY
LIBERTY MUTUAL INSURANCE COMPANY

_____
Surety Company's Representative

Sandra Diaz, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Grace Laterza

_____
Witness Aklima Noorhassan

Countersigned by:

N/A
Nevada Resident Agent

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual. SURETY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8205735-015009**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aklima Noorhassan; Anne Potter; Cynthia Farrell; Debra A. Deming; Frances Rodriguez; Francesca Kazmierczak; Jennifer L. Jakaitis; Kemal Brkanovic; Nancy Schnee; Pablo Garcia Horcajo; Peter Healy; Sandra Diaz; Susan A. Welsh; Valorie Spates

all of the city of New York state of NY each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 11th day of June, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 11th day of June, 2021 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insuranca Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 11th day of July, 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

Financial Statement – December 31, 2022

Assets

Cash and Bank Deposits	$3,908,755,039
*Bonds — U.S Government	3,451,999,931
*Other Bonds	18,862,255,155
*Stocks	19,372,953,698
Real Estate	190,092,373
Agents' Balances or Uncollected Premiums	7,929,876,358
Accrued Interest and Rents	166,740,412
Other Admitted Assets	15,968,062,977
Total Admitted Assets	**$69,850,735,943**

Liabilities

Unearned Premiums	$10,133,358,204
Reserve for Claims and Claims Expense	27,953,643,316
Funds Held Under Reinsurance Treaties	368,610,620
Reserve for Dividends to Policyholders	1,379,296
Additional Statutory Reserve	197,278,000
Reserve for Commissions, Taxes and Other Liabilities	9,206,000,954
Total	**$47,860,270,390**
Special Surplus Funds	$195,696,103
Capital Stock	10,000,075
Paid in Surplus	13,324,803,036
Unassigned Surplus	8,459,966,339
Surplus to Policyholders	**21,990,465,553**
Total Liabilities and Surplus	**$69,850,735,943**

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the state of Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2022, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March 2023.

T A Mikolajewski

Assistant Secretary

BIOHORIZONS
IENCE • INNOVATION • SERVICE

Section 9 – Attachment 9

MDEG Administrator Form

07/21/2023

To: Nevada State Board of Pharmacy

Attached is the Medical Devices, Equipment and Gases (MDEG) Administrator for BioHorizons Implant Systems Inc. as requested in Section 9 of the Wholesaler Application. Note, we do not provide MDEG products directly to a patient by a prescription.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG BioHorizons Implant Systems Inc. MDEG License # (if applicable) N/A

Physical Address 2300 Riverchase Center

City Birmingham State Alabama Zip 35244

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 205-967-7880 Website https://www.biohorizons.com/

Licensing Company Email regulatory@biohorizons.com

Section 2: Personal Information

First Jared Middle Owen Last Cooper

Alias(es, nicknames, name changes, etc.) None

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address 2300 Riverchase Center

City Birmingham State AL Zip 35244

Telephone [redacted] Email jcooper@biohorizons.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Joint Program University Of Memphis / University of Tennessee Health Sciences Center			01/08 - 05/13
Address	**City**	**State**	**Zip**
3720 Alumni Ave	Memphis	TN	38152
Diploma/Degree obtained, if any			
Doctor of Philosophy			

School Name			From - To (MM/YY – MM/YY)
Joint Program University Of Memphis / University of Tennessee Health Sciences Center			08/05 - 12/07
Address	**City**	**State**	**Zip**
3720 Alumni Ave	Memphis	TN	38152
Diploma/Degree obtained, if any			
Master of Science			

School Name			From - To (MM/YY – MM/YY)
Auburn University			08/00 - 12/04
Address	**City**	**State**	**Zip**
208 Samford Hall	Auburn	AL	36849
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name			From - To (MM/YY – MM/YY)
Hoover High School			08/96 - 05/00
Address	**City**	**State**	**Zip**
1000 Buccaneer Dr	Hoover	AL	35244
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/21 - Current	[redacted] Sapphire Ridge	Hoover	AL	35244
12/18 - 01/21	[redacted] E 450 N	Leesburg	IN	46538
01/15 - 12/18	[redacted] N. Lighthouse Dr	Warsaw	IN	46582
04/14 - 01/15	[redacted] Briar Ridge Cir.	Warsaw	IN	46582
04/13 - 03/14	[redacted] Briar Ridge Cir.	Warsaw	IN	46582
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
BioHorizons Implant Systems Inc.			11/20 - Current
Business Address	**City**	**State**	**Zip**
2300 Riverchase Center	Birmingham	AL	35244
Phone	**Title**	**Number of Employed Hours**	
205-986-7994	Director, Regulatory Affairs	5,200	

Description of Duties

- Adhere with the company's QMS to ensure compliance with applicable Medical Device requirements.
- Developing and maintaining quality and regulatory systems in conformity with Domestic Medical Device requirements

Business Name			From - To (MM/YY – MM/YY)
Zimmer Biomet			04/13 - 11/20
Business Address	**City**	**State**	**Zip**
56 East Bell Dr	Warsaw	IN	46580
Phone	**Title**	**Number of Employed Hours**	
1-800-348-9500	Manager, Regulatory Affairs	15,200	

Description of Duties

- Adhere with the company's QMS to ensure compliance with applicable Medical Device requirements.
- Developing and maintaining quality and regulatory systems in conformity with Domestic Medical Device requirements

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

07/21/2023
Date

I, Jared Owen Cooper, **certify that as the MDEG Administrator for**

BioHorizons Implant Systems Inc.,

that I (initial that you have read and meet the following requirements):

1. JC Have a high school diploma or its equivalent;
2. JC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jared Cooper
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/21/2023
Date

Board Use Only	Date Received:

BIOHORIZONS
SCIENCE • INNOVATION • SERVICE

Section 9 – Attachment 4

Designated Representative Application Form

07/21/2023

To: Nevada State Board of Pharmacy

Attached is the completed Designated Representative Application form for Jared Cooper from BioHorizons Implant Systems Inc. as requested in Section 9 of the Wholesaler Application.

2300 Riverchase Center • Birmingham, Alabama 35244 • corporate: 866.872.9785 or 205.967.7880 • fax: 205.870.0304
BioHorizons products are available in 90 countries throughout the world • www.biohorizons.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler BioHorizons Implant Systems, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2300 Riverchase Center

City Birmingham State Alabama Zip 35244

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 205-967-7880 Website https://www.biohorizons.com/

Licensing Company Email regulatory@biohorizons.com

Section 2: Personal Information

First Jared Middle Owen Last Cooper

Alias(es, nicknames, name changes, etc.) None

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 2300 Riverchase Center

City Birmingham State AL Zip 35244

Telephone [redacted] Email jcooper@biohorizons.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Joint Program University Of Memphis / University of Tennessee Health Sciences Center		01/08 - 05/13	
Address	**City**	**State**	**Zip**
3720 Alumni Ave	Memphis	TN	38152
Diploma/Degree obtained, if any			
Doctor of Philosophy			

School Name		From - To (MM/YY – MM/YY)	
Joint Program University Of Memphis / University of Tennessee Health Sciences Center		08/05 - 12/07	
Address	**City**	**State**	**Zip**
3720 Alumni Ave	Memphis	TN	38152
Diploma/Degree obtained, if any			
Master of Science			

School Name		From - To (MM/YY – MM/YY)	
Auburn University		08/00 - 12/04	
Address	**City**	**State**	**Zip**
208 Samford Hall	Auburn	AL	36849
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Hoover High School		08/96 - 05/00	
Address	**City**	**State**	**Zip**
1000 Buccaneer Dr	Hoover	AL	35244
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/21 - Current	[redacted] Sapphire Ridge	Hoover	AL	35244
12/18 - 01/21	[redacted] E 450 N	Leesburg	IN	46538
01/15 - 12/18	[redacted] N. Lighthouse Dr	Warsaw	IN	46582
04/14 - 01/15	[redacted] Briar Ridge Cir.	Warsaw	IN	46582
04/13 - 03/14	[redacted] Briar Ridge Cir.	Warsaw	IN	46582
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
BioHorizons Implant Systems, Inc.			11/20 - Current
Business Address	**City**	**State**	**Zip**
2300 Riverchase Center	Birmingham	AL	35244
Phone	**Title**	**Number of Employed Hours**	
205-986-7994	Director, Regulatory Affairs	5,200 +	

Description of Duties

- Adhere with the company's QMS to ensure compliance with applicable Medical Device requirements.
- Developing and maintaining quality and regulatory systems in conformity with Domestic Medical Device requirements

Business Name			From - To (MM/YY – MM/YY)
Zimmer Biomet			04/13 - 11/20
Business Address	**City**	**State**	**Zip**
56 East Bell Dr	Warsaw	IN	46580
Phone	**Title**	**Number of Employed Hours**	
1-800-348-9500	Manager, Regulatory Affairs	15,200 +	

Description of Duties

- Adhere with the company's QMS to ensure compliance with applicable Medical Device requirements.
- Developing and maintaining quality and regulatory systems in conformity with Domestic Medical Device requirements

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

06/20/23
Date

I, Jared Owen Cooper, **certify that as the designated representative for**

BioHorizons Implant Systems, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jared Cooper
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/20/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jared Cooper

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/20/23

Date

Please have this section completed in the presence of a Notary Public.

State of Alabama, ss. County of State at large

I, Karly Casey, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Karly Casey

Original Signature

06/20/2023

Date

Subscribed and Sworn to before me this 20 day of June 2023

Karly Casey 06/20/2023

Notary Public Signature

Notary Public, Alabama State at Large
Karly Casey
Expires 9/19/2026

(Seal)

BIOHORIZONS
SCIENCE • INNOVATION • SERVICE

Section 9 – Attachment 5

Personal History Application – N/A

07/21/2023

To: Nevada State Board of Pharmacy

The completion of the Personal History Application is Not Applicable (N/A) to BioHorizons Implant Systems Inc. as requested in Section 9 of the Wholesaler Application. BioHorizons, Inc. is the 100% entity/corporation shareholder as defined in Section 9 – Attachment 2 of this application.

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Section 9 – Attachment 6

Copy of DEA Certificate – N/A

07/21/2023

To: Nevada State Board of Pharmacy

The provision of a DEA Certificate is Not Applicable (N/A) to BioHorizons Implant Systems Inc. as requested in Section 9 of the Wholesaler Application since BioHorizons does not handle or distribute controlled substances. BioHorizons distributes well-established, legacy dental devices and applicable dental accessories/instruments.

BIOHORIZONS

Section 9 – Attachment 7

Active Employee Listing

07/21/2023

To: Nevada State Board of Pharmacy

Attached is the Active Employee Listing for BioHorizons Implant Systems Inc. as requested in Section 9 of the Wholesaler Application.

BioHorizons Implant Systems Inc. - List of Active Employees
(7/21/2023)

Payroll Name	Worker Category Description	Location Description	Home Department Code	Home Department Description	Position ID	Job Title
Attaway, Don	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q099781	Application Systems Engineer
Nilo, Patricio	Regular Full-Time	Corporate Headquarters	650	International Sales	P4Q099442	Area Vice President of Latin and So America
Edwards, Terry Wayne	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q100562	ASP.NET Programmer
Hu, Jerry	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q100060	ASP.NET Programmer
Pennington, Clayton Alexander	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q100533	ASP.NET Programmer
Rainey, John	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q100555	ASP.NET Programmer
Halliwill, Morgan	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q100595	Associate Digital Product Engineer
Neely, Susan H	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q099939	Associate Manager, Accounts Receivable
Smith, April Annette	Regular Full-Time	Corporate Headquarters	855	Marketing Operations Direct	P4Q099800	Associate Manager, Assembly
Norton, Christopher W	Regular Full-Time	Corporate Headquarters	850	Marketing Operations	P4Q099877	Associate Manager, Operations
Watz, Jaclyn E	Regular Full-Time	Corporate Headquarters	510	Product Marketing	P4Q100036	Associate Practice Development Manager
Newton, Charles	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q100566	Associate Product Development Engineer
Richardson, Easton Welles	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q100447	Associate Product Development Engineer
Cook, Timothy Hill	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q100559	Associate Product Engineer
Reed, Eric Louis	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q100417	Associate Product Engineer
Carroll, Stephen	Regular Full-Time	Corporate Headquarters	540	Product Management	P4Q100569	Associate Product Manager
Lewis, Laura Frances	Regular Full-Time	Corporate Headquarters	540	Product Management	P4Q100439	Associate Product Manager
Adams, Kelli	Regular Full-Time	Corporate Headquarters	120	Human Resources	P4Q100432	Associate Recruiter
Guy, Justin Alexander	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100258	Business Intelligence Analyst
Whitfield, George	Regular Full-Time	Corporate Headquarters	416	Quality Assurance - QC Indirect	P4Q099553	Calibration Specialist
Ramirez, Tatiana	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100445	Clinical Advisor
Sanderson Jr, James L	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100144	Clinical Advisor
Uribe Botero, Mariana	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100403	Clinical Advisor
Berryhill, Denielle	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q100554	Clinical Affairs Specialist II
Cooper, Jennifer Ann	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100446	Clinical Support Specialist
Curro, Marcia	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100473	Clinical Support Specialist
Dettling, Dwight	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100477	Clinical Support Specialist
Ford, Jahleda Marie	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100464	Clinical Support Specialist
Tilley, Faith Kathryn	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100396	Clinical Support Specialist
Whitfield, Steven Andre	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100493	Clinical Support Specialist
Barrett, Cayla Elaine	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100215	Clinical Support Specialist Lead
Harrison, Sheri Ann	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100211	Clinical Support Specialist Lead
Knowles, Rebecca Kay Wallace	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100319	Clinical Support Specialist Lead
Brown, Scott D.	Regular Full-Time	Corporate Headquarters	540	Product Management	P4Q100462	Content Marketing Manager
Edwards, Ryan Le'Shaun	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100094	Cust Advocate and Technical Product Expert
Jones, Cathy Cato	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q099968	Cust Advocate and Technical Product Expert
Littlefield, Joshua David	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100487	Cust Advocate and Technical Product Expert
O'Barr, Kayla Marie	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100393	Cust Advocate and Technical Product Expert
Pouncey, Matthew Kade	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100391	Cust Advocate and Technical Product Expert
Standfield, Cleotra O.	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100483	Cust Advocate and Technical Product Expert
Varden, Sarah Grace	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100452	Cust Advocate and Technical Product Expert
Walker, Cassandra Ellen	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100484	Cust Advocate and Technical Product Expert
Wilkerson, Timothy	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100565	Cust Advocate and Technical Product Expert
Cepukenas, Kristi	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100538	Customer Advocate, Account Maintenance
Kennessey, Heather Lauren	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100101	Customer Advocate, DSO Administration
Howard, Katlyn Renee'	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100482	Customer Advocate, Sales Operations Support
Tucker, Robyn Brittney Weston	Regular Full-Time	Corporate Headquarters	510	Product Marketing	P4Q100193	Digital Media & Content Manager
Haynes, Candice	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q099342	Dir of Institutions and Government Affairs
Smith, Ilona	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q099541	Director of Financial Operations
Hines, Marcus	Regular Full-Time	Corporate Headquarters	510	Product Marketing	P4Q001420	Director of Full Arch Solutions
Ahmed, Sara	Regular Full-Time	Corporate Headquarters	540	Product Management	P4Q100545	Director of Product Marketing
Swartz, Tina	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q099544	Director of Quality Assurance
Hu, Joshua	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q099826	Director of Software Engineering
Niebler, Craig W.	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100594	Director of Strategic Accounts
Cordell, Jason R	Regular Full-Time	Corporate Headquarters	540	Product Management	P4Q100385	Director, Biomaterials
Brasher, Jimmy	Regular Full-Time	Corporate Headquarters	810	Global Distribution	P4Q099478	Director, Distribution
Koe, Nicholas James	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100092	Director, Financial reporting & Business Inte
Cochran, Jamie L.	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100137	Director, Financial Systems & Cost
Bessiere, Kathy M	Regular Full-Time	Corporate Headquarters	120	Human Resources	P4Q100453	Director, Human Resources
Lewis, Corey Daniel	Regular Full-Time	Corporate Headquarters	850	Marketing Operations	P4Q100016	Director, Operations
Cooper, Jared O	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100383	Director, Regulatory Affairs

BioHorizons Implant Systems Inc. - List of Active Employees
(7/21/2023)

Atieh, Rana	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q099952	Director, Research Engineering
Rorer, Oliver William	Regular Full-Time	Central Region	610	Domestic Sales	P4Q100028	Director, Sales
Bond, Charles G	Regular Full-Time	Florida Region	610	Domestic Sales	P4Q099831	Director, Sales
Smith, Joel Thomas	Regular Full-Time	Gulf South Region	610	Domestic Sales	P4Q099758	Director, Sales
Dehling, Dean	Regular Full-Time	Midwest Region	610	Domestic Sales	P4Q099302	Director, Sales
Arsac, Kelly Ann	Regular Full-Time	Pacific Northwest	610	Domestic Sales	P4Q100142	Director, Sales
Hansen, Andrew Dayton	Regular Full-Time	Southwest	610	Domestic Sales	P4Q100448	Director, Sales
Cerwick, Jennifer	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q099484	Director, Treasury and Risk
Armstrong, Molly	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100561	Distribution Associate
Cantrell, Terrance	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100522	Distribution Associate
Cayson, Mya	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100537	Distribution Associate
Gibson, Latrice Denielle	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100416	Distribution Associate
Ward, Maria	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100577	Distribution Associate
Waston, William Daniel	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100476	Distribution Associate
Wilkerson, Reanna	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100540	Distribution Associate
Bowlin, Gavin	Regular Part-Time	Corporate Headquarters	610	Global Distribution	P4Q100520	Distribution Associate
Bessiere, Peter	Temporary Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100506	Distribution Associate
Jonss, Fatimah Aneesah	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q100392	Document Control Specialist I
Woody, Natasha Owens	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q100399	Document Control Specialist I
Shaw, Nathan Joel	Regular Full-Time	Midwest Region	610	Domestic Sales	P4Q100359	Education Support Specialist
Dedeaux, Chase Rylan	Temporary Full-Time	Corporate Headquarters	210	Research and Development	P4Q100507	Engineer Co-op - R and D
Pody, Benjamin Charles	Temporary Full-Time	Corporate Headquarters	210	Research and Development	P4Q100373	Engineer Co-op - R and D
Williams, Lawson Neff	Temporary Full-Time	Corporate Headquarters	210	Research and Development	P4Q100601	Engineer Co-op - R and D
Benge, Christopher	Regular Full-Time	Central Region	610	Domestic Sales	P4Q100141	Executive Territory Manager
Cooper, Kevin	Regular Full-Time	Central Region	610	Domestic Sales	P4Q100103	Executive Territory Manager
Krakover, Matthew S	Regular Full-Time	Central Region	610	Domestic Sales	P4Q100040	Executive Territory Manager
Mahla, Robert Patrick	Regular Full-Time	Central Region	610	Domestic Sales	P4Q099966	Executive Territory Manager
McFarland, Damon L	Regular Full-Time	Central Region	610	Domestic Sales	P4Q099851	Executive Territory Manager
Sisney, Jason M	Regular Full-Time	Central Region	610	Domestic Sales	P4Q099828	Executive Territory Manager
Larrauri, Julio	Regular Full-Time	Florida Region	610	Domestic Sales	P4Q099406	Executive Territory Manager
Crisp, Michael S	Regular Full-Time	Gulf South Region	610	Domestic Sales	P4Q099876	Executive Territory Manager
London, Steven Hunter	Regular Full-Time	Gulf South Region	610	Domestic Sales	P4Q100022	Executive Territory Manager
Motl, Lawrence Alan	Regular Full-Time	Gulf South Region	610	Domestic Sales	P4Q099965	Executive Territory Manager
Ritchey, Jeremy	Regular Full-Time	Gulf South Region	610	Domestic Sales	P4Q099753	Executive Territory Manager
Baumbach, Ryan A	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q099920	Executive Territory Manager
Holler, Marc Douglas	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q099948	Executive Territory Manager
Oberg, John	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q099605	Executive Territory Manager
Mills, John M	Regular Full-Time	Corporate Headquarters	100	Administration	P4Q100088	Executive Vice President and CFO
Strong, Jeffery	Regular Full-Time	Corporate Headquarters	100	Administration	P4Q099543	Executive Vice President and COO
Chaffin, Justin Michael	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100397	Expense Management Analyst
Hauswirth, Eric Joseph	Regular Full-Time	Corporate Headquarters	100	Administration	P4Q099859	Facilities Manager
Schubert, Sean	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100556	Financial Analyst
Brewer, Michael William	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100419	Financial Reporting Analyst
Gault, Justin Michael	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100414	Financial Systems Analyst II
Brush, Stacey Leigh	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100513	Global Accounts Payable Specialist
Hutchinson, Sarah Jane	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100423	Global Accounts Payable Specialist
Sanders, Jamie	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100429	Global Accounts Payable Specialist
Beach, Rachael Denae	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100524	Global Accounts Receivable Specialist
Tubbs, Shaqueta Roshea	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100426	Global Accounts Receivable Specialist
Weaver, Sara Ann	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100572	Global Accounts Receivable Specialist
Boston, Christi	Regular Full-Time	Corporate Headquarters	100	Administration	P4Q100450	Global Business Support Project Coordinator
McCluskey, Meghann	Regular Full-Time	Corporate Headquarters	120	Human Resources	P4Q100603	Human Resources Generalist
Nichols, Aimee	Regular Full-Time	Corporate Headquarters	120	Human Resources	P4Q100131	Human Resources Manager
Goolsby, Candice	Regular Full-Time	Corporate Headquarters	120	Human Resources	P4Q100436	Human Resources Reporting Analyst
Stanford, Whitney Brooke	Regular Full-Time	Corporate Headquarters	650	International Sales	P4Q100346	International Business Account Manager
Reeves, Lucas Alexander	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100273	International Distribution Manager
Miller, Jeremiah James	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100127	International Distribution Specialist
Ware, Jolen Terrill	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q100181	International Distribution Specialist
Hyde, Andrea Del Pilar	Regular Full-Time	Corporate Headquarters	550	International Marketing & Education	P4Q099760	International Marketing Manager
Newport, Melissa	Regular Full-Time	Corporate Headquarters	550	International Marketing & Education	P4Q099657	International Marketing Manager
Simmons, Cody A	Regular Full-Time	Corporate Headquarters	850	Marketing Operations	P4Q099957	Inventory Control Coordinator
Wells, Juriel R	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q100062	IT Network Technician

BioHorizons Implant Systems Inc. - List of Active Employees
(7/21/2023)

England, Gayle	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100499	Manager, Accounts Payable
Weimorts, Teresa Phillips	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q099942	Manager, Accounts Receivable
Torres Jose, Linda Arnell	Regular Full-Time	Corporate Headquarters	540	Product Management	P4Q100272	Manager, Clinical Product Support
Sessums, Adam	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100602	Manager, Corporate Accounting
Deischter, Mark	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100609	Manager, Cost Accounting
Boggs, Ashley Lane	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q100026	Manager, Digital Dentistry Engineering
Amerson, Mortez	Regular Full-Time	Corporate Headquarters	610	Global Distribution	P4Q099882	Manager, Distribution
Champion, Iveta Namike	Regular Full-Time	Corporate Headquarters	650	International Sales	P4Q099959	Manager, International Business Support
Lewis, Thomas Pearson	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q099796	Manager, Product Engineering
Calamusa, Cynthia Annette	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q099514	Manager, Returns and Complaints
Robertson, Rachel Burton	Regular Full-Time	Corporate Headquarters	530	Communication & Education	P4Q100117	Manager, Teaching Institutes & Trade Shows
York, Emma Grace Mayfield	Regular Full-Time	Corporate Headquarters	510	Product Marketing	P4Q100382	Marketing Associate
Musser, Everett James	Regular Full-Time	Corporate Headquarters	530	Communication & Education	P4Q100585	Marketing Shipping Specialist
Evans, Kristin	Regular Full-Time	Corporate Headquarters	530	Communication & Education	P4Q100329	Marketing Support Specialist
Gould, Jessica	Regular Full-Time	Corporate Headquarters	850	Marketing Operations	P4Q100488	Materials Control Coordinator II
Waldrop, Bradley T	Regular Full-Time	Corporate Headquarters	850	Marketing Operations	P4Q099972	Materials Control Coordinator, I
Priest, Nicole	Regular Full-Time	Corporate Headquarters	850	Marketing Operations	P4Q100509	Materials Control Coordinator, I
Rmeily, Ralph	Regular Full-Time	Corporate Headquarters	850	International Sales	P4Q099837	Middle East Territory Manager
Moore, Michelle Renee'	Regular Full-Time	Corporate Headquarters	120	Human Resources	P4Q100449	Payroll & HRIS Manager
Weems, Jenny	Regular Part-Time	Corporate Headquarters	120	Human Resources	P4Q100604	Payroll Specialist
Boggan, Roy S.	Regular Full-Time	Corporate Headquarters	100	Administration	P4Q099477	President and CEO
Bell, Paul W.	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q100587	Product Development Engineer
Anderson, Anitra Jawan	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100046	Product Investigator I
Knott, Rahshandalyn S	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100420	Product Investigator I
Williams, Claresa Olivia	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100255	Product Investigator I
Dowdell, Meka N	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q099918	Product Investigator III
Tanner, Teresa ReChelle	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q099847	Product Investigator III
Moore, Joshua Michael	Regular Full-Time	Corporate Headquarters	540	Product Management	P4Q100269	Product Manager
Chance, Heather Pennington	Regular Full-Time	Corporate Headquarters	540	Product Management	P4Q100082	Product Marketing Administrator
Cupps, Lucy Ann	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100547	Product Representative I
Ford, LaNiya Zakeyia	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100044	Product Representative I
Ford, LaRonda Gholston	Regular Part-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q099766	Product Representative II
Crawford, Daniel Ware	Regular Full-Time	Corporate Headquarters	855	Marketing Operations Direct	P4Q100510	Production Assistant
Hart, Andrea Michelle	Regular Full-Time	Corporate Headquarters	855	Marketing Operations Direct	P4Q100089	Production Assistant
Jones, Kezia Elane	Regular Full-Time	Corporate Headquarters	850	Marketing Operations	P4Q099867	Purchasing Agent
Gray, Anna	Regular Full-Time	Corporate Headquarters	850	Marketing Operations	P4Q100480	Purchasing Manager
Craig, Jeremy Dewayne	Regular Full-Time	Corporate Headquarters	416	Quality Assurance - QC Indirect	P4Q099868	Quality Control Inspection Supervisor
Blair, George Albert	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q099947	Quality Control Supervisor / Metrologist
Gray, Richard Ben	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q100498	Quality Engineer
Outlaw, Sonya	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q100472	Quality Engineer
Taylor, Andrew	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q099663	Quality Engineering Manager
Hogan, Thelmica	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100541	Quality Inspector
McCaa, Kimiko	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100576	Quality Inspector
Njoroge, Mike	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100501	Quality Inspector
Swift, Theodore	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100580	Quality Inspector
Amos, Ryan	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100575	Quality Inspector II
Boykin, Jamicha	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100543	Quality Inspector II
Davis, Lakisia	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100377	Quality Inspector II
Hall, Charles	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100511	Quality Inspector II
Bagrowski, Felicitas Francisco	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100030	Quality Inspector II - California
Knudson, Rosario C	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100324	Quality Inspector II - California
Burgin, Jessica Sanquetta	Regular Full-Time	Corporate Headquarters	415	Quality Assurance Direct	P4Q100307	Quality Inspector III
Wiley, Stephen Niles	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q100285	Quality Program Maneger
Patton, Derryck	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q100584	Quality Specialist
Simmons, Brittney Nations	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q100421	Quality Specialist
Roane, Terry J	Regular Full-Time	Corporate Headquarters	715	Manufacturing Direct	P4Q100370	Quality Specialist (P1 East)
Strong, Norma	Regular Part-Time	Corporate Headquarters	120	Human Resources	P4Q099732	Receptionist
Casey, Karly Nicole	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100165	Regulatory Affairs Associate II
Harris, James Holden	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100402	Regulatory Affairs Associate II
Rosa, Iza Maria	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100474	Regulatory Affairs Associate III
Smith, Anissa	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q099811	Regulatory Affairs Complaints Maneger
Fickling, Barbara Georganne	Temporary Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100470	Regulatory Affairs Co-op

BioHorizons Implant Systems Inc. - List of Active Employees
(7/21/2023)

Hombuckle, William R	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q100267	Regulatory Affairs Manager
Hyde, Joshalyn Nicole	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q100341	Research and Development Administrative Coord
Atkinson, Heather Thorn	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q100548	Research Engineer
Cotton, Julie Standfield	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100335	Returns and Complaints Representative
Futrell, Larry	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100496	Returns and Complaints Representative
Harris, Natorya	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100570	Returns and Complaints Representative
Moore, Annie Bell Patricia A	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q010080	Returns and Complaints Representative
Carroll, Susan Cook	Regular Full-Time	Corporate Headquarters	610	Domestic Sales	P4Q100118	Sales Support Specialist
Dutil, Kimiko	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q099912	Senior Accountant I
Portis, Nancy Ann Rembert	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q099536	Senior Accountant I
Byzek, Cynthia Ketchersid	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q099765	Senior Accountant III, Corporate Accouting
Watson, Loralyn Wanda	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q100161	Senior ASP.NET Programmer
Taylor, Jasmin	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q099578	Senior Complaint Specialist
Bell, John C	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100225	Senior Cost Accountant
Bennett, Heather	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q099685	Senior Director Corporate Accounting
Chapman, Michael	Regular Full-Time	Corporate Headquarters	520	Creative Services	P4Q099485	Senior Director of Global Creative Services
Mapstone, Michael	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q099903	Senior Director of Sales
Bonanni, Justin J	Regular Full-Time	Central South	610	Domestic Sales	P4Q100096	Senior Director of Sales
Brogan, Timothy Michael	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q100242	Senior Director of Sales
Shoultz, Lana	Regular Full-Time	Corporate Headquarters	510	Product Marketing	P4Q099677	Senior Director, Practice Development
Goff, Matthew L	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q099889	Senior Director, Strategic Accounts
Grant, Rodney	Regular Full-Time	Corporate Headquarters	810	Global Distribution	P4Q099787	Senior Distribution Associate
Johnson II, Joey J	Regular Full-Time	Corporate Headquarters	810	Global Distribution	P4Q100236	Senior Distribution Associate
Morgan, Jerrod	Regular Full-Time	Corporate Headquarters	810	Global Distribution	P4Q100083	Senior Distribution Associate
Wilson, Tina	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q099565	Senior Document Control Specialist
Cooper, Martin Darek	Regular Full-Time	Corporate Headquarters	100	Administration	P4Q100086	Senior Executive Administrator
Li, Weiwei	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100551	Senior Financial Analyst
Bolton, Shawna	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100488	Senior Global Accounts Payable Specialist
DonJuan, Meribel Moreno	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100167	Senior Global Accounts Payable Specialist
Johnson, Amy	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100485	Senior Global Accounts Receivable Specialist
Caponetto, Catherine	Regular Full-Time	Corporate Headquarters	520	Creative Services	P4Q099482	Senior Graphics Designer
Richardson, David Gray	Regular Full-Time	Corporate Headquarters	520	Creative Services	P4Q099793	Senior Graphics Designer
Bowlin, Maria A	Regular Full-Time	Corporate Headquarters	650	International Sales	P4Q099960	Senior International Business Account Manager
Hansen, Lauren Michele	Regular Full-Time	Corporate Headquarters	650	International Sales	P4Q100485	Senior International Business Account Manager
Hale, Timothy Michael	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q100011	Senior IT Network Technician
Ross, Lee	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q099720	Senior Manager, Customer Care Group
Silvey, Joseph Paul	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100139	Senior Manager, Financial Planning & Analysis
Rait, John Stephen	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100394	Senior Manager, Financial Systems
Han, Bo Myong	Regular Full-Time	Corporate Headquarters	655	Marketing Operations Direct	P4Q100178	Senior Production Associate
Mincey, Shirley Ann	Regular Full-Time	Corporate Headquarters	655	Marketing Operations Direct	P4Q100320	Senior Production Associate
Ritch-Nolend, Loneta Ball	Regular Full-Time	Corporate Headquarters	850	Marketing Operations	P4Q099764	Senior Purchasing Specialist
Simmons, Shannon	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q099561	Senior Quality Engineer - Software
Sadler, Brittney Gwen	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100226	Senior Receivable Specialist - Strategic Acco
Meadows, Glenn Forman	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100081	Senior Returns and Complaints Rep
Smith, Patricia Jackson	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q099900	Senior Returns and Complaints Rep
Young, Justin Ross	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q100018	Senior Systems Administrator
Brock, Kristy D	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100114	Senior Territory Manager
Jacoby, Christopher John	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q099980	Senior Territory Manager
Jeffcoat, Jeffrey Sean	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100089	Senior Territory Manager
Maguire, Jonathan Richard	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100122	Senior Territory Manager
Lyons, Sarah Elizabeth	Regular Full-Time	Central Region	610	Domestic Sales	P4Q100159	Senior Territory Manager
Isaacson, Brandon Christopher	Regular Full-Time	Central South	610	Domestic Sales	P4Q100104	Senior Territory Manager
Mena, April Diana	Regular Full-Time	Central South	610	Domestic Sales	P4Q100143	Senior Territory Manager
Highsmith, Eric J	Regular Full-Time	Florida Region	610	Domestic Sales	P4Q100249	Senior Territory Manager
Sizemore, Lindsey Steel	Regular Full-Time	Florida Region	610	Domestic Sales	P4Q100337	Senior Territory Manager
de la Torre, Ethan	Regular Full-Time	Florida Region	610	Domestic Sales	P4Q100129	Senior Territory Manager
Wyland, Daniel James	Regular Full-Time	Gulf South Region	610	Domestic Sales	P4Q100153	Senior Territory Manager
Schmitt, Tim Alan	Regular Full-Time	Midwest Region	610	Domestic Sales	P4Q100164	Senior Territory Manager
Liotta, Joseph	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q099630	Senior Territory Manager
O'Malley, Paul	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q099782	Senior Territory Manager
Staples, Jeffrey Charles	Regular Full-Time	Pacific Northwest	610	Domestic Sales	P4Q100179	Senior Territory Manager
Krogh, Justin M	Regular Full-Time	Southwest	610	Domestic Sales	P4Q100015	Senior Territory Manager

BioHorizons Implant Systems Inc. - List of Active Employees
(7/21/2023)

Le, Dai Loan Pham	Regular Full-Time	Southwest	610	Domestic Sales	P4Q099971	Senior Territory Manager
Cole, James W	Regular Full-Time	Corporate Headquarters	520	Creative Services	P4Q099487	Senior Web Designer
Bolton, Celeste N	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q100248	Software Quality Assurance Manager
Shelton, Brandon	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q100497	Software Quality Engineer
Njoroge, Sylvia Mweru	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q100175	Software Tester
Gandy, Derek	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q099560	Sr Cust Advocate and Tech Product Expert
Jeffries, Tamra	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q099679	Sr Cust Advocate and Tech Product Expert
DeCola, Morgan Haley	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q100296	Sr Cust Advocate and Tech Product Expert, Tra
Elliott, Summer Dawn	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q099887	Sr Cust Advocate and Tech Product Expert, Tra
Vargas, Maria Veronica	Regular Full-Time	Corporate Headquarters	550	International Marketing & Education	P4Q100438	Sr Director of International Marketing & Educ
Bellanca, John Joseph	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q099944	Sr. Director, Product & Technology Developmen
Eades, Elizabeth McGuire	Regular Full-Time	Corporate Headquarters	120	Human Resources	P4Q100291	Sr. HR Generalist & Benefit Program Manager
Martin, Bruna	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100410	Staff Accountant I
Freeman, Michael Tucker	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100379	Staff Accountant I - Payroll
Smith, KeLisha Lashonda	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100317	Staff Accountant I - Risk
Hatcher, Meghan	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100525	Staff Accountant I - Treasury
Ray, Nicole	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100574	Staff Accountant II
Riojas, Carlos	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100235	Strategic Account Support Specialist
Coleman, William Blake	Regular Full-Time	Corporate Headquarters	601	DSO	P4Q100055	Strategic Accounts Analyst
Thornton, Barry	Regular Full-Time	Corporate Headquarters	420	Regulatory Affairs	P4Q099545	SVP, Quality Assurance & Regulatory Affairs
Russell, Brandon Scott	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q100400	Systems Administrator
Davis, Jonathan Mark	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100351	Territory Manager
Euker, Mark A	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100166	Territory Manager
Lamont, Joseph P	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100247	Territory Manager
Macalino, John	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100475	Territory Manager
Manganaro, Cara J	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100115	Territory Manager
McNeely, Kilpatrick M	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100183	Territory Manager
Rees, Aubrey Smith	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100283	Territory Manager
Sauerberger, Leilani A.	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100068	Territory Manager
Spurlin, Sara Bopp	Regular Full-Time	Atlantic Region	610	Domestic Sales	P4Q100284	Territory Manager
Bradley, Matthew L	Regular Full-Time	Central Region	610	Domestic Sales	P4Q100552	Territory Manager
Deveney, James R	Regular Full-Time	Central Region	610	Domestic Sales	P4Q100252	Territory Manager
Fisz, Lael	Regular Full-Time	Central Region	610	Domestic Sales	P4Q100546	Territory Manager
Klintworth, Brandon Michael	Regular Full-Time	Central Region	610	Domestic Sales	P4Q100425	Territory Manager
Palagi, David	Regular Full-Time	Central Region	610	Domestic Sales	P4Q100535	Territory Manager
Aduddell, Blake Allen	Regular Full-Time	Central South	610	Domestic Sales	P4Q100275	Territory Manager
Baker, Danielle	Regular Full-Time	Central South	610	Domestic Sales	P4Q100427	Territory Manager
Birch, Larry A	Regular Full-Time	Central South	610	Domestic Sales	P4Q100197	Territory Manager
Krupczak, Ellen Lindsay	Regular Full-Time	Central South	610	Domestic Sales	P4Q100180	Territory Manager
Morah, Chukwunweike Chukwuzita	Regular Full-Time	Central South	610	Domestic Sales	P4Q100274	Territory Manager
Vashaw, Jill Lauren	Regular Full-Time	Central South	610	Domestic Sales	P4Q100218	Territory Manager
Bastoe, Heath	Regular Full-Time	Corporate Headquarters	610	Domestic Sales	P4Q100573	Territory Manager
DeVito, Joseph Anthony	Regular Full-Time	Corporate Headquarters	610	Domestic Sales	P4Q100608	Territory Manager
Llop, Hannah Danielle	Regular Full-Time	Corporate Headquarters	610	Domestic Sales	P4Q100304	Territory Manager
Boucher, Matthew James	Regular Full-Time	Florida Region	610	Domestic Sales	P4Q100227	Territory Manager
Dolphin, Jennifer Jean	Regular Full-Time	Florida Region	610	Domestic Sales	P4Q100228	Territory Manager
Lacey, Robert Kenneth	Regular Full-Time	Florida Region	610	Domestic Sales	P4Q099919	Territory Manager
McCastlain, Michael	Regular Full-Time	Florida Region	610	Domestic Sales	P4Q100461	Territory Manager
Ettus-Johnson, Pamela Ann	Regular Full-Time	Gulf South Region	610	Domestic Sales	P4Q100582	Territory Manager
Fisher, TaBoris L	Regular Full-Time	Gulf South Region	610	Domestic Sales	P4Q100355	Territory Manager
Price, Paul Douglas	Regular Full-Time	Gulf South Region	610	Domestic Sales	P4Q100132	Territory Manager
Rottger, Richard A	Regular Full-Time	Gulf South Region	610	Domestic Sales	P4Q100301	Territory Manager
Dumas, Elizabeth M	Regular Full-Time	Midwest Region	610	Domestic Sales	P4Q100387	Territory Manager
Hall, Bradley Joseph	Regular Full-Time	Midwest Region	610	Domestic Sales	P4Q100192	Territory Manager
Jones, Ryan	Regular Full-Time	Midwest Region	610	Domestic Sales	P4Q100435	Territory Manager
McCauley, Nick	Regular Full-Time	Midwest Region	610	Domestic Sales	P4Q100495	Territory Manager
Montoya, Nash Paul	Regular Full-Time	Midwest Region	610	Domestic Sales	P4Q100231	Territory Manager
Nagel, Timothy Kevin	Regular Full-Time	Midwest Region	610	Domestic Sales	P4Q100184	Territory Manager
Smith, Tyler Ashton	Regular Full-Time	Midwest Region	610	Domestic Sales	P4Q100190	Territory Manager
Biondo, Frank	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q100031	Territory Manager
Downs, James	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q100479	Territory Manager
Kell, Jessica H	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q100381	Territory Manager

BioHorizons Implant Systems Inc. - List of Active Employees
(7/21/2023)

Kotchick, Chloe Rose	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q100444	Territory Manager
Montigelli, Christopher Joseph	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q100349	Territory Manager
Riehl, Lindsey Rebecca	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q100342	Territory Manager
Baker, Wesley Robert	Regular Full-Time	Pacific Northwest	610	Domestic Sales	P4Q100388	Territory Manager
Bianchi, Antonello	Regular Full-Time	Pacific Northwest	610	Domestic Sales	P4Q100583	Territory Manager
Langley, Douglas Glenn	Regular Full-Time	Pacific Northwest	610	Domestic Sales	P4Q100368	Territory Manager
Moberly, Mariana	Regular Full-Time	Pacific Northwest	610	Domestic Sales	P4Q100467	Territory Manager
Nicklos, Zach	Regular Full-Time	Pacific Northwest	610	Domestic Sales	P4Q100456	Territory Manager
Oline, Angela Marie	Regular Full-Time	Pacific Northwest	610	Domestic Sales	P4Q100322	Territory Manager
Asamura, Robby Y.	Regular Full-Time	Southwest	610	Domestic Sales	P4Q100505	Territory Manager
Dabir, Yasamen	Regular Full-Time	Southwest	610	Domestic Sales	P4Q100196	Territory Manager
Donat, Tyler C	Regular Full-Time	Southwest	610	Domestic Sales	P4Q100523	Territory Manager
Milla, Eric Donald	Regular Full-Time	Southwest	610	Domestic Sales	P4Q100321	Territory Manager
Raponi, Richard Lee	Regular Full-Time	Southwest	610	Domestic Sales	P4Q100124	Territory Manager
Schmidt, Sarah E	Regular Full-Time	Southwest	610	Domestic Sales	P4Q100084	Territory Manager
Szymonik, David Justin	Regular Full-Time	Southwest	610	Domestic Sales	P4Q100387	Territory Manager
Williams, Nathan	Regular Full-Time	Southwest	610	Domestic Sales	P4Q100518	Territory Manager
Murad, Mohammed	Temporary Part-Time	Northeast Region	610	Domestic Sales	P4Q100146	Territory Manager
Slough, Lanna	Regular Full-Time	Central South	610	Domestic Sales	P4Q100163	Territory Manager
Goodhue, Nathan O.	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q100073	Territory Manager - Massachusetts
Levin, Joshua G	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q100309	Territory Manager - Massachusetts
Soucy, David Allan	Regular Full-Time	Northeast Region	610	Domestic Sales	P4Q099932	Territory Manager - Vermont
Hand, Mark	Regular Full-Time	Corporate Headquarters	530	Communication & Education	P4Q099501	Tradeshows and Event Materials Manager
Lucas, Ashley	Regular Full-Time	Corporate Headquarters	110	Accounting	P4Q100156	Treasury Manager
Molz, Fred J.	Regular Full-Time	Corporate Headquarters	210	Research and Development	P4Q099525	Vice President, Research & Development
Jaramillo, Juan	Regular Full-Time	Corporate Headquarters	100	Administration	P4Q099511	Vice President, Global Business Support
Jenkins Jr, Elbert L	Regular Full-Time	Corporate Headquarters	150	Information Technology	P4Q099969	Vice President, Information Technology
Peters, Boyd	Regular Full-Time	Corporate Headquarters	510	Product Marketing	P4Q099534	Vice President, Marketing and Education
Rosene, William	Regular Full-Time	Corporate Headquarters	850	Marketing Operations	P4Q099537	Vice President, Operations
Walters, Michael	Regular Full-Time	Corporate Headquarters	410	Quality Assurance	P4Q099551	Vice President, Quality Assurance
Baroody, Andrew	Regular Full-Time	Corporate Headquarters	680	Customer Care	P4Q099473	Vice President, Sales Operations
Nau, James	Regular Full-Time	Corporate Headquarters	601	DSQ	P4Q100521	Vice President, Strategic Markets

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: BioLineRx USA, Inc.

Physical Address: 77 Fourth Ave., Suite 330

City: Waltham State: MA Zip: 02451

Mailing Address (if different from physical address): Same as physical address above.

City: _____ State: _____ Zip: _____

Telephone: 617-859-6409 Website: Biolinerx.com

Name of Designated Representative (DR): Holly May

Licensing Company Email: info@BioLineRx.com DR Email: HollyM@biolinerx.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer (Virtual)
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Specialty Distributors		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - Start up location.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): BioLineRx Ltd.

Corporation/Organization Name: BioLineRx USA, Inc.

Mailing Address: 77 Fourth Ave., Suite 330

City: Waltham State: MA Zip: 02451

Telephone: 617-859-6409 Email: info@BioLineRx.com

Contact Person Name: Holly May

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
N/A 1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment B		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment C		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See Attachment D	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment E		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - See Attachment C		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment C	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment F	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
N/A - See Attachment A • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

BioLineRx USA, Inc.
Facility Name

Holly May
Print Name of Authorized Person Submitting Application

Holly May
Original signature of Authorized Person (copies or stamps not accepted)

03/15/2023
Date

Board Use Only	Date Received: 7/10/23	Amount: 1000 - CK - 701 ✓ 7/12/23

Attachment C

Personnel Information

BioLineRx USA, Inc.

BioLineRx USA, Inc. is wholly-owned by its parent company, BioLineRx Ltd.

Corporate Officer and Designated Representative:

Holly May
US President

Enclosed please find a list of all site employees.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BIOLINERX USA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-EIGHTH DAY OF NOVEMBER, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4484841 8300

SR# 20224114900

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204948414

Date: 11-28-22

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0001191	11/21/2022	11/21/2023	Virtual Drug Manufacturers

ISSUED TO

BIOLINERX USA, INC
77 FOURTH AVE
SUITE 330
WALTHAM, MA 02451
ATTN: HOLLY MAY US PRESIDENT

Margit Moore

NEW

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0001191	11/21/2022	11/21/2023	Virtual Drug Manufacturers

ISSUED TO

BIOLINERX USA, INC
77 FOURTH AVE
SUITE 330
WALTHAM, MA 02451
ATTN: HOLLY MAY US PRESIDENT

Margit Moore

NEW

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0001191	11/21/2022	11/21/2023	Virtual Drug Manufacturers

ISSUED TO BIOLINERX USA, INC
77 FOURTH AVE
SUITE 330
WALTHAM, MA 02451
ATTN: HOLLY MAY US PRESIDENT

Margit Moore

NEW

Lam, Maggie P.

From: edrls@fda.hhs.gov
Sent: Monday, May 16, 2022 8:37 AM
To: Phil Serlin
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 16-MAY-2022
Labeler DUNS: 118674652
Labeler Name: BioLineRx USA, Inc.
Labeler Code Assigned: 82737

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 1104951

Application/License No. _____

BioLineRx USA, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 77 Fourth Ave, Waltham, MA 02451 (Address of Applicant/Principal), as PRINCIPAL, and The Hanover Insurance Company (Surety Company), a corporation organized under the laws of the state of New Hampshire (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 440 LINCOLN STREET, WORCESTER, MA 01653 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 26, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of April, 2023.

APPLICANT/PRINCIPAL

Holly W May
Authorized Representative

SURETY COMPANY
The Hanover Insurance Company

Surety Company's Representative

Steve Shike, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Cynthia D. Sasso
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
August 19, 2027

Witness

SIGNED and SEALED in the presence of:

Mary Chase
Witness

Sara Torstrom
Witness

Countersigned by:

N/A
Nevada Resident Agent

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

POWER OF ATTORNEY

THIS Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

KNOW ALL PERSONS BY THESE PRESENTS:

That THE HANOVER INSURANCE COMPANY and MASSACHUSETTS BAY INSURANCE COMPANY, both being corporations organized and existing under the laws of the State of New Hampshire, and CITIZENS INSURANCE COMPANY OF AMERICA, a corporation organized and existing under the laws of the State of Michigan, (hereinafter individually and collectively the "Company") does hereby constitute and appoint,

Corban Maxwell Enns, Beulah Marie Hadley-Voth, Steve Shike and/or Megan L. Burns

Of **Surety Solutions, A Gallagher Company of Salem, OR** each individually, if there be more than one named, as its true and lawful attorney(s)-in-fact to sign, execute, seal, acknowledge and deliver for, and on its behalf, and as its act and deed any place within the United States, any and all surety bonds, recognizances, undertakings, or other surety obligations. The execution of such surety bonds, recognizances, undertakings or surety obligations, in pursuance of these presents, shall be as binding upon the Company as if they had been duly signed by the president and attested by the secretary of the Company, in their own proper persons. Provided however, that this power of attorney limits the acts of those named herein; and they have no authority to bind the Company except in the manner stated and to the extent of any limitation stated below:

Any such obligations in the United States, not to exceed Fifteen Million and No/100 ($15,000,000) in any single instance

That this power is made and executed pursuant to the authority of the following Resolutions passed by the Board of Directors of said Company, and said Resolutions remain in full force and effect:

RESOLVED: That the President or any Vice President, in conjunction with any Vice President, be and they hereby are authorized and empowered to appoint Attorneys-in-fact of the Company, in its name and as it acts, to execute and acknowledge for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, waivers of citation and all other writings obligatory in the nature thereof, with power to attach thereto the seal of the Company. Any such writings so executed by such Attorneys-in-fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company in their own proper persons.

RESOLVED: That any and all Powers of Attorney and Certified Copies of such Powers of Attorney and certification in respect thereto, granted and executed by the President or Vice President in conjunction with any Vice President of the Company, shall be binding on the Company to the same extent as if all signatures therein were manually affixed, even though one or more of any such signatures thereon may be facsimile. (Adopted October 7, 1981 – The Hanover Insurance Company; Adopted April 14, 1982 – Massachusetts Bay Insurance Company; Adopted September 7, 2001 – Citizens Insurance Company of America)

IN WITNESS WHEREOF, THE HANOVER INSURANCE COMPANY, MASSACHUSETTS BAY INSURANCE COMPANY and CITIZENS INSURANCE COMPANY OF AMERICA have caused these presents to be sealed with their respective corporate seals, duly attested by two Vice Presidents, this 31st day of **January, 2022**.

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

John C. Roche, EVP and President

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

James H. Kawiecki, Vice President

THE COMMONWEALTH OF MASSACHUSETTS)
COUNTY OF WORCESTER) ss.

On this 31st day of **January 2022** before me came the above named Vice Presidents of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, to me personally known to be the individuals and officers described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, respectively, and that the said corporate seals and their signatures as officers were duly affixed and subscribed to said instrument by the authority and direction of said Corporations.

DIANE J. MARINO
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
March 4, 2022

Diane J. Marino, Notary Public
My Commission Expires March 4, 2022

I, the undersigned Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, hereby certify that the above and foregoing is a full, true and correct copy of the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Powers of Attorney are still in force and effect.

GIVEN under my hand and the seals of said Companies, at Worcester, Massachusetts, this 26th day of April, 2023

CERTIFIED COPY

Theodore G. Martinez, Vice President

SURETY SOLUTIONS
A Gallagher Company

Invoice # 98904	Page 1 of 1
ACCOUNT NUMBER	DATE
BIOLUSA-02	04/26/2023
BALANCE DUE ON	TOTAL AMOUNT DUE
Upon Receipt	$500.00

Surety Solutions, a Gallagher Company
4285 Commercial St. SE Suite 110
Salem, OR 97302

BioLineRx USA, Inc.
77 Fourth Ave
Waltham, MA 02451

Questions: billing@suretysolutions.com
Pay online at http://www.suretysolutions.com/payment

Description	Credit	Amount Due
New Business - Bond#: 1104951 Term: 4/26/2023 - 4/26/2024 Eff Date: 4/26/2023 $100,000.00 - Nevada Pharmaceutical Wholesaler Bond Principal: BioLineRx USA, Inc.		$500.00

Please visit http://www.suretysolutions.com/payment to remit payment via ACH or Credit Card online using your Account Number BIOLUSA-02 and your Zip Code 02451 for the balance due.

Please Note: All premium, commission, and/or fees are considered fully earned upon issuance of a bond even if the bond is canceled mid-term.

Total
$500.00

Thank You

To pay by mail, please make your check payable to "Surety Solutions" and send your checks to the address below with a copy of the Invoice. Please note your cleared check will be your receipt if mailing payment.

Surety Solutions, a Gallagher Company
4285 Commercial St. SE Suite 110
Salem, OR 97302

SURETY SOLUTIONS
A Gallagher Company

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: BioLineRx USA, Inc.

Pharmacy/Wholesaler License # (if applicable): Pending

Physical Address: 77 Fourth Ave., Suite 330

City: Waltham State: MA Zip: 02451

Mailing Address (if different from physical address): Same as physical address above.

City: State: Zip:

Telephone: 617-859-6409 Website: Biolinerx.com

Licensing Company Email: info@BioLineRx.com

Section 2: Personal Information

First: Holly Middle: Last: May

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: Sex: ☐ M ☒ F ☐ X

Mailing Address: 77 Fourth Ave., Suite 330

City: Waltham State: MA Zip: 02451

Telephone: [redacted] Email: HollyM@biolinerx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

School Name		From - To (MM/YY – MM/YY)	
Miami University			
Address	City	State	Zip
501 East High Strett	Oxford	OH	45056
Diploma/Degree obtained, if any			
BA, Zoology			
School Name		From - To (MM/YY – MM/YY)	
The University of Akron			
Address	City	State	Zip
302 Buchtel Common	Akron	OH	44325
Diploma/Degree obtained, if any			
MBA, Marketing			
School Name		From - To (MM/YY – MM/YY)	
Boardman High School			
Address	City	State	Zip
7777 Glenwood Ave.	Youngstown	OH	44512
Diploma/Degree obtained, if any			
HS Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]Blackberry Hill Road	Wrentham	MA	02093
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

[redacted]

Business Name			From - To (MM/YY – MM/YY)
BioLineRx USA, Inc.			06/22 - present
Business Address	**City**	**State**	**Zip**
77 Fourth Ave., Suite 330	Waltham	MA	02451
Phone	**Title**		**Number of Employed Hours**
617-859-6409	US President		40 hours/week

Description of Duties
President of the US company. Previous Chief Commercial Officer.

Business Name			From - To (MM/YY – MM/YY)
AVROBIO			10/19 - 06/22
Business Address	**City**	**State**	**Zip**
100 Technology Square, 6th Floor	Cambridge	MA	02139
Phone	**Title**		**Number of Employed Hours**
617-914-8420	Chief Commercial Officer		40 hours/week

Description of Duties
Responsible for building the global commercial organization and over-arching commercial capabilities. Key member of the executive team, driving the development and execution of commercial strategy. Leading the pre-market activities for AVROBIO's product pipeline and working in concert with internal and external stake holders to provide input on all product development activities.

Business Name			From - To (MM/YY – MM/YY)
Sobi - North America			01/18 - 08/19
Business Address	**City**	**State**	**Zip**
77 4th Avenue, 3rd Floor	Waltham	MA	02451
Phone	**Title**		**Number of Employed Hours**
781-786-7364	Head Commercial, VP Marketing & Sales		40 hours/week

Description of Duties
Leadership and oversight for Marketing, Sales, Business Analytics, Commercial Operations and Training for Sobi US Rare Disease brands. Responsible for all aspects of Commercial strategy, operations, and performance.

/A

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Holly May

Original Signature (electronic, copies or stamps not accepted)

03/15/2023

Date

I, Holly May, **certify that as the designated representative for**

BioLineRx USA, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HM I am at least 21 years of age;
3. HM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Holly May

Print Name (First, Last)

Holly May

Original Signature (electronic, copies or stamps not accepted)

June 14, 2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Holly May

Print Name (First, Last)

Holly May

Original Signature (electronic, copies or stamps not accepted)

March 15, 2023

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Middlesex

I, Holly May, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Holly May

Original Signature

March 15, 2023

Date

Subscribed and Sworn to before me this 15 day of March 2023

Cynthia D Sasso

Notary Public Signature

Cynthia D. Sasso
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
August 19, 2027

(Seal)

Henry, Heather M.

From: Amy Plourde <amyp@biolinerx.com>
Sent: Thursday, April 13, 2023 4:44 PM
To: Henry, Heather M.
Subject: Employee info

EXTERNAL MESSAGE

There are 7 HQ employees.

Adam	Janoff
Cynthia	Sasso
Gregory	Bush
Holly	May
John	Lacey
Joshua	Rodriguez
Kwame	Osei-Boateng

Amy Plourde
Associate Director, Distribution

BIOLINERX
77 Fourth Avenue, Suite 330
Waltham, MA 02451
USA

Mobile: 1-610-256-7206
Email: amyp@biolinerx.com

4L

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Carl Zeiss Meditec, Inc.

Physical Address: 5300 Central Parkway

City: Dublin State: CA Zip: 94568

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 408-239-7105 Website: www.zeiss.com/med

Name of Designated Representative (DR): Marifi Lim

Licensing Company Email: Marifi.Lim@zeiss.com DR Email: Marifi.Lim@zeiss.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/14/23		NV	Reno	Washoe

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
23-039-O	Nevada State Board of Pharmacy

Reason/Charge
Unlicensed furnishing of prescription medical devices

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Carl Zeiss Meditec USA, Inc.	N/A

Name of Business/Industry/Entity
Carl Zeiss Meditec USA, Inc.

Provide explanation below:

Carl Zeiss Meditec, Inc., through its sales and service organization Carl Zeiss Meditec USA, Inc., recently received a Cease-and-Desist and Citation-and-Fine Order (attached) from the Nevada State Board of Pharmacy dated August 14, 2023, for not holding a license under NRS 639.233. Upon receipt, we contacted the Board's Chief Operating Officer to indicate our compliance with the order, and we are submitting this application in accordance with the Board's guidance.



Original Signature (electronic, copies or stamps not accepted)

8/28/23

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Flextronics Manufacturing
Address: 1 Kallang Place City: Singapore State: SG Zip: 339211

Name: 20/20 Medical Systems
Address: 55 Parkview Ct. City: Crystal Lake State: IL Zip: 60012

Name: MPE Inc.
Address: 10597 W Glenbrook Ct. City: Milwaukee State: WI Zip: 53224

Name: James Allyn Printing
Address: 6575 Trinity Ct. Ste. B. City: Dublin State: CA Zip: 94568

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NY
Parent Company (if any): Carl Zeiss Meditec, AG
Corporation/Organization Name: Carl Zeiss Meditec, Inc.
Mailing Address: 5300 Central Parkway
City: Dublin State: CA Zip: 94568
Telephone: +19255574110 Email: Anuj.Kalra@Zeiss.com
Contact Person Name: Anuj Kalra

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Carl Zeiss Meditec, Inc.

Facility Name

Marifi Lim

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8/28/23

Date

Board Use Only	Date Received: 8/29/23	Amount: 1000-CK-356752

Mark I. Sedar

From: Swift, Paul <paul.swift@zeiss.com>
Sent: Tuesday, September 12, 2023 1:19 PM
To: Mark I. Sedar
Cc: Peter Keegan; Kim, Aaron
Subject: Case 23-039-O Carl Zeiss Meditec

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good afternoon Mark,

I'm writing to confirm that today we sent, via FedEx, a cashier's check for $5,000 to settle payment for the administrative fine levied against ZEISS by the Board in the August 14, 2023 Cease and Desist Order.

Additionally, we are submitting this statement in support of a temporary Wholesaler Permit in the state of Nevada to allow for continued operations while the Nevada State Board of Pharmacy reviews its pending nonresident Wholesaler Application.

We manufacture a wide range of medical devices used in the treatment and care for ophthalmology/optometry patients, and our products are also used in surgery for neurology, ENT, spine and dental patients. ZEISS has supplied over 900 advanced surgical and diagnostic instruments to over 350 customers in the State of Nevada. Our array of customers includes VA Medical Centers and other US Armed Services facilities, the US Public Health Service, university health systems, hospitals, clinics and practitioners. Many of these facilities reach vulnerable and underserved patient populations e.g., through the USPHS IHS and pediatric care facilities. Nevada patients have benefitted from the use of ZEISS's medical devices.

On August 16, 2023, Carl Zeiss Meditec, Inc. ceased all shipment of Rx medical devices into Nevada in response to the August 14, 2023 Cease and Desist Order it received from the Nevada Board of Pharmacy. We currently have pending orders from 15 customers across the State, including products such as intraocular lenses, ophthalmic diagnostic devices and neurosurgical microscopes and accessories. Several orders are capital equipment purchases, where the hold on shipping and installing product can push to a new budget cycle, significantly delaying patients' and caregivers' access to necessary medical care. Further, supply chain conditions are such that in many cases a comparative product may not be readily available from one of our competitors.

To ensure the continuity of care of Nevada patients, ZEISS respectfully requests a temporary Wholesaler Permit in the State of Nevada.

We look forward to working with your team and the Board to resolve this matter as expeditiously as possible.

Best,
Paul

Paul Swift, RAC
Head of Regulatory and Clinical Affairs, Americas
ZEISS Medical Technology Segment

Carl Zeiss Meditec USA, Inc.
ZEISS Group
5300 Central Parkway
Dublin, CA 94568, USA

Mobile: +1 817.925.8507
Paul.Swift@zeiss.com

TEMP APPROVED 9/12/23

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
CARL ZEISS MEDITEC INC
5300 Central Parkway
DUBLIN, CA 94568
Registration Number: 2918630
FEI Number*: 2918630
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2023

Owner/Operator:
Carl Zeiss Meditec, Inc.[6]
5300 Central Parkway
Dublin, CA US 94568
Owner/Operator Number: 9053564[7]

Official Correspondent:
Maria Golovina
CARL ZEISS MEDITEC INC
5300 Central Parkway
Dublin, CA 94568
Phone: 925-2161078

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 08/21/2023

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	CARL ZEISS MEDITEC, INC.
Entity No.:	2264919
Registration Date:	10/12/2000
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	NEW YORK
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of August 23, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 139960839

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/30/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Marsh USA Inc.
1717 Arch Street
Philadelphia, PA 19103-2797
Attn: Philadelphia.Certs@marsh.com

CN102209443-Medit-GAWU-22-23

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Allianz Global Risks US Insurance Company	35300
INSURER B : N/A	N/A
INSURER C : Travelers Property Casualty Company of America	25674
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Carl Zeiss Meditec, Inc.
5300 Central Parkway
Dublin, CA 94568

COVERAGES **CERTIFICATE NUMBER:** CLE-006618127-10 **REVISION NUMBER:** 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X **COMMERCIAL GENERAL LIABILITY**			USL00103122	09/30/2022	09/30/2023	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 1,000,000
	OTHER:							$
C	**AUTOMOBILE LIABILITY**			T1NJ-CAP-824K2281-TIL-22	09/30/2022	09/30/2023	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / HIRED AUTOS ONLY / SCHEDULED AUTOS / NON-OWNED AUTOS ONLY						BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
A	X **UMBRELLA LIAB** X OCCUR			USL00103322	09/30/2022	09/30/2023	EACH OCCURRENCE	$ 5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 5,000,000
	DED RETENTION $							$
C	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y/N			UB-3R67483A-51-22-K (AOS)	09/30/2022	09/30/2023	X PER STATUTE OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N / N/A			'(Except: AZ, MA, WI)'			E.L. EACH ACCIDENT	$ 1,000,000
C	**(Mandatory in NH)**			UB-3R685578-51-22-R (AZ, MA, WI)	09/30/2022	09/30/2023	E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
For Evidence Only

CERTIFICATE HOLDER

Carl Zeiss Meditec, Inc.
5300 Central Parkway
Dublin, CA 94568

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

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STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Carl Zeiss Meditec, Inc
5300 Central Parkway
Dublin, CA 94568

LICENSE NUMBER: 114848
EXPIRATION DATE: 9/7/2025

The person named herein is licensed to manufacture devices through the **expiration date of this license. This license is issued in accordance** with the California Health and Safety **Code and is not transferable to any other person or place. The** licensee is required by law to immediately notify **the California Department of Public Health of any change** in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 7/27/2023

OSP 07 102308

Legal Name in General Display Format	Business Title
Aanish Nair	Data Scientist
Aaron H Buch	Sales Executive
Aaron Kho	Concept Engineer, Sr.
Aaron Kim	General Counsel
Abby Berry	Sales Success Specialist
Abdullah Qazi	Manager, Complaint Handling
Abhilash Boggavarapu	Software Engineer, Staff
Adam Coghlan	Third Party Logistics Operations Manager
Adam Craig Altschuler	Head of Finance
Aditya Ramesh Rao	Regulatory Affairs Specialist
Adnan Ziauddin	Digital Controller
Afaaq Zarger	Senior Platform Engineer
Akansha Gupta	Software Engineer, Staff
Akeisha Rogers	Surgical Applications Specialist
Alan Finke	Manager, Software
Alan Robbins	Technical Support Representative III
Alan Suarez	Senior Advanced Manufacturing Engineer
Albert Hong	Product Manager
Aleksander Roman Ustaszewski	Software Engineer, Staff
Alex Grillo	Senior Regional Sales Manager, Lens Extraction
Alexander Barrington Stepans	Technical Support Engineer I
Ali Motafakker Fard	Head of Remote Care, R&D
Ali Neghabat	Mgr, Sustaining Quality Engineering
Ali Salehi	Staff Scientist
Allen Jeffrey Jones	Director, OCT Business Sector
Allen Kim	Technical Support Engineer I
Amanda Carpenter	Manager, Ophthalmic Diagnostics Technology & Solutions
Amarjeet Singh	Manager, Production Value Stream

Amber G Lamendola	Sales Success Specialist
Amy L Anderson	Project Management Coordinator
Andrea Colombo	Group Product Manager
Andrea Michael	Regional Sales Manager, Surgical
Andrew Audsley	Digital Sales Manager
Andrew Chang	Head of Global Sales - Ophthalmic Devices
Andrew Edwin Simpson	Field Service Project Manager
Andrew Kevin Uy	Technical Support Representative I
Andrew P Keenan	Sales Executive
Andrew Potter	Field Support Engineer 2
Andrew S Costantino	Field Implementation Specialist I
Andy Hu	Staff Incoming Inspector
Aneta Rozwadowska	Senior Strategic Sourcing Engineer
Angela Cate	Sales Success Specialist
Angela Renee Elliott	Director, Clinical OPT
Angelina Covita	Clinical Research Scientist
Angelique Nasution	Digital Technical Support Engineer
Anh Tuan Do	Field Support Engineer I
Anibal Mauricio Matasol	Technical Support Engineer III
Anirudh Ashok	Sr Concept Engineer
Anita Huiping Tan	Associate Manufacturing Technician 2
Anita L Burton	VP Human Resources
Ann Carter	Clinical Applications Coordinator
Ann M McCafferty	Head of Marketing
Anna Vazquez	Marketing Manager - Refractive
Anne Santilli	Market Development Manager
Anthony Allan Montello	Field Support Engineer I
Anthony B Sumabat	Sales Success Specialist
Anthony Gregory Sena	Sales Success Specialist
Anthony Hall	Field Support Engineer I
Anthony James Sullivan Jr.	Field Support Engineer II
Anthony Morin	Software Engineer, Staff

Anthony Parker	Senior Clinical Trial Specialist
Antonio Alunni	Staff Quality Assurance Engineer
Anuj Kalra	Head of Finance
Aparna Kamath	Sr Staff Technical Writer
Aravindguhan Loganathan	Sr ERP Business Analyst
Archana Kolli	Software Engineer, Staff
Archie Asilo	Systems Test Engineer, Sr
Arismendi Blanco	Regional Sales Manager, Surgical
Arleen Joana Xayasone	Executive Assistant
Arlena Carrozzi	Sr. Corporate Counsel
Armin Joseph Allam	Manufacturing Engineer
Arun Meth	Global Technical Support II
Ashwini Tamhankar	Program Manager
Asim Ali	Financial Analyst, Sr
Atef K Zaroura	Field Support Engineer III-CA
Athas G Dounelis	Sales Executive
Aubrey Bowman	Supervisor Field Service
Aurelio A Gecale	Digital Support Engineer II
Aurelio Magallon	Field Support Engineer II
Austin Chatterton	Field Support Engineer I
Austin Ghiossi	Marketing Manager – Remote Care
Ayad Zaroura	Field Support Engineer I
Barbara Comito	Technical Writer, Sr
Barbara J Williams	Sales Success Specialist
Barbra Lassalle	Service Operations Administrator
Beemnet A Asfaw	Field Support Engineer III
Ben Kin-Yuen Kwok	Software Engineer, Staff
Benjamin Kohler	Field Support Engineer, Refractive
Benjamin Schumacher	Sr Regional Sales Manager
Benjamin Turley	Sr. Global Marketing Manager
Bernard Lepri	Sr. Advisor, Regulatory & Clinical Affairs

Brad Golden	Sr Regional Sales Manager
Bradley Andrew Martin	Sales Executive
Bradley Bernier	Field Support Engineer I
Bradley Botelho	Practice Development Manager
Brandon Solomon	Marketing Manager
Brent R Dalton	Supervisor, Field Service
Brent Williams	Field Support Engineer II
Brett Morris	Sales Manager, Digital Sales
Brett Pennock	Sr Regional Sales Manager
Brian Kun	Aggregate Spend Analyst
Brian L Close	Director, U.S. Federal Government and Military Sectors
Brian M Kotler	Sales Success Lead
Brian M Rowell	Digital Market Development Manager
Brian Mark Normand	Electronic Design Eng, Sr Staff
Brian Porter	Software Engineer, Support & Integration
Brian Tucker	Regional Sales Manager
Brian Weals	Sr. Regional Sales Manager, Surgical
Bridget Cunningham	Head of Customer Engagement
Bruce D Bailey	Clinical Application Spec-CA
Bruce Johnson	Technical Support Engineer, Sr
Bryan Rogoff	Head of Disease Management
Buck J Cunningham	Software Engineer, Sr Staff
Caleb A Ruckdeschel	Sr Regional Director, Sales
Calee Hartman	Clinical Applications Specialist II
Calvin Birkenmair	Senior Inventory Control Analyst
Calvin Carter	Technical Support Representative III
Cambyse Keshavarz	Sr Regional Director, Sales

Cameron Evans	Regional Sales Associate
Carl Bernard Mallard Jr.	Field Support Engineer I
Carl P Freimanis	Software Config & Release Engineer, Staff
Carlos Davila	Field Support Engineer II
Carlos E Klos	Field Support Engineer II
Carlos Romero	Concept Engineer, Principal
Carol-Anne Poursaied	Senior Practice Development Manager, Refractive
Cecilia Ayson Erspamer	Manager, Planning
Celso Hernandez Jr.	Field Support Engineer I
Chad A Miles	Head of Ophthalmic Diagnostics Sales -US
Chaitali Gawde	Senior Regulatory Affairs Specialist
Chanell Stephanie Watkins	Senior Inside Sales Specialist
Chang K Yeo	Material Handler, Senior
Charles Patrick Brophy Mr.	Systems Design Engineer, Staff
Chendra Sekhar Garikipati	Senior Program Manager
Cherice Bacosa	Service Operations Administrator
Cheryl L Moretti	Executive Assistant
Cheryl Padden	Refractive Account Manager III
Chheang Kev You	Manufacturing Associate I
Chhoeupdarvy Montes	Document Control Specialist
Christian LoBuglio	Sr Regional Sales Manager
Christina Owyang	Head of Finance and Controlling ODX
Christine L Vazquez	Data Analyst, Sr.
Christine Lindsay	Surgical Applications Specialist
Christine Ricamara	Technical Support Representative I
Christinne Haw	Document Control Specialist
Christoph Hoffmann	Global Marketing Manager

Christopher Eugene Barnett	Sales Executive
Christopher Gallegos	Field Support Engineer I
Christopher J Burns	Head of R&D and Functional Testing
Christopher Mintsioulis	Digital Technical Support Engineer I
Christopher OBrien	Senior Regional Sales Manager, Surgical
Christopher Palmer	Dental Sales Rep
Christopher Paul Nuciforo	Director, Strategic Accounts
Christopher R Danko	Regional Director Sales
Christopher Schaefer	Dental Sales Rep
Christopher Scofield	Sales Executive
Cindy Chiu	Sales Effectiveness Trainer
Clayton Kennedy	Technical Support Engineer I
Colin M Campbell	Sales Executive
Collins Opoku-Baah	Staff Scientist
Connie LeAnn McKeehen	Clinical Applications Lead
Connor Jackson	Manufacturing Engineer
Conor Leahy	Principal Scientist
Corinne A Debenedetti	Lead Service Operations Administrator
Cortland Selman	Sr Regional Sales Manager
Cruz Buchanan	Regional Director Sales
Crystal Ceaser	Service Operations Administrator
Cyntelle Renteria	Software QA Engineer 2
Cynthia J Metrose	Head of Strategic Accounts
Daljit Singh	CRC Technician II
Damien Smith	Field Support Engineer I
Dan Corbett	Digital Market Development Manager
Dana Calkins	Refractive Account Manager III
Dane Mitro	Sr. Manager Global KOL Management
Daniel Andrew Attema	Mechanical Engineer, Sr.
Daniel Bagby	Field Support Engineer 1
Daniel Clarke	Sales Executive
Daniel Diep	Field Support Engineer I

Daniel J Ketner	Clinical Applications Specialist II
Daniel La Brada III	Field Support Engineer 2
Daniel Li-Kong Wu	Staff Quality Assurance Engineer
Daniel Mattsson-Boze	System Design Eng, Staff
Daniel R Chavers	Sr. Strategic Accounts Manager
Danielle Ouk	Service Operations Administrator
David B Moss	OS/MS Field Service Specialist
David Best	Head of Product Cyber Security and Privacy
David Christian Richter	Software Engineer
David Dommel	Dir, US Dental Sales
David J Nolan	Head of Device Software
David Peterson	Field Implementation Specialist I
David Richardson	Sales Manager, Refractive Laser, US
David Ross Skalky	Refractive Account Manager, Lead
David Ruckdeschel	Regional Sales Director, Surgical
David Swoik	Sr Regional Sales Manager
David Thomas	Inside Sales Specialist
David Tran	Field Support Engineer II
David Wayne Lebel	Sr Regional Director, Sales
Davina Calvillo	Manager, Service Operations
Dawn M Langefels	Executive Assistant
Dawn Tauber	Enterprise Account Manager
Deanne Giles	Dir, Call Center
Dennis M Ramirez	Senior Enterprise Account Manager - Government Sector
Desiree Estrada	Executive Assistant
Devon Kennedy	Sr. Manager, Refractive OD Co-Management
Dhara Buch	Sr. Regulatory Affairs Specialist
Diana Jasive Cabello Hernandez	Field Support Engineer I

Diane M Del Vigna	Supervisor, Operations Stockroom
Diego E. Ramirez	Senior Advanced Manufacturing Engineer
Dilipkumar Patel	Field Support Engineer II
Donaire Andara	Field Support Engineer I
Donald Michael Nasso	Field Support Engineer III
Donald Mills	Field Support Engineer II
Donald R Renfrow	New Product Introduction Engineer
Donna Downham	Sr. Marketing Communications Specialist
Donna Nobida	Trade Show and Events Manager
Donovan Plummer	Sr Regional Sales Manager
Douglas Arthur Linn	Field Support Engineer III
Douglas Barden	Sr Regional Sales Manager
Douglas Jacobus Nuijten	Clinical Applications Specialist II
Douglas Runt	Senior Product Manager
Dr. Benjamin Kaminski	Head of ODX Research & Development
Dr. Euan Stuart Thomson	Head of Strategic Business Unit OPT / President of Ophthalmic Devices
Dr. Franz Patrik Grimmeisen	Controller CoCE Surgical Instruments
Dr. Hugang Ren	Manager, Software
Dr. Jochen Straub	Head of Advanced Technology & Concepts
Dr. Monika Patel	Systems Engineering Manager, R&D
Dr. Rick Alan Williams	System Dsgn Eng Sr Staff
Dr. Zahra Nafar	Staff Concept Engineer
Eddie Haythorn	Field Support Engineer II
Edgar Allan Escueta Daluz	CRC Technician, Sr
Edmund Balugo	Technical Support Representative I
Edward Hartford	SW Engineer, Sr Staff
Edward L Mcdaniel	CRC Planner

Elesh Modi	National Surgical Consultant
Elizabeth Peartree	Head of Marketing Communications
Ella Rabkina	Software QA Engineer, Sr
Ellen Polley	Sr. Buyer/Planner
Elleonore B Fisher	CRC Technician II
Elliott W Hutton	Head of Sustaining Engineering (Director level)
Elsa A Eadus	CRC Technician II
Emil Karakolev	Senior Global Marketing Communications Specialist
Emmanuel Kazanis	Senior Regional Sales Manager, Surgical
Enrique Moreno	QA Specialist, Sr
Eric Alvarez	OS/MS Field Service Specialist
Eric R Larson	Product Manager Sr
Eric Schorsch	Head of Clinical Affairs
Erica Bigham	Senior Strategic Accounts Manager
Erich Schwinn	Sales Executive
Erick Carrasquillo	Field Support Engineer II
Erick John E. Cuenco	Technical Support Engineer II
Erick Kwan	Regional Sales Manager
Erik Kramme	Regional Director Sales
Erik Ramirez	Software Engineer, Sr
Erwin T Antonio	Sr. Customer Repair Center Technician
Eshwara Nandhini Thirumoorthy	Software QA Engineer, Staff
Esperanza Villalta	Sales Success Supervisor
Evan Bertucci	Sr Regional Sales Manager
Fabian Gross	Sr. Financial Analyst-Project Manager
Fabio Feroldi	Sr. Scientist
Fermin Sierra	Field Support Engineer II
Fernando Mendez	Service Operations Administrator
Fernando Morales	Clinical Application Specialist I

Francis Edward Hackett	Sr Regional Director, Sales
Francis Gatdula	Technical Support Representative III
Francis Sullivan	Sr Regional Sales Manager
Francisco Javier Palma Medina	Field Support Engineer II
Francisco Sousa	CAD Specialist
Frank Kruki	Sr. Surgical Application Specialist
Frank Mauro	Field Support Engineer II
Frank Mock	Software Engineer 2
Frank Smith	Head of OPT Global Communications
Frank Watley	Field Support Engineer 2
Franklin Hipona	Sr. Quality Engineer
Frederick Ouding	Concept Engineer
Gabriela Denise Leal Fuentes	Field Support Engineer III
Gabriela Sonsino	Sr. Manager Marketing Communications
Gary Bakker	Technical Support Engineer II
Gary C Lee	Principal Scientist
Gary Jefferson	Technical Support Engineer, Sr
Gary Lyerla	Field Support Engineer III-CA
Gary S Michalec	Senior Clinical Relations Manager
George Field	Field Support Engineer I
George Krzeczkowski	Field Support Engineer I
Gerald Corgill	Regional Sales Manager, Surgical
Gerardo Keys	Technical Support Engineer I
Gerhard Arthur Voegele	Field Support Engineer III
Gina M Giuliano	Customer Care Project Manager
Grace Tsai	Senior Clinical Research Scientist
Graham Michael Hindley	Head of ODX, CoCe Operations
Grant Solofsky	Field Support Engineer 2
Graydon Hodges	Regional Sales Associate

Gregory Baker	Field Support Engineer 2
Gregory Duane Glassman	National Surgical Consultant, Lens Extraction
Gregory L Jones	Field Support Engineer II
Gregory L Pope	Sr Regional Sales Manager
Guandi Lamar George	Field Support Engineer I
Guch Ear Ly	QA Inspector
Guido Marcel Hattendorf	Sr US KOL Management and Clinical Development Manager
Gwen Musial	Senior Scientist
Haley Twitchell	Sales Success Specialist
Hanayo Spitz	Sr. ODX Professional Education Manager
Hanifah Solachuddin	Software Engineer, Sr
Harold Perez-Miranda	Sr. Surgical Application Specialist
Harrison Holtzinger	Manufacturing Engineer, Staff
Harry Colas	Head of ODx Data Management and HDP Applications
Harry Ree	Technical Support Engineer, Sr
Harsimran Singh	Manufacturing Engineer, Sr
Hartmut Koenig	Head of Competence Center Surgical Instruments
Harveyzon Delapena	Regional Sales Manager
Henry Heering	Sr. Manager, Post-Approval Studies
Hetal Patel	Market Research Program Manager
Heyjin C Park	Product Manager
Hinsley Critchlow	Manager, Technical Support
Hoang Nguyen	CAPA and Audit Manager
Homayoun Bagherinia	Principal Scientist, Application Development
Howard Chen	Manager, Service Supply Chain
Hugo Fernandes	Project Manager - Information Systems

Huu D Dao	CRC Technician, Sr
Ian Raden	Senior Product Manager
Idia Huntley	Document Control Spec
Igor Koruga	Head of Strategic Innovations
Indira P Vemala	Director, Tools & Analytics
Irina Reynov	Business Intelligence Analyst
Irina Smith	Supervisor, Software QA
Iryna Zhukava	Practice Development Manager
Itzel Zaldivar Zamora	Global Technical Support II
Ivan Neikov	Manufacturing Test Engineer
Ivan Slavov	Field Support Engineer 1
Izabel George	Sr. Inventory Control Analyst
Jack H Chin	Systems Administrator, Staff
Jacob Samuel Gluck	Field Support Engineer I
Jaejung Chang	SW Engineer, Sr Staff
Jake P Chua	CRC Technician II
James Carpenter	Sr. New Product Introduction Engineer
James Codinha	CRC Technician, Sr
James E Urban	Sales Executive
James I Arnold	Field Service Specialist
James Mays	Field Support Engineer I
James Nicholas Rudick	Field Support Engineer II
James O'Connor	Head of Global KOL's
James O'Hara	Dental Sales Representative
James Price	Americas Surgical & Refractive Professional Education, Sr. Manager
James R Carter	VP Ophthalmic Surgical Sales
James Rice	Senior Regional Sales Manager, Surgical
James Saviola	Sr. Advisor, Regulatory & Clinical Affairs
Jami Dodge	Clinical Care Specialist RT
Jamie Reyes	Service Operations Administrator

Janice Procassini	HR Business Partner, Sr.
Janine McDonald	Marketing Manager, Sr
Janis Guthrie	Senior Technical Writer
Jarrod Ashmore	Field Support Engineer I
Jasmine Sethi	Sr. Market Readiness Program Manager
Jason Carozza	Head of Forum Installation & Training
Jason G Kennedy	Technical Support Engineer, Sr
Jason Hornback	Field Support Engineer 2
Jason Stiles	Regional Director Sales
Jatinder Pal Singh	Technical Support Engineer I
Javaria Rizvi	Project Manager - Operations
Javed Ahmed	Technical Support Engineer II
Javier Sanchez	Manager, Benefits & Leaves
Jeffery David Rospert	Radiotherapy Sales Director, Americas
Jeffery Pratt	Sr. Regional Sales Manager, Surgical
Jeffery Scott May	Field Support Engineer I
Jeffrey Keeling	Senior Regional Sales Manager, Surgical
Jeffrey M Maynard	Supervisor, Field Service
Jeffrey O'Hara	Sr Regional Sales Manager
Jeffrey Rogers	Regional Sales Manager
Jeffrey Stokes II	Supervisor, Field Service
Jenifer Nicole Jackson	Service Operations Administrator
Jennifer Ann Ambra	Marketing Communications Program Manager
Jennifer Hiller	Senior Buyer/Planner
Jennifer Lee Ide	Business Process Analyst
Jennifer Pittman	Head of Americas Professional Education ODX
Jeremy Holland	Refractive Account Manager III
Jeremy Morris	Technical Support Representative III
Jerry Lee Estraca	Field Support Engineer II

Jessica Gurskis	Senior Product Manager
Jessica Leia Whittle	Senior Clinical Trial Specialist
Jessica Millan de Resendiz	Service Operations Administrator
Jessica Serpa	Marketing Communications Specialist- Ophtalmic Diagnostic
Jessica Tsai	Sr. Buyer/Planner
Jessie A Acosta	CRC Technician II
Jesus Rivera-Santos	Field Support Engineer 2
Jim Pariso	Business Process Analyst
Jimmy C Chau	Technical Trainer III
Jimmy V Leyva	Inside Sales Specialist
Joann Gira	Sr. Global HCP Engagement Specialist
Joanne Chen	QA Specialist, Sr
Joe Liang	Electronic Design Eng, Staff
Johannes Schaefer	Head of Manufacturing
John Clark	Field Support Engineer I
John Howard	Senior Regional Sales Manager, Surgical
John Mark Cowan	VP Customer Care
John Matthew Alberini	Sales Executive
John R Moynahan	Field Support Engineer II
John Smoot	Global Technical Support II
John Stephenson	Senior Regional Sales Manager, Surgical
John Stone	Sr. Regional Sales Director, Surgical
John Thayer	Field Support Engineer 3
John Walker	Electronic Design Engineer, Sr Staff
Jonathan A Minard	Product Manager
Jonathan Bumstead	Optics Design Engineer, Staff
Jonathan Eric Fann	CRM Regional Coordinator
Jonathan Garcia	Teamhead Logistics 2
Jonathan Lim	Technical Support Representative I
Jonathan Murillo-Ron	Field Service Engineer II
Jonathan Patton	Sr. Regional Sales Manager, Surgical

Jonathan Thomas	Trade Show & Events Manager
Jonnathan Chang Hyun Kim	SW Engineer, Sr Staff
Jordan Wilson	Senior UX-Human Factor Engineer
Jorge Ozuna Adams	Field Support Engineer I
Joseph B Affel	Field Support Engineer III
Joseph Claytor	Field Support Engineer 1
Joseph Masazi Beaulieu	Technical Trainer II
Joseph T Lake III	HR Manager/Sr. HR Business Partner
Joseph Waddell	Software QA Engineer, Sr
Joshua Duane Dale	Field Support Engineer III
Joshua Joseph Chaney	Sr Regional Sales Manager
Joshua Kreplick	Senior Regional Sales Manager, Surgical
Joshua LeBlanc	Technical Support Engineer I
Josue Gamez	Field Support Engineer 1
Jovita Ann Yim	Calibration Coordinator
Juan Carlos Cattaneo Garcia	Software Engineer
Juan Felix	Field Support Engineer II
Juan P Liu	Manufacturing Associate I
Jule Sims	Technical Support Engineer I
Julia Jacome	Billing Specialist
Julian Bolter	Sr. Concept Engineer
Julian Concepcion Salazar	Software Engineer, Sr
Juliana Barrios	Executive Assistant
Julie Day	Refractive Account Manager II
Julio asdruval Mier	Field Support Engineer I
Justin Gearhart	Field Support Engineer II
Justin Kelley	Sr Regional Sales Manager
Kafui Kpordze	Global Grants Administration Manager
Karla Dement	Manager, Sales Excellence

Kasey Grabiec	Refractive Account Manager
Katharina Barbara Custer Mrs.	Marketing Communications Specialist Sr
Katharina Foote	Scientist, Sr
Katherine Elizabeth Martinez	Service Operations Administrator
Kay DeMonge	Academic & Stategic Accounts Sales Sr Manager, Dental
Keith Lebish	Refractive Field Support Engineer III
Keith Papulski	Technical Support Representative II
Keith Rich	Sales Executive
Kelly McDonough	Sr Regional Sales Manager
Kenneth Fraley	Refractive Account Manager
Kenneth Ko	Senior Inventory Control Analyst
Kenneth Patrick Garrido	Software Applications Operations Manager
Kent S Suzuki	Field Support Engineer III-CA
Kerrie Lindstrom	Sr. Digital Marketing Communications Specialist
Kerry Boykins	Field Support Engineer II
Kevin Batewell	RMA Spares Coordinator/ Administrator
Kevin Borie	Sr Sales Manager, Digital Sales
Kevin Brigham	Field Support Engineer, Refractive
Kevin Flanagan Jr.	Regional Sales Associate
Kevin Joseph Pigford	Supervisor, Field Service
Kevin Meng	Software Engineer, Staff
Kevin Patterson	Sales Manager, Refractive Laser, US
Kevin Robert Langton	Director, Global ODX Professional Education
Kevin Scott	Certification Engineer
Kevin W Steadman	Technical Support Engineer II

Khadijah Rasheen Miller	Senior In-House Repair Coordinator
Khai Bui	Field Support Engineer III
Kimberly Dawn Pelfrey	National Manager, Refractive Account Managers
Kimberly Ong	Clinical Application Spec
Kimberly Pesola	Marketing Manager
Kimela Hilleary Mihara	Research Network Coordinator Sr.
Kripa Santhanakrishnan	Sr. Software Engineer
Kristen Cavazos	Clinical Applications Specialist I
Kristen Hansen Kulovany	Digital Market Development Manager
Kristin Leary	Strategic Sourcing Analyst
Krysten Corey	Service Operations Administrator
Kyle Blank	Field Support Engineer II
Kyle Freeman	Field Support Engineer I
Kyle Hamilton	Field Support Engineer I
Lacretia E. Smith	Data Privacy Manager
Laleh Shikh Gholamhosseinghandehari	Software Engineer, Sr
Laura Brost	Senior Regional Sales Manager, Surgical
Laura Gaughan	Head of Market Development - Remote Care
Laura Schweizer	Refractive Account Manager
Lauren Blazer	Buyer/Planner
Le Du Trinh	Sales Analyst
Leah L Sigg	Sales Success Specialist
Leonard Marquez	Technical Support Representative III
Leonid Gruzman	Software QA Engineer, Staff
Lev Briskin	Service Product Supervisor
LIANG HU	Field Support Engineer I
Lila Han	Contract Manufacturing Production Manager
Lilia Ramos	Sales Success Specialist I

Linda Clarke	Sr. Credit Management Specialist
Linda Faye Shirley	OS/MS Field Service Specialist
Linda Trinidad	Supervisor, Order Administration
Linda Villanueva	Director, Global Post-Approval Studies
Lingxiao Schandel	Staff Regulatory Affairs Specialist
Lisa Gail Romo	Head Of Microsurgery US, Head Of Sales Neuro/ENT, Americas
Lorena Cerrillo	Sales Success Specialist
Louis McCray	Field Support Engineer 1
Luis Osuna Jr.	Sales Success Specialist
Luisa M Ramirez	Sr. Clinical Research Coordinator
Lukas Rothmann	Concept Engineer
Lung Di	Clinical Research Associate II
Mackenzie Stoney	Professional Education Manager SUR and REF
Madhuchhanda Bhadra	Software Cloud Architect
Mahsa Darvishzadeh Varcheie	Staff Concept Engineer, Remote Care
Maksim Afanasov	Field Support Engineer I
Malissa Towne	Director, Learning MED U.S.
Manjaya Hegde	Head of Quality Management
Manuel Dechitang Solomon Jr	CRC Technician II
Marco Carrillo	National Field Service Manager
Mareike Breitling	Head of Compliance Operations
Maria Eugenia Garcia	Sales Success Specialist
Maria Feth	Clinical Application Spec II
Maria Golovina	Head of Regulatory Affairs - US
Maria Mionchinskaia	Validation Engineer
Maria Seredkina	Marketing Manager
Maria-Luisa Corpuz Martinez	Executive Assistant
Marifi A Lim	Sales Success Supervisor

Marina Broytman	Sales Success Specialist
Marina Pekelis	Senior Program Manager, FoB
Mark Bautista	Clinical Application Specialist I
Mark Casebeer	Manufacturing Engineer, Staff
Mark Kaderli	Sales Manager, Refractive Laser, US
Mark Kuehner	Field Support Engineer I
Mark Nicola	Manager, Service Contract Sales
Mark R Acebedo	Software QA Engineer, Sr
Mark T Berry	Clinical Application Spec III
Mark T Weise	QA Engineer, Staff Sr
Martin Gene Beckman	Refractive Field Support Engineer III
Marty L Rohman	Mgr, Customer Support
Martyn Richard Reyes	Electronic Technician, Sr
Mary Ann Valdez	Customer Order Specialist
Mary Catherine Meadows	Refractive Account Manager
Mary Elizabeth Barber	Sr. Sales Controller
Marysa Elizabeth Loustalot	Staff Regulatory Affairs Specialist
Massimo DeCarli	Field Support Engineer III
Matt Meade	Field Support Engineer I
Matthew Boudreau	Senior Practice Development Manager, Refractive
Matthew Cavanaugh	Regional Sales Associate
Matthew Conahan	Regional Sales Manager, Surgical
Matthew Everett	Chief Scientist
Matthew Jonathan Wess	Digital Market Development Manager
Matthew Kirkpatrick McLaughlin	Sales Executive
Matthew Miller	Sales Executive
Matthew Muller	Sr. Staff Concept Engineer, Remote Care
Matthew Paul	Senior Inside Sales Specialist

Matti Harjama	Sr. Regional Sales Manager, Surgical
Mattie T Thompson	In-House Repair Coordinator
Maureen M Kelleher	Sales Inventory Lead
Maxwell Dawson	Field Support Engineer II
Melissa M Dowell	Head of Tradeshows & Events
Melito C Deguzman	Technical Support Engineer I
Melvin E Edwards	Field Support Engineer, Refractive
Michael A Doyle	Electronic Design Eng, Staff
Michael A Romano	Sales Executive
Michael A Wiebelt	Sr. Sales Effectiveness Trainer
Michael Barbetti	Field Support Engineer II
Michael Benvenuto	Regional Sales Manager
Michael C. Dixon	Supervisor, Field Service
Michael Contreras	Inside Sales Specialist
Michael Cullinane	Head of Commercial Operations
Michael Dominici	Marketing Manager - Advanced Visualization
Michael Guffin	Sr Enterprise Account Manager
Michael Heieck	Field Support Engineer II
Michael J Zoch	Field Support Engineer, Refractive
Michael Jacoub	Digital Technical Support Engineer I
Michael Joseph Probst Jr.	Quality Engineering Technician
Michael Kevin Porcuna	HR Coordinator
Michael Morton	Field Implementation Specialist I
Michael Posada	Sales Inventory Specialist
Michael R Turano	Sr Manager US Digital Systems Sales
Michael Yamzon	Field Implementation Specialist II
Michele Meert	Regional Sales Manager
Michelle A Ambrecht	Senior Staff Regulatory Affairs Specialist, US

Michelle L Meyer	Inventory Demand & Control Manager
Michelle Mazzie	Service Sales Administrator
Michelle Miranda-Albanese	Senior Paralegal
Michelle Secoquian	Project Manager, Documentation Control
Miguel Diaz	Field Support Engineer III
Mina Habib	Field Support Engineer 2
Mingzhong Wei	Software Engineer, Staff
Mirella Rodriguez	Customer Order Specialist
Monica Aguilar	Service Operations Administrator
Monica McGlaston	Sales Success Specialist
Monique Chambers	Service Sales Administrator
Mudzhib Dadgar	Senior Marketing Communications Specialist
Munis Thahir	Systems Design Engineer
Mwafak M Ibrahim	Certification Engineer, Sr.
Nakeya Tranay Pewitt	Clinical Application Specialist II
Nan Li	Accounting Manager
Nancy M Calderon	Customer Order Specialist
Nancy Miller	Production & Inventory Planner
Nancy Pham	Sr Marketing Manager
Nasim S Kamran	Commissions Analyst
Natalie Campos	Service Sales Administrator
Natalie Elliott Hamilton	Clinical Applications Lead
Natasha French	Strategic Account Administrator
Natasha Gawande	Systems Design Engineer 2
Nathan Sichter	Supervisor, Field Service
Nathan Tanabe	Sr. Program Manager
Neil D DSouza	Head of ODx Applications and Software Development

Nelliana Calvert	Digital Support Engineer II
Nelly Covarrubias	Logistics Coordinator
Nelson Dominguez	Field Support Engineer 2
Nelson Elias	Field Support Engineer I
Nelson Tate	Systems Design Engineer, Sr
Ngoc Tran	ERP CRM Service Process Administrator
Nicholas Mascelli	Regional Sales Associate
Nicholas Van Derpool	Technical Support Engineer I
Nichols Nhut Minh Hua	Technical Support Engineer, Sr
Nicole Hoffman	Sr. Labeling Specialist
Nihir Shah	Head of Software Platform
Nilan Lovelace	Sr. UX & Human Factors Engineer
Nimish Tolat	Head of Neuro Marketing
Niranchana Manivannan	Head of Algorithms Development & Clinical Research
Noah Thompson	Software Engineer
Noah Westberry	Technical Support Representative III
Noha I Mahmoud	Field Support Engineer, Refractive
Norman Miranda	Field Support Engineer II
Olga Restrepo	Surgical Applications Specialist
Omar Eldasher	Field Support Engineer, Refractive
Paige Wycoff	Global Post-Approval Studies Manager
Parag Patel	Program Manager
Parker Bellinger	Regional Sales Manager
Parminder kaur	Manufacturing Associate III Lead
Patricia Anne Baker	Commissions Analyst
Patricia Maria Seiden	Head of Product Marketing
Patricia Sha	Head of Clinical Research (Sr Mgr)
Patrick Cavanaugh	Sr Regional Sales Manager

Patrick Devin Embody	Warehouse Lead
Patrick Rivers	Regional Sales Manager, Microsurgical Instruments
Paul Cullenen	National Field Service Manager
Paul Rousseau	Head of Refractive Sales & Marketing
Paul Swift	Head of Regulatory & Clinical Affairs
Pavel Apostolov Iliev	Customer Service Engineer 2
Perfecto C Aquino Jr	CRC Technician, Sr
Perry Himsl	Field Support Engineer, Refractive
Peter Boaz	Product Security Officer
Peter J O'Connor	Field Implementation Specialist III
Peyton Drouhard	UX/Human Factors Engineer, Sr.
Phat Luong	Field Support Engineer, Refractive (CA)
Philip Anthony Barone Jr	Supv, Repair Center Operations
Philip Howard	Dental Sales Rep
Philip Loprinzi	Sr Regional Sales Manager
Philip Makram	Field Support Engineer II
Phuong My To	CRC Technician, Sr
Pranav Malvania	Chief Software Architect
Preethi Nalanagula	Staff SQA Engineer
Preethi Venkatesan	Financial Analyst, Sr
Preetika J Perez	Enterprise Account Manager
Qinqin Zhang	Sr. Application Development Scientist
Quan Gu	Sr Staff Quality Systems Engineer
Quinn Schmidt	Software Engineer
Rachel Echols	Sales Success Specialist
Rachel Harper	Sales Success Specialist
Rachel R Groh	Clinical Application Spec III
Radhika Poduval	Advanced Optics and Photonics Engineer
Ramesh Ramachandran	Software Engineer, Staff
Ramona Lewis	Sales Success Specialist

Ramya Basavaraj	Scrum Master/Agile Coach
Randy Fong	Senior Inside Sales Specialist
Randy Killman	Manager, Document Control
Randy Manna	Manager, Technical Support
Ranie Acebedo	Customer Order Specialist
Ranjit K Mundh	Manufacturing Associate II
Ranjit Singh Dosanjh	Technical Support Engineer I
Rashmi Pandurangi	Senior Program Manager
Rastinder Singh Brar	Associate Manufacturing Technician 2
Raymond San Nicolas	Sr. Quality Engineer
Raymundo Ruiz Rosales	Head of Finance & Controlling
Regina Harris-Nau	HR Business Partner, Sr.
Regina Jones	Surgical Applications Specialist
Reginald Paul	Software Quality Manager
Renae Cazet	Global Communications Manager
Renato N Giron	Technical Support Engineer II
Renee Reid	Head of Intellectual Property and Innovation Development
Richard Backus	Sr Regional Sales Manager
Richard C Ashley	Technical Support Engineer I
Richard David Swilley	UX/Human Factor Engineer, Staff
Richard Fahd Jr.	Senior Regional Sales Manager, Lens Extraction
Richard Gomes	Head of Materials Control and Shipping
Richard Orlowski	Software Engineer, Sr
Richard Overby	Inside Sales Specialist
Richard Pettit	Software Engineer, Staff
Richard Pusateri	Sr Regional Sales Manager

Richard Solis	Technical Support Engineer I
Richard Toth	Supervisor Field Service
Rikka Mejia	Import Export Compliance and Logistics Manager
Rizaldy De Los Santos	Technical Support Engineer I
Robert A Sprowl	Optics Design Eng, Sr Staff
Robert Arguello	Supervisor, Field Service
Robert Bailey	Field Support Engineer I
Robert D Emerson	Clinical Application Spec III-CA
Robert Elias	Field Support Engineer IV
Robert Gibson	Head of Product and Solutions
Robert Smith	Marketing Communications Program Manager
Robert T Moore	Sales Executive
Robert Tourijigian	Senior Regional Sales Manager, Surgical
Robert W Knight	Field Support Engineer IV
Robert Wall	Field Support Engineer I
Robert Zorovic	Senior Buyer/Planner
Roberto Andrade	Material Handler, Senior
Roberto Carlos Menendez	Sr. Hardware Technician
Robin Julene Eckett	Sales Effectiveness Training Coordinator
Robyn Barry	Trade Show Specialist
Roger Allen Carey	CRC Technician, Sr
Ron Santoni	Field Support Engineer II
Ronald Arnold Lawson	Sr Global Tech Support Engineer II
Ronald Terwilleger	Enterprise Account Manager
Ronnie Terrill Harris	Field Support Engineer II
Rosalind Sweet Nichols	Customer Order Specialist
Rosalio Haro	Staff Patent Engineer
Rosalva Everett	Document Control Specialist
Rosemary Bowcutt	CRC Technician, Sr

Rowena Asilo	Manufacturing Associate II
Rowena Baltazar	Sr. Material and Inventory Planner
Ruchi Dutta	Manager, Program Operations
Rupinder Singh	Technical Support Engineer I
Ryan Bortz	Senior Surgical Application Specialist
Ryan Mock	Sr Systems Design Engineer
Ryan Moore	Sr Regional Sales Manager
Ryan Nagi	Senior Regional Sales Manager, Surgical
Ryan Seabourn	Field Support Engineer II
Ryan Vida	Refractive Global Post-Approval Studies, Sr. Manager
Sai Venkata Sravan Putikam	System Design Engineer 2
Sailaja Kowta Mangipudi	Software QA Engineer, Staff
Sam Ewing	Field Support Engineer I
Samantha J Flynn	Digital Market Development Manager
Sameer Raz	Quality Management System Manager
Samer Salman	Concept Engineer 2, Robotics
Samuel Griffiths	Regional Sales Manager
Samuel J Iezzi	Sr Regional Director, Sales
Samuel Patrick Sample	Global Technical Support II
Sandra Doan	CRC Technician II
Sandra Favaro	Refractive Account Manager III
Sandra L Padilla	Service Sales Administrator
Sandra Lynn Morris	Sales Inventory Specialist
Sangeetha Sandeep	Software QA Engineer, Sr
Sanjay Laroia	Technical Support Representative II

Sarah Foster	Field Support Engineer II
Sarah Smith	Master Database Administrator, Strategic Accounts
Saravani Venigalla	Business Applications Expert
Satyadevi Ponugupati	Staff SQA Engineer
Sayed H Haschemi	Supv, Repair Center Operations
Scott A Meyer	Head of Mergers & Acquisitions
Scott D Tucker	Sales Executive
Scott Smith	Corporate Counsel
Scott Thorson	Field Support Engineer I
Scott Tucker	Regional Sales Manager
Sejal Ghate	Data Scientist
Shane Ring	Sr. Strategic Accounts Manager
Sharmiane Swygert	Customer Care Advocate
Sharonda Harris	Sales Inventory Specialist
Shashank Shreekant Bhat	Software Engineer
Shawn Harris	Field Support Engineer III
Shawn Vang	CRC Technician II
Shawn Vaughn-Reed	Clinical Application Spec
Sheila Red	Department Assistant
Shelby Newbolt	Sales Executive
Sheng Yang (YangSheng)	Senior Product Manager
Shereen Elezaby	Head of Systems Design Engineering & UX
Shivani Anderson	Marketing Manager, Sr
Shruti Neshti	HR Generalist (CW)
Sidi Marouane Sbai	Supervisor, Field Service
Simeon Wayne Caulder	Head of US Sales - Ophthalmic Device
Simona Martin	Refractive Account Manager III
Siva Chellappa	Software Engineer 2
Skyler C Briggs	Supervisor, Field Service
Smitarani Shah	MDM Analyst
Smriti Rajagopalan	Program Manager, Cybersecurity
Sonia Afrin	QA Specialist, Staff
Sophia Yu	Data Specialist, Staff

Sri Chitra Mulukutla	Regulatory Affairs Specialist Associate
Stefan Jabkiewicz	Sr Regional Sales Manager
Stephanie Canna	Digital Clinical Application Specialist II
Stephen Hampton	Senior Regional Sales Manager, Lens Extraction
Stephen Morris	Regional Sales Director, Surgical
Steve A Kaatmann	System Design Eng, Staff
Steven A Braman	Technical Trainer III
Steven D. Ponder	Technical Support Engineer I
Steven Edwin Deutsch	Software Engineer, Sr Staff
Steven Holt	Inside Sales Specialist
Steven R Goluskin	Sales Success Specialist
Steven Schallhorn	Chief Medical Officer Ophthalmic Devices
Stuart Watts	Senior Regional Sales Manager, Surgical
Sunil S Kulkarni	Head of Cybersecurity & Agile Process
Surjit Kaur Dhesi	Manufacturing Associate III
Suzette N Erian	ERP CRM Service Process Administrator
Sweta Kurpad	Senior Financial Analyst
Sybelle Monteiro	IT Applications and Compliance Specialist
Tali Tolliver	Technical Trainer II
Tammy Wharton	Staff RA Spc
Tanesha Bland	Regulatory Affairs Specialist, Sr
Tara Pahlevan-Chaleshtari	Clinical Research Scientist, Staff
Tatad Jarean	Software Engineer, Staff
Tennie Wong	Senior Inspector
Teodulo E Bernados	Traffic Administrator
Terence Macias	Technical Support Engineer I
Terry Lankford	National Field Service Manager, Refractive
Terry Lee Hillman	Field Support Engineer II
Terry Wayne Nastasi	Field Support Engineer III

Thad Jacob Bertrand	Field Support Engineer II
Theodore Kluge	Field Support Engineer I
Theresa Luna	Billing Specialist
Thierno Ka	Field Support Engineer I
Thomas A Roush	Sales Executive
Thomas E Welsh	Planning Specialist
Thomas Fitzmorris	Director, Business Sectors-Glaucoma
Thomas Getty	Regional Sales Associate
Thomas Gleason	Field Support Engineer II
Thomas H Caouette Jr.	Senior Regional Sales Manager, Surgical
Thomas Halloran	Field Support Engineer III
Thomas Kelly	Senior Sales Effectiveness Trainer
Thomas M Callan	Principal Clinical Research Scientist
Thomas W Breitschwerd	Field Support Engineer III
Tien T Tran	Global Technical Support Engineer II
Timothy H Wong	New Product Introduction Engineer
Timothy Michael Lewandowski	PMI Project Manager, Sr.
Timothy Ritchey	National Sales Manager, Dental Independent Reps
Timothy Scarano	Supervisor, Hardware Engineering
Timothy Surber	Mechanical Design Eng, Sr Staff
Timothy Tzinieris	Mergers and Acquisition Manager
Tina Braga	Aggregate Spend Manager
Tina Renee Schinella	Sales Contracts Administrator
Todd Allen	Technical Support Representative III
Todd McDaniels	Strategic Sourcing Analyst
Todd Milholland	Head of Regulatory and Clinical Affairs
Todd Otani	Clinical Scientist, Sr
Tofan kumar Mohapatra	Business Process Analyst

Tony Vincent Valenzuela	Field Service Buyer/Planner
Tracy Carrie Morales	Clinical Application Spec II
Tracy S. Ripley	Executive Assistant to the Global President, Ophthalmic Devices
Tran Vu Nguyen	Field Service Project Manager
Travis Brooks	Field Support Engineer I
Trevor Sutton	Head of Marketing - Ophthalmic & Surgical
Troy Bamann	Sales Executive
Troy Jackson	Head of Supply Chain Management
Truc Thanh Thi Nguyen	Head of North America Supply Chain
Tyler D Olsby	Clinical Application Spec II
Tyler Davis	Sr Regional Sales Manager
Tyler Jaskowiak	Regional Sales Manager
Ugur Saritac	Threat and Vulnerability Manager
Valerie Bagala	Senior Buyer Planner
Vanessa Beliso	In-House Repair Coordinator
Vanessa Ly	Digital Technical Support Engineer
Vanezza Silos	Sales Success Specialist
Vani Ayyar	Software Engineer, Sr
Varun Kamboj	Senior Demand Planner
Venkiteshwar Subbaram Manoj	Head of Medical Affairs and Professional Education
Victor J Bailon	Field Support Engineer 1
Victoria Isabell Norris	Head of Service Operations
Victoria Mendez	Sales Success Specialist
Vidita Desai	Senior Regulatory Affairs Specialist
Viet Nguyen	QMR, PRRC, Head of Quality Management
Vikas Jyoty	Software Engineer, Sr
Viktor Schaitan	Development Engineer
Vincent Venturo	Sr Mgr, Quality Engineering

Wade Damon	Digital Support Engineer II
Wayne Helfrich	Regional Sales Manager
Wayne Staples	Sr Mgr, Intl Trade + Traffic
Weilu Tan	Marketing Manager
Wenzel Peikert	Senior Regional Sales Manager, Lens Extraction
Weylin Anthony Snider	Field Support Engineer III
William Andrews	Sr Regional Sales Manager
William Fassett	Field Implementation Specialist I
William Patrick Burke	Sr. Regional Sales Manager, Surgical
William R Machesney	Clinical Sales Director
Willie Brinkley	Field Implementation Specialist I
Willie Yip	Manufacturing Engineer, Sr
Wing K Leung	Software Engineer, Staff
Xavier White	Senior Regional Sales Manager, Surgical
Yajaira Ramirez	Clinical Research Associate I
Yakov Golovin	Surgical Applications Specialist
Yimei Yu	Associate Global Product Marketing Manager
Yohannes Dagne	Surgical Applications Specialist
Yongxiang Zhang	SW Engineer, Sr Staff
Yuanmu Deng	Software Engineer, Staff
Yuliya Berenshteyn	Software QA Engineer, Staff
Yun Long	Project Manager
Yvonne Lamb	Refractive Account Manager III
Yvonne Noble	Lead Service Operations Administrator
Zac Baker	Regional Sales Associate
Zachary Foreman	Field Support Engineer I
Zakory Hofer	Field Support Engineer I
Zane Frazier	Regional Sales Associate
Zheng Zhang	Manager, Strategic Sourcing

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Carl Zeiss Meditec, Inc. MDEG License # (if applicable) _____

Address 5300 Central Parkway

City Dublin State CA Zip 94568

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 408-239-7105 Website www.zeiss.com/med

Licensing Company Email marifi.lim@zeiss.com

Section 2: Personal Information

First Marifi Middle A Last Lim

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 5300 Central Pkwy

City Dublin State CA Zip 94568

Telephone 408-239-7105 Email marifi.lim@zeiss.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
MONTGOMERY COLLEGE		09/95-07/96	
Address	**City**	**State**	**Zip**
3232 COLLEGE PARK	THE WOODLANDS	TX	77384
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
THE WOODLANDS HIGH SCHOOL (FORMALLY MCCULLOUGH)		09/93-6/95	
Address	**City**	**State**	**Zip**
6101 Research Forest Dr.	THE WOODLANDS	TX	77381
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
HANFORD HIGH SCHOOL		09/91-6/96	
Address	**City**	**State**	**Zip**
450 HANFORD ST	RICHLAND	WA	99354
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/06-PRESENT	[redacted] BRAMANTE COURT	ANTIOCH	CA	94509
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
CARL ZEISS MEDITEC USA, INC			05/11-PRESENT
Business Address	**City**	**State**	**Zip**
5300 CENTRAL PKWY	DUBLIN	CA	94568
Phone	**Title**	**Number of Employed Hours**	
925-557-4477	SALES SUCCESS SUPERVISOR	approx. 25,480	

Description of Duties

Manage a 12 person team, covering tasks such as quoting, order processing, shipment coordination, inventory management, and invoicing for Carl Zeiss Meditec's medical device portfolio (see resume)

Business Name			From - To (MM/YY – MM/YY)
BD BIOSCIENCES			05/05-04/11
Business Address	**City**	**State**	**Zip**
2350 QUME DR	SAN JOSE	CA	95131
Phone	**Title**	**Number of Employed Hours**	
	CUSTOMER SERVICE LEAD	approx. 12,480	

Description of Duties

Responsible for reagent rental contracts, service contracts and call center order management (see resume)

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone			Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, MARIFI LIM, **certify that as the MDEG Administrator for**

Carl Zeiss Meditec, Inc.,

that I (initial that you have read and meet the following requirements):

1. MF Have a high school diploma or its equivalent;
2. MF Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MARIFI LIM
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/28/23
Date

Board Use Only	Date Received:

August 28, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

Re: Carl Zeiss Meditec, Inc. – MDEG Application, Section 2

Dear Board members,

Pursuant to the MDEG Application being submitted for your consideration for Carl Zeiss Meditec, Inc., please find below the required answers to Section 2 of the Application.

Carl Zeiss Meditec, Inc., through its sales and service organization Carl Zeiss Meditec USA, Inc., recently received a Cease-and-Desist and Citation-and-Fine Order (attached) from the Nevada State Board of Pharmacy dated August 14, 2023, for not holding a license under NRS 639.233. Upon receipt, we contacted the Board's Chief Operating Officer to indicate our compliance with the order, and we are submitting this application in accordance with the Board's guidance.

Sincerely,

Marifi Lim
Sales Success Supervisor

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Carl Zeiss Meditec, Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 5300 Central Parkway

City: Dublin State: CA Zip: 94568

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 408-239-7105 Website: www.zeiss.com/med

Licensing Company Email: marifi.lim@zeiss.com

Section 2: Personal Information

First: MARIFI Middle: A Last: LIM

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 5300 CENTRAL PKWY

City: CENTRAL State: CA Zip: 94568

Telephone: 408-239-7105 Email: MARIFI.LIM@ZEISS.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Montgomery College		09/95-07/96	
Address	City	State	Zip
3232 College Park	The Woodlands	TX	77384
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
The Woodlands High School (formally McCullough HS)		09/93-06/95	
Address	City	State	Zip
6101 Research Forest Dr.	The Woodlands	TX	77381
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Hanford High School		09/91-6/96	
Address	City	State	Zip
450 Hanford st	Richland	WA	99354
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/06-present	[redacted] Bramante Court	Antioch	CA	94509
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
CARL ZEISS MEDITEC USA, INC.			05/11-present
Business Address	**City**	**State**	**Zip**
5300 Central Pkwy	Dublin	CA	94568
Phone	**Title**		**Number of Employed Hours**
925-557-4477	Sales Success Supervisor		approx. 25,480

Description of Duties

Manage a 12 person team, covering tasks such as quoting, order processing, shipment coordination, inventory management, and invoicing for Carl Zeiss Meditec's medical device portfolio (see resume)

Business Name			From - To (MM/YY – MM/YY)
BD Biosciences			05/05-04/11
Business Address	**City**	**State**	**Zip**
2350 Qume Dr	San Jose	CA	95131
Phone	**Title**		**Number of Employed Hours**
	Customer Service Rep lead		approx. 12,480

Description of Duties

Responsible for reagent rental contracts, service contracts and call center order management (see resume)

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Marifi Lim, **certify that as the designated representative for**

Carl Zeiss Meditec, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MW I am at least 21 years of age;
3. MW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Marifi Lim

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/28/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Marifi Lim

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/28/23

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

See attached

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Alameda)

On August 28, 2023 before me, Michelle A. Miranda - Albanese, Notary Public
(insert name and title of the officer)

personally appeared Marifi Lim,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/~~are~~ subscribed to the within instrument and acknowledged to me that ~~he/she/they~~ executed the same in ~~his/her/their~~ authorized capacity(~~ies~~), and that by ~~his/her/their~~ signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

MICHELLE A. MIRANDA-ALBANESE
COMM. # 2305453
NOTARY PUBLIC - CALIFORNIA
ALAMEDA COUNTY
COMM. EXPIRES SEPT. 16, 2023

Signature _____ **(Seal)**

4M

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	N/A * If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Catalent Greenville, Inc.

Physical Address: 5440 Martin Luther King Jr Highway

City: Greenville State: NC Zip: 27834

Mailing Address (if different from physical address): Same as physical address.

City: _____ State: _____ Zip: _____

Telephone: 252-752-3800 Website: www.catalent.com

Name of Designated Representative (DR): Troy Woelfel

Licensing Company Email: GMB-CatalentGreenvilleInc@catalent.com DR Email: GMB-CatalentGreenvilleInc@catalent.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Legend Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Manufacturers, Distuibutors, Re-packers, Clinics, and Pharmaceutical Companies		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Name: Curia (Euticals, Inc.)

Address: 2460 W Bennett Street City: Springfield State: MO Zip: 65807

Name: Cambrex Profarmaco Milano S.R.L.

Address: Via Curiel City: S.t. Paullo State: Italy Zip: 20067

Name: Johnson Matthey Materials - USA

Address: 2003 Nolte Drive City: West Deptford State: NJ Zip: 08066-1742

Name: Noramco LLC

Address: 500 Swedes Landing Road City: Wilmington State: DE Zip: 19801

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

State of Incorporation/Organization: Delaware

Parent Company (if any): Catalent Pharma Solutions, Inc.

Corporation/Organization Name: Catalent Greenville, Inc.

Mailing Address: 5440 Martin Luther King Jr Highway

City: Greenville State: NC Zip: 27834

Telephone: 252-752-3800 Email: GMB-CatalentGreenvilleInc@catalent.com

Contact Person Name: Troy Woelfel

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
N/A 1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration Refer to Attachment A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. Enclosed		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** Refer to Attachment B	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** Refer to Attachment B		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** Refer to Attachment C	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ Enclosed - Please note that the original form was mailed to your office on December 12th, 2022.		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Refer to Attachment B		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** Refer to Attachment E	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** Refer to Attachment D	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8) N/A				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Catalent Greenville, Inc.

Facility Name

Steven Fasman

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12/1/2022

Date

Board Use Only	Date Received: 12-13-22	Amount: 1000.00 CC ✓ 12/14/22

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Catalent Greenville, Inc.

Facility Name

Joseph Ferraro

Print Name of Authorized Person Submitting Application

Joseph Ferraro

Original signature of Authorized Person (copies or stamps not accepted)

08/10/2023

Date

Board Use Only	Date Received: 8/21/23	Amount: 1000-CC ✓ 8/31/23

Attachment A

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Catalent Greenville**

CSVExcel

Filter: Martin

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
CATALENT GREENVILLE, INC.	3000209735	118814439	MANUFACTURE;	5440 MARTIN LUTHER KING JR BLVD, Greenville, North Carolina (NC) 27834, United States (USA)	12/31/2023

Showing 1 to 1 of 1 entries (filtered from 2 total entries)
Previous1Next
Data Current through: Monday, Aug 7, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Catalent

Attachment B

Ownership and Officer Information

Parent Company:
Catalent Pharma Solutions, Inc.
14 Schoolhouse Road
Somerset, NJ 08873

Catalent Greenville, Inc. is 100% owned by its parent company, Catalent Pharma Solutions, Inc.

Corporate Officers:

Alessandro Maselli
President & Chief Executive Officer

Steven L. Fasman
Executive Vice President & Chief Administrative Officer

Lawrence Shapiro
Vice President, Global Tax & Treasurer

Joseph Ferraro
Senior Vice President, General Counsel & Secretary

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CATALENT GREENVILLE, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF APRIL, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CATALENT GREENVILLE, INC." WAS INCORPORATED ON THE TWENTY-SIXTH DAY OF JULY, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6933672 8300

SR# 20231662085

Authentication: 203225611

Date: 04-26-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

2023

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
566

LICENSE/CERTIFICATE: Manufacturer
TYPE PRESCRIPTION DRUG REGISTRATION
Expiration Date 12/31/2023

LICENSEE OR CERTIFICATOR
CATALENT GREENVILLE INC
5440 MARTIN LUTHER KING JR BLVD
GREENVILLE NC 27834

LICENSED 2023 NORTH CAROLINA

Steven W. Troxler
STEVE TROXLER, COMMISSIONER

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

Attachment D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. SUR0073955

Application/License No. _____

CATALENT GREENVILLE, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5440 Martin Luther King Jr Highway Greenville, NC 27834 (Address of Applicant/Principal), as PRINCIPAL, and ARGONAUT INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is P.O. Box 469011 San Antonio, TX 78246 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 9, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639 515 and NAC 639 5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639 5937 Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court Payment of any such claim shall be payable to the Nevada State Board of Pharmacy
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 9th day of November, 2022.

APPLICANT/PRINCIPAL
CATALENT GREENVILLE, INC

Authorized Representative

SURETY COMPANY
ARGONAUT INSURANCE COMPANY

Surety Company's Representative

Frances Rodriguez, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Halina Kazmierczak

Witness Sandra Diaz

Countersigned by:

N/A
Nevada Resident Agent

Argonaut Insurance Company
Deliveries Only: 225 W. Washington, 24th Floor
Chicago, IL 60606
United States Postal Service: P.O. Box 469011, San Antonio, TX 78246
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the Argonaut Insurance Company, a Corporation duly organized and existing under the laws of the State of Illinois and having its principal office in the County of Cook, Illinois does hereby nominate, constitute and appoint:

Sandra Diaz, Debra A Deming, Anne Potter, Beverly A Woolford, Valorie Spates, Jennifer L Jakaitis, Susan A Wolfe, Peter Hedly, Nancy Schiree, Ahlma Noorhassan, Frances Rodriguez, Francesca Kazmierczak, Kemal Drkanovic

Their true and lawful agent(s) and attorney(s)-in-fact, each in their separate capacity if more than one is named above, to make, execute, seal and deliver for and on its behalf as surety, and as its act and deed any and all bonds, contracts, agreements of indemnity and other undertakings in suretyship provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed the sum of:

$97,550,000.00

This Power of Attorney is granted and is signed and sealed under and by the authority of the following resolution adopted by the Board of Directors of Argonaut Insurance Company:

"RESOLVED, That the President, Senior Vice President, Vice President, Assistant Vice President, Secretary, Treasurer and each of them hereby is authorized to execute powers of attorney, and such authority can be executed by use of facsimile signature, which may be attested or acknowledged by any officer or attorney, of the Company, qualifying the attorney or attorneys named in the given power of attorney, to execute in behalf of, and acknowledge as the act and deed of the Argonaut Insurance Company, all bond undertakings and contracts of suretyship, and to affix the corporate seal thereto."

IN WITNESS WHEREOF, Argonaut Insurance Company has caused its official seal to be hereunto affixed and these presents to be signed by its duly authorized officer on the 19th day of November, 2021

Argonaut Insurance Company

ARGONAUT INSURANCE COMPANY CORPORATE SEAL 1948 ILLINOIS

by: Gary E Grosc , President

STATE OF TEXAS
COUNTY OF HARRIS SS:

On this 19th day of November, 2021 A.D. before me, a Notary Public of the State of Texas, in and for the County of Harris, duly commissioned and qualified, came THE ABOVE OFFICER OF THE COMPANY, to me personally known to be the individual and officer described in, and who executed the preceding instrument, and he acknowledged the execution of same, and being by me duly sworn, deposed and said that he is the officer of the said Company aforesaid, and that the seal affixed to the preceding instrument is the Corporate Seal of said Company, and the said Corporate Seal and his signature as officer were duly affixed and subscribed to the said instrument by the authority and direction of the said corporation, and that Resolution adopted by the Board of Directors of said Company, referred to in the preceding instrument is now in force August

IN TESTIMONY WHEREOF, I have hereunto set my hand, and affixed my Official Seal at the County of Harris, the day and year first above written

KATHLEEN M MEEKS
NOTARY PUBLIC
STATE OF TEXAS
MY COMM. EXP. 07/15/25
NOTARY ID 557902-8

Kathleen M. Meeks
(Notary Public)

I, the undersigned Officer of the Argonaut Insurance Company, Illinois Corporation, do hereby certify that the original POWER OF ATTORNEY of which the foregoing is a full, true and correct copy is still in full force and effect and has not been revoked.

IN WITNESS WHEREOF, I have hereunto set my hand, and affixed the Seal of said Company, on the 9th day of November 2022

ARGONAUT INSURANCE COMPANY CORPORATE SEAL 1948 ILLINOIS

Austin W. King , Secretary

IF YOU HAVE QUESTIONS ON AUTHENTICITY OF THIS DOCUMENT CALL (833) 820 - 9137.

FINANCIAL STATEMENT
ARGONAUT INSURANCE COMPANY
STATUTORY BASIS as of 12/31/2021

ASSETS	
CASH & INVESTED ASSETS	$248,880,956
BONDS	$1,181,510,880
STOCKS	$674,977,267
INVESTMENT INCOME DUE AND ACCRUED	$5,760,648
PREMIUM BALANCES	$114,[illegible]88
NET DEFERRED TAX ASSET	$11,335,137
REINSURANCE RECOVERABLE	$92,[illegible]64
OTHER ASSETS	$40,514,092
TOTAL ASSETS	$2,391,360,830

LIABILITIES AND SURPLUS	
UNEARNED PREMIUMS	$804,943,789
LOSSES	$595,583,927
LOSS ADJUSTMENT EXPENSES	$198,245,975
COMMISSIONS	-$4,787,791
TAXES, LICENSES, AND FEES	$10,269,848
OTHER EXPENSES	$9,373,605
FUNDS HELD UNDER REINSURANCE TREATIES	$72,371,315
CURRENT FEDERAL AND FOREIGN INCOME TAXES	$0
REMITTANCES AND ITEMS NOT ALLOCATED	$2,510,048
AMOUNTS WITHHELD/RETAINED BY COMPANY FOR OTHERS	$11,771,886
PAYABLES TO PARENT, SUBSIDIARIES, & AFFILIATES	$52,193,204
PAYABLE FOR SECURITIES	$3,999,469
PROVISION FOR REINSURANCE	$16,445,734
CEDED REINSURANCE PREMIUMS PAYABLE	$47,083,249
OTHER ACCRUED EXPENSES AND LIABILITIES	$1,997,817
TOTAL LIABILITIES	$1,321,205,703
COMMON CAPITAL STOCK	$4,500,000
GROSS PAID IN AND CONTRIBUTED SURPLUS	$535,520,936
UNASSIGNED SURPLUS	$541,137,091
TOTAL SURPLUS TO POLICYHOLDERS	$1,071,158,927
TOTAL LIABILITIES & SURPLUS	$2,392,360,630

Jose Westbrook, being duly sworn, says that he is Head of US Segment Accounting of Argonaut Insurance Company and that to the best of his knowledge, and belief, the foregoing Statement is a true and correct Statement of the financial condition of said Company as of the 31st of December, 2021.

Subscribed and sworn to before me this 5th day of April 2022

Notary Public

Julian Sandler Westbrook III, Head of US Segment Accounting

RIDER

To be attached to and form part of:

Bond Number SUR0073955

dated November 9, 2022

issued by the ARGONAUT INSURANCE COMPANY

in the amount of $ 100,000.00

on behalf of CATALENT GREENVILLE, INC.
(Principal)

and in favor of NEVADA STATE BOARD OF PHARMACY
(Obligee)

Now therefore, it is agreed that in consideration of the premium charged, the attached bond shall be amended as follows:

The following location shall be added to the bond:

1240 Sugg Parkway, Greenville, NC 27834

It is further understood and agreed that all other terms and conditions of this bond shall remain unchanged.

This Rider is to be Effective this 9th day of November, 2022.

Signed, Sealed & Dated this 9th day of November, 2022.

CATALENT GREENVILLE, INC.
(Principal)

By: _____

ARGONAUT INSURANCE COMPANY
(Surety)

By: _____
Sandra Diaz, Attorney-in-Fact

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Catalent Greenville, Inc. (formerly licensed as Mayne Pharma, Inc.)

Pharmacy/Wholesaler License # (if applicable): WH02126

Physical Address: 5440 Martin Luther King Jr Highway

City: Greenville State: NC Zip: 27834

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: (252) 752-3800 Website: www.catalent.com

Licensing Company Email: GMB-CatalentGreenvilleInc@catalent.com

Section 2: Personal Information

First: Troy Middle: Thomas Last: Woelfel

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 5440 Martin Luther King Jr Highway

City: Greenville State: NC Zip: 27834

Telephone: (252) 752-3800 Email: GMB-CatalentGreenvilleInc@catalent.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Washington High School		09/84-05/88	
Address	City	State	Zip
301 South Main Ave	Sioux Falls	SD	57104
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
United States Naval Academy		07/88-06/92	
Address	City	State	Zip
121 Blake Road	Annapolis	MD	21402
Diploma/Degree obtained, if any			
BS Aerospace Engineering			

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina			
Address	City	State	Zip
	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/20 - Present	[redacted] Vassar Road	Greenville	NC	27858
07/19 - 08/20	[redacted] Benjamin W	Marlton	NJ	8053
12/16 - 08/17	[redacted] Quarterhorse Court	Marlton	NJ	8053
08/16 - 12/16	[redacted] Yardley Drive	Wake Forest	NC	27587
05/08-07/16	[redacted] Shelburne Drive	Clayton	NC	27527
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Catalent Greenville / Mayne Pharma Greenville			04/19 - present	
Business Address		**City**	**State**	**Zip**
1240 Sugg Parkway		Greenville	NC	27834
Phone	**Title**		**Number of Employed Hours**	
252-955-8233	General Manager		7,280	
Description of Duties				
Responsible for overall management of all aspects of the manufacturing, testing and packaging of pharmaceutical products.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Troy Woelfel, **certify that as the designated representative for**

Catalent Greenville, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TTW I am at least 21 years of age;
3. TTW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TTW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TTW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TTW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TTW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Troy Woelfel
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

30 Nov 2022
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Troy Woelfel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

30 Nov 2022

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Pitt

I, Troy Woelfel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

30 Nov 2022

Date

Subscribed and Sworn to before me this 30th day of November.

Rachel L. Rasberry

Notary Public Signature

RACHEL L. RASBERRY
Notary Public
Pitt
County
My Comm. Exp.
05-15-23
NORTH CAROLINA

(Seal)

Attachment E

Employee List	
Legal Name - Last Name	**Legal Name - First Name**
Allette	Acacia
Allette	Miriam
Alonso	Jeymi
Alston	Tyrek
Alzer	Fatima
Ambrose	Michael
Anaya	Michael
Anderson	Suzanne
Anthony	Jessica
Arnold	Rebecca
Artuso	Mackenzie
Askew	Timothy
Asmar	Sara
Awere	Edward
Babar	Digvijay
Barnes	Eric
Barrios	Alexia
Barry	Lindzie
Barth	Curtis
Bartley	Shawn
Basden	William
Batts	Charlton
Baxley	Tamatha
Becker	Ryan
Beissner	Brad
Bell	Harry
Beltran Bejarano	Cristhian
Berry	Terry
Best	Colene
Blackard	Warren
Bogard	David
Bonfiglio	Jamie
Bordner	Angela
Bowen	James
Bowen	Jeffery
Bowers	Tess
Carrow	Matthew
Boyce	Takiyest
Branch	Carl
Bratton	Bruce
Brewer	Brittany
Brewer	Justin
Brewer	Richard
Brickhouse	Wesley

Brown	Jerry
Brown	Linwood
Bryan	Ivory
Buck	Ashley
Bullard	Joshua
Bunn	William
Burgos Aguilar	Julio
Burke	Loralea
Bush	Mercedes
Butcher	Katherine
Calvo	William
Campbell	Terrance
Carlis	Christopher
Carr	Travis
Padley	Joseph
Carrow	Paul
Casteen	Charles
Castor	Morgan
Cherok	Courtney
Chilton	Matthew
Clark	Michael
Clark	Rodney
Clift	Shaelyn
Clipperton	Randall
Cocolas	Harry
Coleman	Jordan
Combs	Juliana
Cortes	Dylan
Cotter	Christie
Coward	Kristin
Cox	Peggy
Cox	Will
Credle	Kenneth
Creech	Clyde
Croom	Josh
Crutchfield	Deborah
Cummings	Kasey
Cutler	Harold
Dail	Cynthia
Daly	Debra
Dancy	Debra
Daniels	Dylan
Daniels	Emmanuel
Daniels	Jesse
Dattilo	Lauren
Davenport	Alison
Davis	Bonnie
Davis	Damius

Davis	David
Day	Chadwick
de Araujo Melo	Rahyanne
Decker	Amber
DeRose	Luciano
Dickerson	Scott
Dionne	Matthew
Dixon	Alan
Dixon	Brian
Dixon	Lakia
Doetzl	Eric
Donadio	Kyle
Donehoo	Martin
Dover	Lloyd
Dowell	Matthew
Downing	Jalisa
Ducharme	Jodie
Dunn	Jonathon
East	Julianne
Edwards	Ashton
Edwards	Ryan
Elicati	Gino
Elks	James
Emerson	Michael
Emory	Stephanie
Epps	Robert
Euler	Hailey
Evans	Lisa
Ewell	Scott
Fairweather	Haidyn
Faughnan	Caitey
Faulkner	Grayson
Faulkner	Julianne
Foster	Dylan
Foster	Milton
Fowler	Kelli
Franklin	Dustin
French	William
Friend	Scott
Fucci	Megan
Fugit	Kyle
Gadson Brown	Kyana
Gainer	Richard
Galloway	Joshua
Garcia Reyes	Veronica
Gardner	Franklin
Gardner	Richard
Garrell	Justin

Garrett	Kristi
Garris	Jillia
Gaskins	Janet
Geiger	Micah
Genovese	Steven
Gilbert	Jennifer
Gillikin	Justin
Gilmore	Kayla
Ginn	Carolyn
Gladson	Amy
Gladson	David
Glisson	Jason
Godard	John
Godard	Lucas
Godley	William
Gold	Thomas
Goldson	Victoria
Gonzalez	Maria
Gooding	Ringo
Grady	Gail
Gray	Breigh
Gray	Christina
Green	Stacey
Green	William
Greer	Thomas
Griffin	Allison
Griffin	Jerry
Grubich	Nicholas
Gupte	Anshul
Gutierrez Nuno	Jimena
Hammons	Katie
Harleaux-Lopez	Nicholas
Harper	Delora
Harrell	Tabitha
Harris	Dylan
Harris	Henry
Harris	Raybon
Hawkins	Dana
Heckman	Russell
Henne	Michele
Hill	David
Hogan	Garrett
Holiday	Latricia
Holzkamm	Rebecka
Honeycutt	Joseph
Hooter	Paul
Hormilla	Maxwell
Horton	Holly

Howell	Steven
Huff	Thomas
Hunt	Brett
Huynh	Diana
Hyatt	Jacob
Ingles	Daniel
Israel	William
Jefferson	Holly
Jenkins	Austin
Jenkins	Melvin
Johnson	Kimberly
Jones	Kenneth
Jones	Lauren
Jones	Seth
Kancharla	Joseph Paul
Kearney	Kenneth
Kelly	Devon
Kettler	Caleb
Kiely	Richard
Kinion	Chase
Kinkton	James
Kiser	Christopher
Knox	Derrick
Kobylkevich	Myriam
Kunkel	Cooper
Lassiter	Gerald
Latham	Clarence
Lawrence	Kendall
Lawson	Allen
Lawson	Christopher
Leary	David
Leitschuh	Tori
Lomas	Karen
Lynch	Jaylin
Lynn	Brandon
Majette	Elizabeth
Mallard	Todd
Manning	Jessica
Marshburn	Timothy
Martens	Christian
Mason	Sammy
Mattheu	Emily
Mccarter	Mary A
Mccotter	Kamal
McCoy	Michelle
McCoy	Steven
McDaniel	Timothy
McGuire	Gregory

McLawhorn	Avery
McLawhorn	Matthew
McNally	James
McNeill	John
Meeks	Joseph E
Melton	Andrew
Miles	Kristen
Mills	Amanda
Mills	Blake
Miranda Colon	Zenaida
Mizell	Jerry
Mizelle	Allen
Moore	Rachel
Whitehurst	Jeffrey
Morris	Patricia
Morris	Teresa
Morrow	Leslie
Mukadam	Ninad
Murchison	Ashley
Navarro	Michelle
Neal	Ellis
Neal	Jerry
Nelson	David
Nelson	Gregory
Nelson	Melissa
Newman	Chivonne
Nguyen	Hien
Norman	Phawn
ONeal	Gary
Boyce	Dontre
Pannell	Robert
Papageorge	William
Paramore	William
Parker	Kay
Parrish	Sherry
Pate	Michelle
Pate	Troy
Patel	Aditya
Patel	Monika
Payton	William
Peaden	Jeannette
Pence	Leyna
Perry	Jacob
Peterson	Alston
Peterson	Evan
Phelps	Brandon
Philbee	Timothy
Phillips	Amber

Pick	Nicholas
Plumley	Zoe
Podruchny	Walter
Pofahl	Walter
Poole	Kevin
Popovich	Anthony
Popovich	Jennifer
Poston	Elizabeth
Powell	Matthew
Prayer	Torrey
Price	Gilley
Price	Jacob
Price	Michael
Proctor	Matthew
Pryor	Sterling
Rambert	Shantez
Randolph	Diantha
Rasberry	Rachel
Raynor	Alex
Reichardt	Randi
Reyes	Alba
Rhodes	Leah
Rice	Franklin
Richardson	Allison
Riggs	Gary
Riley	Trisha
Rios	Nicolas
Rivera	Lesly
Rivera Rios	Jonathan
Roberson	Tracey
Robinson	Kaylynn
Rodriguez	Clemente
Rogers	Jeffrey
Rogerson	Becky
Rogerson	Jerry
Rogerson	Michael
Rogerson	Robert
Ross	John
Ryan	Heather
Sadhale	Yogesh
Saleh	Waleed
Sanchez	Fabricio
Sanford	Monica
Scannell	Teisha
Sesma	Sarabeth
Shaf	Bernard
Shanken	Michael
Sheppard	Cheryl

Sheppard	Vonda
Shirley	Jonathan
Simonetti	Nicholas
Simpkins	Bradley
Simpson	Julie
Singleton	Clarence
Singleton	Lewis
Sloan	Binford
Smith	Christopher
Smith	DeJuan
Smith	Matthew
Smith-Joyner	Annalisa
Soroko	Jacob
Southerlin	Sierra
Spear	Camron
Spruill	Christopher
Stallings	Steven
Stancill	Wendy
Staton	William
Steinert	Ralph
Stephens	Javonna
Stocks	Tommy
Stokes	Angelina
Stox	Merritt
Streeter	Lenora
Styons	Ellen
Suarez	Gracie
Suozzo	Sandra
Suter	Elizabeth
Sutton	Holly
Sweet	Chris
Szumigala	Craig
Tanhauser	Justin
Taylor	Robert
Taylor	Tony
Tello Lopez	Zoila
Terlizzi	Francesca
Terry	Crystal
Terry	William
Thereault	Brian
Thomas	Garland
Thomas	Logan
Thota	Shyam Sunder
Tice	Shayna
Tolson	Lory
Trimble	Malcolm
Trimpi	Benjamin
Tubi	Olaitan

Tucciarone	Patricia
Turner	Tia
Tyndall	Karen
Tyree	Jonathan
Tyson	Troy
Vaughan	Susan
von Lehmden	Thomas
Walden	Glenn
Waldrop	Kenneth
Walker	Charles
Wantland	Sidney
Ward	Brandon
Ward	Brett
Warren	Jimmy
Watkins	Gerald
Webb	Daniel
Webb	Erica
Whitaker	Alexander
Whitaker	Hayley
Whitaker	Leticia
Whitaker	Matthew
White	Ashlee-Danielle
White	Caitlin
White	Dylan
White	Gregory
White	Lemont
Wiggins	Travis
Whitford	Lindsey
Whitworth	Tenesha
Moore	Zavian
Wiggs	Lisa
Wilkes	Brittany
Williams	Ainsley
Williams	Alneeiqua
Williams	Christopher
Williams-Dixon	Tonya
Wilson	Ashleigh
Wilson	Tony
Woelfel	Troy
Woolard	Carlton
Woolard	Christopher
Woolard	Marshall
Wurtele	Heather
Wynn	Mason

4N

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	N/A * If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Catalent Greenville, Inc.

Physical Address: 1240 Sugg Parkway

City: Greenville State: NC Zip: 27834

Mailing Address (if different from physical address): Same as physical address.

City: _____ State: _____ Zip: _____

Telephone: (252) 752-3800 Website: www.catalent.com

Name of Designated Representative (DR): Michael Rogerson

Licensing Company Email: GMB-CatalentGreenvilleInc@catalent.com DR Email: GMB-CatalentGreenvilleInc@catalent.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☒ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Legend Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Manufacturers, Distributors, Repackagers, Clinics and Pharmaceutical Companies		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Name: Curia (Euticals Inc.)
Address: 2460 W Bennett Street City: Springfield State: MO Zip: 65807
Name: Cambrex Profarmaco Milano S.R.L.
Address: Via Curiel City: 34, Paullo State: Italy Zip: 20067
Name: Johnson Matthey Materials -USA
Address: 2003 Nolte Drive City: West Deptford State: NJ Zip: 08066-1742
Name: Noramco LLC
Address: 500 Swedes Landing Road City: Wilmington State: DE Zip: 19801

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

State of Incorporation/Organization: Delaware
Parent Company (if any): Catalent Pharma Solutions, Inc.
Corporation/Organization Name: Catalent Greenville, Inc.
Mailing Address: 1240 Sugg Parkway
City: Greenville State: NC Zip: 27834
Telephone: (252) 752-3800 Email: GMB-CatalentGreenvilleInc@catalent.com
Contact Person Name: Michael Rogerson

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
N/A 1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		
1. Copy of FDA registration See Attachment A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. Enclosed		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment B	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment B		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment C	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ Enclosed (Please note that the original form was mailed to your office on December 12th, 2022)		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - See Attachment B		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** See Attachment D	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment E	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment F	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Catalent Greenville, Inc.
Facility Name

Joseph Ferraro
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7-12-2023
Date

Board Use Only	Date Received: 7/26/23	Amount: 1000- CC ✓ 8/2/23

Attachment A

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Catalent Greenville**

CSVExcel

Filter: Sugg

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Catalent Greenville, Inc.	3000209735	118812386	ANALYSIS; LABEL; MANUFACTURE; PACK;	1240 Sugg Parkway, Greenville, North Carolina (NC) 27834, United States (USA)	12/31/2023

Showing 1 to 1 of 1 entries (filtered from 2 total entries)
Previous1Next
Data Current through: Monday, Jun 19, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Catalent

Attachment B

Ownership and Officer Information

Parent Company:
Catalent Pharma Solutions, Inc.
14 Schoolhouse Road
Somerset, NJ 08873

Catalent Greenville, Inc. is 100% owned by its parent company, Catalent Pharma Solutions, Inc.

Corporate Officers:

Alessandro Maselli
President & Chief Executive Officer

Steven L. Fasman
Executive Vice President & Chief Administrative Officer

Lawrence Shapiro
Vice President, Global Tax & Treasurer

Joseph Ferraro
Senior Vice President, General Counsel & Secretary

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CATALENT GREENVILLE, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF APRIL, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CATALENT GREENVILLE, INC." WAS INCORPORATED ON THE TWENTY-SIXTH DAY OF JULY, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6933672 8300

SR# 20231662085

Authentication: 203225611

Date: 04-26-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment F

2023

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
1404

LICENSE/CERTIFICATE: Manufacturer
TYPE PRESCRIPTION DRUG LICENSE
Expiration Date 12/31/2023

LICENSEE OR CERTIFICATOR
CATALENT GREENVILLE INC
1240 SUGG PARKWAY
GREENVILLE NC 27834

[redacted]

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

STEVE TROXLER, COMMISSIONER

Attachment D

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0638607	08-31-2023	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5,L1	MANUFACTURER	11-22-2022

CATALENT GREENVILLE, INC.
1240 SUGG PKWY
GREENVILLE, NC 278349006

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0638607	08-31-2023	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5,L1	MANUFACTURER	11-22-2022

CATALENT GREENVILLE, INC.
1240 SUGG PKWY
GREENVILLE, NC 278349006

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0638607	08-31-2023	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5,L1	MANUFACTURER	11-22-2022

CATALENT GREENVILLE, INC.
1240 SUGG PKWY
GREENVILLE, NC 278349006

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
1100 1105 1205 1228 1724 2100 7285 8112 9041 9050 9120 9143 9170 9193 9300 9652 9801

RIDER

To be attached to and form part of:

Bond Number SUR0073955

dated November 9, 2022

issued by the ARGONAUT INSURANCE COMPANY

in the amount of $ 100,000.00

on behalf of CATALENT GREENVILLE, INC.
(Principal)

and in favor of NEVADA STATE BOARD OF PHARMACY
(Obligee)

Now therefore, it is agreed that in consideration of the premium charged, the attached bond shall be amended as follows:

The following location shall be added to the bond:

1240 Sugg Parkway, Greenville, NC 27834

It is further understood and agreed that all other terms and conditions of this bond shall remain unchanged.

This Rider is to be Effective this 9th day of November, 2022.

Signed, Sealed & Dated this 9th day of November, 2022.

CATALENT GREENVILLE, INC.
(Principal)

By: _____

ARGONAUT INSURANCE COMPANY
(Surety)

By: _____
Sandra Diaz, Attorney-in-Fact

Argonaut Insurance Company
Deliveries Only: 225 W. Washington, 24th Floor
Chicago, IL 60606
United States Postal Service: P.O. Box 469011, San Antonio, TX 78246
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the Argonaut Insurance Company, a Corporation duly organized and existing under the laws of the State of Illinois and having its principal office in the County of Cook, Illinois does hereby nominate, constitute and appoint:

Sandra Diaz, Debra A Deming, Anne Potter, Beverly A Woolford, Valorie Soates, Jennifer L Jakaitis, Susan A Welsh, Peter Healy, Nancy Schnee, Aklima Nourhassan, Frances Rodriguez, Francesca Kazmierczak, Kemal Brkanovic

Their true and lawful agent(s) and attorney(s)-in-fact, each in their separate capacity if more than one is named above, to make, execute, seal and deliver for and on its behalf as surety, and as its act and deed any and all bonds, contracts, agreements of indemnity and other undertakings in suretyship provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed the sum of:

$97,550,000.00

This Power of Attorney is granted and is signed and sealed under and by the authority of the following Resolution adopted by the Board of Directors of Argonaut Insurance Company:

"RESOLVED, That the President, Senior Vice President, Vice President, Assistant Vice President, Secretary, Treasurer and each of them hereby is authorized to execute powers of attorney, and such authority can be executed by use of facsimile signature, which may be attested or acknowledged by any officer or attorney, of the Company, qualifying the attorney or attorneys named in the given power of attorney, to execute in behalf of, and acknowledge as the act and deed of the Argonaut Insurance Company, all bond undertakings and contracts of suretyship, and to affix the corporate seal thereto."

IN WITNESS WHEREOF, Argonaut Insurance Company has caused its official seal to be hereunto affixed and these presents to be signed by its duly authorized officer on the 19th day of November, 2021.

Argonaut Insurance Company

ARGONAUT INSURANCE COMPANY CORPORATE SEAL 1948 ILLINOIS

by: _____

Gary E Grose, President

STATE OF TEXAS
COUNTY OF HARRIS SS:

On this 19th day of November, 2021 A.D., before me, a Notary Public of the State of Texas, in and for the County of Harris, duly commissioned and qualified, came THE ABOVE OFFICER OF THE COMPANY, to me personally known to be the individual and officer described in, and who executed the preceding instrument, and he acknowledged the execution of same, and being by me duly sworn, deposed and said that he is the officer of the said Company aforesaid, and that the seal affixed to the preceding instrument is the Corporate Seal of said Company, and the said Corporate Seal and his signature as officer were duly affixed and subscribed to the said instrument by the authority and direction of the said corporation, and that Resolution adopted by the Board of Directors of said Company, referred to in the preceding instrument is now in force August

IN TESTIMONY WHEREOF, I have hereunto set my hand, and affixed my Official Seal at the County of Harris, the day and year first above written.

KATHLEEN M MEEKS
NOTARY PUBLIC
STATE OF TEXAS
MY COMM. EXP. 07/15/25
NOTARY ID 557902-8

_____
(Notary Public)

I, the undersigned Officer of the Argonaut Insurance Company, Illinois Corporation, do hereby certify that the original POWER OF ATTORNEY of which the foregoing is a full, true and correct copy is still in full force and effect and has not been revoked.

IN WITNESS WHEREOF, I have hereunto set my hand, and affixed the Seal of said Company, on the 9th day of November 2022.

ARGONAUT INSURANCE COMPANY CORPORATE SEAL 1948 ILLINOIS

_____
Austin W. King, Secretary

IF YOU HAVE QUESTIONS ON AUTHENTICITY OF THIS DOCUMENT CALL (833) 820 - 9137.

FINANCIAL STATEMENT
ARGONAUT INSURANCE COMPANY
STATUTORY BASIS as of 12/31/2021

ASSETS

CASH & INVESTED ASSETS	$248,860,950
BONDS	$1,181,510,930
STOCKS	$972,377,267
INVESTMENT INCOME DUE AND ACCRUED	$5,760,618
PREMIUM BALANCES	$21,828,956
[illegible]	[illegible]
[illegible]	[illegible]
OTHER ASSETS	$40,514,092
TOTAL ASSETS	$2,392,360,630

LIABILITIES AND SURPLUS

UNEARNED PREMIUMS	$304,943,789
LOSSES	$595,583,927
LOSS ADJUSTMENT EXPENSES	$198,245,975
COMMISSIONS	-$4,782,791
TAXES, LICENSES AND FEES	$10,269,846
[illegible]	[illegible]
[illegible]	[illegible]
CURRENT FEDERAL AND FOREIGN INCOME TAXES	$0
REMITTANCES AND ITEMS NOT ALLOCATED	$4,510,048
AMOUNTS WITHHELD/RETAINED BY COMPANY FOR OTHERS	$11,771,696
PAYABLES TO PARENT, SUBSIDIARIES, & AFFILIATES	$52,193,204
PAYABLE FOR SECURITIES	$3,599,489
PROVISION FOR REINSURANCE	$16,445,734
CEDED REINSURANCE PREMIUMS PAYABLE	$47,083,249
OTHER ACCRUED EXPENSES AND LIABILITIES	$1,597,617
TOTAL LIABILITIES	$1,321,201,703
COMMON CAPITAL STOCK	$4,500,000
GROSS PAID IN AND CONTRIBUTED SURPLUS	$928,520,936
UNASSIGNED SURPLUS	$641,137,991
TOTAL SURPLUS TO POLICYHOLDERS	$1,071,158,927
TOTAL LIABILITIES & SURPLUS	$2,392,360,630

Jace Westbrook, being duly sworn, says that he is Head of US Segment Accounting of Argonaut Insurance Company and that to the best of his knowledge and belief, the foregoing statement is a true and correct statement of the financial condition of said Company as of the 31st of December, 2021.

Subscribed and sworn to before me this 5th day of April 2022

Notary Public

Julian Chandler Westbrook III, Head of US Segment Accounting



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. SUR0073955

Application/License No. _____

CATALENT GREENVILLE, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5440 Martin Luther King Jr Highway Greenville, NC 27834 (Address of Applicant/Principal), as PRINCIPAL, and ARGONAUT INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is P.O. Box 469011 San Antonio, TX 78246 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 9, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 9th day of November, 20 22.

APPLICANT/PRINCIPAL
CATALENT GREENVILLE, INC

Authorized Representative

SURETY COMPANY
ARGONAUT INSURANCE COMPANY

Surety Company's Representative

Frances Rodriguez, Attorney-in-fact
print name

SIGNED and SEALED in the presence of

Witness

Witness

SIGNED and SEALED in the presence of

Witness Halina Kazmierczak

Witness Sandra Diaz

Countersigned by:

N/A
Nevada Resident Agent

Argonaut Insurance Company
Deliveries Only: 225 W. Washington, 24th Floor
Chicago, IL 60606
United States Postal Service: P.O. Box 469011, San Antonio, TX 78246
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the Argonaut Insurance Company, a Corporation duly organized and existing under the laws of the State of Illinois and having its principal office in the County of Cook, Illinois does hereby nominate, constitute and appoint:

Sandra Diaz, Debra A Deming, Anne Potter, Beverly A Woolford, Valorie Spates, Jennifer L Jakaitis, Susan A Welsh, Peter Healy, Nancy Schiree, Alvina Noorhassan, Frances Rodriguez, Francesca Kazmierczak, Kemal Brkanovic

Their true and lawful agent(s) and attorney(s)-in-fact, each in their separate capacity if more than one is named above, to make, execute, seal and deliver for and on its behalf as surety, and as its act and deed any and all bonds, contracts, agreements of indemnity and other undertakings in suretyship provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed the sum of

$97,550,000.00

This Power of Attorney is granted and is signed and sealed under and by the authority of the following Resolution adopted by the Board of Directors of Argonaut Insurance Company:

"RESOLVED, That the President, Senior Vice President, Vice President, Assistant Vice President, Secretary, Treasurer and each of them hereby is authorized to execute powers of attorney, and such authority can be executed by use of facsimile signature, which may be attested or acknowledged by any officer or attorney, of the Company, qualifying the attorney or attorneys named in the given power of attorney, to execute in behalf of, and acknowledge as the act and deed of the Argonaut Insurance Company, all bond undertakings and contracts of suretyship, and to affix the corporate seal thereto."

IN WITNESS WHEREOF, Argonaut Insurance Company has caused its official seal to be hereunto affixed and these presents to be signed by its duly authorized officer on the 19th day of November, 2021

Argonaut Insurance Company

ARGONAUT INSURANCE COMPANY CORPORATE SEAL 1948 ILLINOIS

by:

Gary E. Grose, President

STATE OF TEXAS
COUNTY OF HARRIS SS:

On this 19th day of November, 2021 A.D. before me, a Notary Public of the State of Texas, in and for the County of Harris, duly commissioned and qualified, came THE ABOVE OFFICER OF THE COMPANY to me personally known to be the individual and officer described in, and who executed the preceding instrument, and he acknowledged the execution of same, and being by me duly sworn, deposed and said that he is the officer of the said Company aforesaid, and that the seal affixed to the preceding instrument is the Corporate Seal of said Company, and the said Corporate Seal and his signature as officer were duly affixed and subscribed to the said instrument by the authority and direction of the said corporation, and that Resolution adopted by the Board of Directors of said Company, referred to in the preceding instrument is now in force August

IN TESTIMONY WHEREOF, I have hereunto set my hand, and affixed my Official Seal at the County of Harris, the day and year first above written

KATHLEEN M MEEKS
NOTARY PUBLIC
STATE OF TEXAS
MY COMM. EXP. 07/15/25
NOTARY ID 557902-8

Kathleen M. Meeks

(Notary Public)

I, the undersigned Officer of the Argonaut Insurance Company, Illinois Corporation, do hereby certify that the original POWER OF ATTORNEY of which the foregoing is a full, true and correct copy is still in full force and effect and has not been revoked

IN WITNESS WHEREOF, I have hereunto set my hand, and affixed the Seal of said Company, on the 9th day of November 2022

ARGONAUT INSURANCE COMPANY CORPORATE SEAL 1948 ILLINOIS

Austin W. King, Secretary

IF YOU HAVE QUESTIONS ON AUTHENTICITY OF THIS DOCUMENT CALL (833) 820 - 9137.

ARGO POWER OF ATTORNEY

FINANCIAL STATEMENT
ARGONAUT INSURANCE COMPANY
STATUTORY BASIS as of 12/31/2021

ASSETS	
CASH & INVESTED ASSETS	$248,880,956
BONDS	$1,181,510,880
STOCKS	$674,977,267
INVESTMENT INCOME DUE AND ACCRUED	$5,760,648
PREMIUM BALANCES	$114,829,986
NET DEFERRED TAX ASSET	$31,325,137
REINSURANCE RECOVERABLE	$97,560,864
OTHER ASSETS	$40,514,092
TOTAL ASSETS	$2,392,360,630

LIABILITIES AND SURPLUS	
UNEARNED PREMIUMS	$304,943,789
LOSSES	$595,583,927
LOSS ADJUSTMENT EXPENSES	$198,243,975
COMMISSIONS	-$4,787,791
TAXES, LICENSES, AND FEES	$10,269,846
OTHER EXPENSES	$9,373,605
FUNDS HELD UNDER REINSURANCE TREATIES	$72,371,315
CURRENT FEDERAL AND FOREIGN INCOME TAXES	$0
REMITTANCES AND ITEMS NOT ALLOCATED	$2,510,048
AMOUNTS WITHHELD/RETAINED BY COMPANY FOR OTHERS	$11,771,686
PAYABLES TO PARENT, SUBSIDIARIES, & AFFILIATES	$52,193,204
PAYABLE FOR SECURITIES	$3,599,489
PROVISION FOR REINSURANCE	$16,445,734
CEDED REINSURANCE PREMIUMS PAYABLE	$47,083,249
OTHER ACCRUED EXPENSES AND LIABILITIES	$1,997,817
TOTAL LIABILITIES	$1,321,201,703
COMMON CAPITAL STOCK	$4,500,000
GROSS PAID IN AND CONTRIBUTED SURPLUS	$535,520,936
UNASSIGNED SURPLUS	$541,137,091
TOTAL SURPLUS TO POLICYHOLDERS	$1,071,158,927
TOTAL LIABILITIES & SURPLUS	$2,392,360,630

Jace Westbrook, being duly sworn, says that he is Head of US Segment Accounting of Argonaut Insurance Company and that to the best of his knowledge, and belief, the foregoing statement is a true and correct statement of the financial condition of said Company as of the 31st of December, 2021.

Subscribed and sworn to before me this 5th day of April 2022

Notary Public

Julian Sandler Westbrook III, Head of US Segment Accounting

CORPORATE SEAL ILLINOIS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Catalent Greenville, Inc. (formerly licensed as Mayne Pharma, Inc.)

Pharmacy/Wholesaler License # (if applicable): WH02987

Physical Address: 1240 Sugg Parkway

City: Greenville State: NC Zip: 27834

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: (252) 752-3800 Website: www.catalent.com

Licensing Company Email: GMB-CatalentGreenvilleInc@catalent.com

Section 2: Personal Information

First: Michael Middle: Kirk Last: Rogerson

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address:

City: Greenville State: NC Zip: 27834

Telephone: (252) 752-3800 Email: GMB-CatalentGreenvilleInc@catalent.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
East Carolina University		08/81-12/84	
Address	City	State	Zip
	Greenville	NC	27858
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Washington High School		08/78-06/81	
Address	City	State	Zip
	Washington	NC	27889
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18 - Present	[redacted]Oxford Rd	Greenville	NC	27858
From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/12 -12/18	[redacted] Bloomsbury Rd	Greenville	NC	27858
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Mayne Pharma, Inc			01/19 - 10/22	
Business Address		**City**	**State**	**Zip**
1240 Sugg Parkway		Greenville	NC	27834
Phone	**Title**		**Number of Employed Hours**	
252-707-6439	Sr. Logistics Manager		6000	
Description of Duties				
Managed logistics/supply chain group.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/01/2022
Date

I, Michael Kirk Rogerson, **certify that as the designated representative for**

Catalent Greenville, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MKR I am at least 21 years of age;
3. MKR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MKR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MKR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MKR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MKR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michael Rogerson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/01/2022
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Rogerson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/01/2022

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Pitt

I, MICHAEL KIRK ROGERSON, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01 DEC 2022

Date

Subscribed and Sworn to before me this 01 day of December.

Rachel L. Rasberry

Notary Public Signature

RACHEL L. RASBERRY
Notary Public
Pitt
County
My Comm. Exp.
05-15-2023
NORTH CAROLINA

(Seal)

Attachment E

Employee List	
Legal Name - Last Name	**Legal Name - First Name**
Allette	Acacia
Allette	Miriam
Alonso	Jeymi
Alston	Tyrek
Alzer	Fatima
Ambrose	Michael
Anaya	Michael
Anderson	Suzanne
Anthony	Jessica
Arnold	Rebecca
Artuso	Mackenzie
Askew	Timothy
Asmar	Sara
Awere	Edward
Babar	Digvijay
Barnes	Eric
Barrios	Alexia
Barry	Lindzie
Barth	Curtis
Bartley	Shawn
Basden	William
Batts	Charlton
Baxley	Tamatha
Becker	Ryan
Beissner	Brad
Bell	Harry
Beltran Bejarano	Cristhian
Berry	Terry
Best	Colene
Blackard	Warren
Bogard	David
Bonfiglio	Jamie
Bordner	Angela
Bowen	James
Bowen	Jeffery
Bowers	Tess
Carrow	Matthew
Boyce	Takiyest
Branch	Carl
Bratton	Bruce
Brewer	Brittany
Brewer	Justin
Brewer	Richard
Brickhouse	Wesley

Brown	Jerry
Brown	Linwood
Bryan	Ivory
Buck	Ashley
Bullard	Joshua
Bunn	William
Burgos Aguilar	Julio
Burke	Loralea
Bush	Mercedes
Butcher	Katherine
Calvo	William
Campbell	Terrance
Carlis	Christopher
Carr	Travis
Padley	Joseph
Carrow	Paul
Casteen	Charles
Castor	Morgan
Cherok	Courtney
Chilton	Matthew
Clark	Michael
Clark	Rodney
Clift	Shaelyn
Clipperton	Randall
Cocolas	Harry
Coleman	Jordan
Combs	Juliana
Cortes	Dylan
Cotter	Christie
Coward	Kristin
Cox	Peggy
Cox	Will
Credle	Kenneth
Creech	Clyde
Croom	Josh
Crutchfield	Deborah
Cummings	Kasey
Cutler	Harold
Dail	Cynthia
Daly	Debra
Dancy	Debra
Daniels	Dylan
Daniels	Emmanuel
Daniels	Jesse
Dattilo	Lauren
Davenport	Alison
Davis	Bonnie
Davis	Damius

Davis	David
Day	Chadwick
de Araujo Melo	Rahyanne
Decker	Amber
DeRose	Luciano
Dickerson	Scott
Dionne	Matthew
Dixon	Alan
Dixon	Brian
Dixon	Lakia
Doetzl	Eric
Donadio	Kyle
Donehoo	Martin
Dover	Lloyd
Dowell	Matthew
Downing	Jalisa
Ducharme	Jodie
Dunn	Jonathon
East	Julianne
Edwards	Ashton
Edwards	Ryan
Elicati	Gino
Elks	James
Emerson	Michael
Emory	Stephanie
Epps	Robert
Euler	Hailey
Evans	Lisa
Ewell	Scott
Fairweather	Haidyn
Faughnan	Caitey
Faulkner	Grayson
Faulkner	Julianne
Foster	Dylan
Foster	Milton
Fowler	Kelli
Franklin	Dustin
French	William
Friend	Scott
Fucci	Megan
Fugit	Kyle
Gadson Brown	Kyana
Gainer	Richard
Galloway	Joshua
Garcia Reyes	Veronica
Gardner	Franklin
Gardner	Richard
Garrell	Justin

Garrett	Kristi
Garris	Jillia
Gaskins	Janet
Geiger	Micah
Genovese	Steven
Gilbert	Jennifer
Gillikin	Justin
Gilmore	Kayla
Ginn	Carolyn
Gladson	Amy
Gladson	David
Glisson	Jason
Godard	John
Godard	Lucas
Godley	William
Gold	Thomas
Goldson	Victoria
Gonzalez	Maria
Gooding	Ringo
Grady	Gail
Gray	Breigh
Gray	Christina
Green	Stacey
Green	William
Greer	Thomas
Griffin	Allison
Griffin	Jerry
Grubich	Nicholas
Gupte	Anshul
Gutierrez Nuno	Jimena
Hammons	Katie
Harleaux-Lopez	Nicholas
Harper	Delora
Harrell	Tabitha
Harris	Dylan
Harris	Henry
Harris	Raybon
Hawkins	Dana
Heckman	Russell
Henne	Michele
Hill	David
Hogan	Garrett
Holiday	Latricia
Holzkamm	Rebecka
Honeycutt	Joseph
Hooter	Paul
Hormilla	Maxwell
Horton	Holly

Howell	Steven
Huff	Thomas
Hunt	Brett
Huynh	Diana
Hyatt	Jacob
Ingles	Daniel
Israel	William
Jefferson	Holly
Jenkins	Austin
Jenkins	Melvin
Johnson	Kimberly
Jones	Kenneth
Jones	Lauren
Jones	Seth
Kancharla	Joseph Paul
Kearney	Kenneth
Kelly	Devon
Kettler	Caleb
Kiely	Richard
Kinion	Chase
Kinkton	James
Kiser	Christopher
Knox	Derrick
Kobylkevich	Myriam
Kunkel	Cooper
Lassiter	Gerald
Latham	Clarence
Lawrence	Kendall
Lawson	Allen
Lawson	Christopher
Leary	David
Leitschuh	Tori
Lomas	Karen
Lynch	Jaylin
Lynn	Brandon
Majette	Elizabeth
Mallard	Todd
Manning	Jessica
Marshburn	Timothy
Martens	Christian
Mason	Sammy
Mattheu	Emily
Mccarter	Mary A
Mccotter	Kamal
McCoy	Michelle
McCoy	Steven
McDaniel	Timothy
McGuire	Gregory

McLawhorn	Avery
McLawhorn	Matthew
McNally	James
McNeill	John
Meeks	Joseph E
Melton	Andrew
Miles	Kristen
Mills	Amanda
Mills	Blake
Miranda Colon	Zenaida
Mizell	Jerry
Mizelle	Allen
Moore	Rachel
Whitehurst	Jeffrey
Morris	Patricia
Morris	Teresa
Morrow	Leslie
Mukadam	Ninad
Murchison	Ashley
Navarro	Michelle
Neal	Ellis
Neal	Jerry
Nelson	David
Nelson	Gregory
Nelson	Melissa
Newman	Chivonne
Nguyen	Hien
Norman	Phawn
ONeal	Gary
Boyce	Dontre
Pannell	Robert
Papageorge	William
Paramore	William
Parker	Kay
Parrish	Sherry
Pate	Michelle
Pate	Troy
Patel	Aditya
Patel	Monika
Payton	William
Peaden	Jeannette
Pence	Leyna
Perry	Jacob
Peterson	Alston
Peterson	Evan
Phelps	Brandon
Philbee	Timothy
Phillips	Amber

Pick	Nicholas
Plumley	Zoe
Podruchny	Walter
Pofahl	Walter
Poole	Kevin
Popovich	Anthony
Popovich	Jennifer
Poston	Elizabeth
Powell	Matthew
Prayer	Torrey
Price	Gilley
Price	Jacob
Price	Michael
Proctor	Matthew
Pryor	Sterling
Rambert	Shantez
Randolph	Diantha
Rasberry	Rachel
Raynor	Alex
Reichardt	Randi
Reyes	Alba
Rhodes	Leah
Rice	Franklin
Richardson	Allison
Riggs	Gary
Riley	Trisha
Rios	Nicolas
Rivera	Lesly
Rivera Rios	Jonathan
Roberson	Tracey
Robinson	Kaylynn
Rodriguez	Clemente
Rogers	Jeffrey
Rogerson	Becky
Rogerson	Jerry
Rogerson	Michael
Rogerson	Robert
Ross	John
Ryan	Heather
Sadhale	Yogesh
Saleh	Waleed
Sanchez	Fabricio
Sanford	Monica
Scannell	Teisha
Sesma	Sarabeth
Shaf	Bernard
Shanken	Michael
Sheppard	Cheryl

Sheppard	Vonda
Shirley	Jonathan
Simonetti	Nicholas
Simpkins	Bradley
Simpson	Julie
Singleton	Clarence
Singleton	Lewis
Sloan	Binford
Smith	Christopher
Smith	DeJuan
Smith	Matthew
Smith-Joyner	Annalisa
Soroko	Jacob
Southerlin	Sierra
Spear	Camron
Spruill	Christopher
Stallings	Steven
Stancill	Wendy
Staton	William
Steinert	Ralph
Stephens	Javonna
Stocks	Tommy
Stokes	Angelina
Stox	Merritt
Streeter	Lenora
Styons	Ellen
Suarez	Gracie
Suozzo	Sandra
Suter	Elizabeth
Sutton	Holly
Sweet	Chris
Szumigala	Craig
Tanhauser	Justin
Taylor	Robert
Taylor	Tony
Tello Lopez	Zoila
Terlizzi	Francesca
Terry	Crystal
Terry	William
Thereault	Brian
Thomas	Garland
Thomas	Logan
Thota	Shyam Sunder
Tice	Shayna
Tolson	Lory
Trimble	Malcolm
Trimpi	Benjamin
Tubi	Olaitan

Tucciarone	Patricia
Turner	Tia
Tyndall	Karen
Tyree	Jonathan
Tyson	Troy
Vaughan	Susan
von Lehmden	Thomas
Walden	Glenn
Waldrop	Kenneth
Walker	Charles
Wantland	Sidney
Ward	Brandon
Ward	Brett
Warren	Jimmy
Watkins	Gerald
Webb	Daniel
Webb	Erica
Whitaker	Alexander
Whitaker	Hayley
Whitaker	Leticia
Whitaker	Matthew
White	Ashlee-Danielle
White	Caitlin
White	Dylan
White	Gregory
White	Lemont
Wiggins	Travis
Whitford	Lindsey
Whitworth	Tenesha
Moore	Zavian
Wiggs	Lisa
Wilkes	Brittany
Williams	Ainsley
Williams	Alneeiqua
Williams	Christopher
Williams-Dixon	Tonya
Wilson	Ashleigh
Wilson	Tony
Woelfel	Troy
Woolard	Carlton
Woolard	Christopher
Woolard	Marshall
Wurtele	Heather
Wynn	Mason

40

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Y

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Chewy Wholesale, LLC

Physical Address: 255 South 143rd Ave, Suite C

City: Goodyear State: AZ Zip: 85338

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 623-932-8158 Website: _____

Name of Designated Representative (DR): Jill Mehrer

Licensing Company Email: PharmacyLicensing@chewy.com DR Email: jmehrer@chewy.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☒ Veterinarians		☒ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Jill Meme
Original Signature (electronic, copies or stamps not accepted)

2/28/2023
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 1950 W. Oak Circle City: 1950 W. Oak Circle State: GA Zip: 30062
Name: Elanco
Address: 2500 Innovation Way City: Greenfield State: IN Zip: 46140
Name: PetIQ
Address: 530 Fentress Blvd City: Daytona Beach State: FL Zip: 32114
Name: The Harvard Drug Group
Address: 5960 E SHELBY DR City: MEMPHIS State: TN Zip: 38141

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Chewy, Inc.
Corporation/Organization Name: Chewy Wholesale, LLC
Mailing Address: 7700 West Sunrise Blvd
City: Plantation State: FL Zip: 33322
Telephone: 617-755-0591 Email: PharmacyLicensing@chewy.com Contact Person Name: Magan Wagner

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Chewy Wholesale, LLC

Facility Name

Jill Mehrer

Print Name of Authorized Person Submitting Application

Jill Mehrer

Original signature of Authorized Person (copies or stamps not accepted)

2/28/2023

Date

Board Use Only	Date Received: 8/28/23	Amount: 1000.00



	A	B
1	**NDC/NHRIC Labeler**	**Firm Name**
4674	0182	Teva Pharmaceuticals Development, Inc.
4675	62670	Bath & Body Works, Inc.
4676	74489	UbiQD, Inc.
4677	72769	BioCryst Pharmaceuticals, Inc.
4678	73845	Lost & Found Distillery, Inc
4679	66394	Sandoz Private Limited
4680	0799	Calmoseptine Inc.
4681	50452	Phoenix Research Industries, Inc.
4682	66829	Novartis Ringaskiddy Limited
4683	73536	Pharmaessentia Usa Corporation
4684	73231	Skin Innovations LLC
4685	51942	Jiangxi Dadi Pharmaceutical Limited Liability Company
4686	13298	ALFA VITAMINS LABORATORIES INC
4687	86109	Chewy, Inc.
4688	69559	MARYHELEN ORIENTAL MEDICINE RESEARCH
4689	82966	Blip Products, Inc.
4690	55676	SHANDONG HELI DAILY NECESSITIES CO.,LTD

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Chewy Wholesale, LLC Officers List and Corporate Shareholder Information:

Name	Title / Percent of Ownership	Business Address
Chewy Wholesale, LLC	Owner, 100%	7700 West Sunrise Blvd, Plantation, FL 33322
Ornel Cotera	President, 0%	7700 West Sunrise Blvd., Plantation, FL 33322
Justin Mills	Vice President, 0%	2815 Watterson Trail, Louisville, KY 40299

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CHEWY WHOLESALE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF APRIL, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

7115452 8300

SR# 20193028943

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication:

202682438 Date: 03-22-23

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 09/08/2023
Receipt Number: 2023154766
Receipt Amount $: 1000.00

Wholesaler - Full Service

PERMIT NO
W003587

EXPIRES
10/31/2025

Issued to :

Chewy Wholesale, LLC
Chewy Wholesale, LLC
255 SOUTH 143RD AVE SUITE C
GOODYEAR, AZ 85338

Chewy Wholesale, LLC
255 SOUTH 143RD ST SUITE C
GOODYEAR, AZ 85338

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF
PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Chewy Wholesale, LLC
LICENSE NUMBER : W003587
EXPIRES : 10/31/2025

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

• Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
• You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

• Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
• In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
• Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.

• Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

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Chewy Wholesale, LLC is not a DEA registrant and does not dispense controlled substances at this time.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 12/15/2021

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Insurance Services West, Inc.
Phoenix AZ Office
2555 East Camelback Rd.
Suite 700
Phoenix AZ 85016 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Safety National Casualty Corp	15105
INSURER B:	XL Specialty Insurance Co	37885
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Chewy, Inc.
1855 Griffin Road, Suite B-428
Dania Beach FL 33004 USA

COVERAGES **CERTIFICATE NUMBER:** 570090631836 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			GL4064502	02/12/2023	02/12/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR			SIR applies per policy terms & conditions			DAMAGE TO RENTED PREMISES (Ea occurrence)	$500,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$5,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$4,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			CA6675895	02/12/2023	02/12/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY X SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
B	X UMBRELLA LIAB X OCCUR			US00107790LI21A	02/12/2023	02/12/2024	EACH OCCURRENCE	$10,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$10,000,000
	DED X RETENTION $10,000							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			LDS4064501	02/12/2023	02/12/2024	X PER STATUTE OTH	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A					E.L. EACH ACCIDENT	$1,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Western Veterinary Conference, Mandalay Corp., Mandalay Bay Resort and Casino and Freeman and their respective directors, officers, employees, agents, representatives, parent companies, subsidiaries and affiliates and any additional entities as required by Mandalay Corp., the "Insured Entities" are included as Additional Insured in accordance with the policy provisions of the General Liability and Automobile Liability policies. General Liability evidenced herein is Primary & Non Contributory to other insurance available to an Additional Insured, but only in accordance with the policy provisions.

CERTIFICATE HOLDER

WVC
dba Viticus Group
2425 E. Oquendo Rd.
Las Vega NV 89120 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Insurance Services West Inc.

Holder Identifier :

Certificate No : 570090631836

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AGENCY CUSTOMER ID: 570000080467

LOC #:

ADDITIONAL REMARKS SCHEDULE

Page _ of _

AGENCY	NAMED INSURED
Aon Risk Insurance Services West, Inc.	Chewy, Inc.
POLICY NUMBER: See Certificate Number: 570090631836	
CARRIER: See Certificate Number: 570090631836 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insured Listing

The following are included as Named Insureds under the referenced policies:

Chewy, Inc.
American Journey, LLC
Chewy Pharmacy, LLC
Chewy Promotions LLC
Chewy Wholesale, LLC
CF Services LLC
Dania Pet Goods, LLC
Dr. Lyon's, LLC
Lab 11, LLC
Spot 11, LLC
Onguard Pet Products, LLC
Paw & Parcel Food Co, LLC
Tiny Tiger, LLC
Tylee's, LLC

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NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 285071853

Application/License No. _____

CHEWY WHOLESALE LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 255 South 143rd Avenue, Suite C Goodyear, AZ 85338 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 1, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 8th day of February, 2023.

APPLICANT/PRINCIPAL
CHEWY WHOLESALE LLC

COMPANY

Authorized Representative

SURETY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Derek J. Elston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of

Witness Ricky Casas

Witness Ann Formhals

Countersigned by

Nevada Resident Agent

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8209007-285057

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aerie Walton, Bartlomiej Siepierski, Christina L. Sandoval, Christopher P. Troha, Corinne Chapman, Dartonya Wright, Derek J. Elston, James B. McTaggart, Jean Torres, Jennifer L. Jakaitis, Jennifer Williams, Jessica B. Dempsey, Judith A. Lucky-Eftimov, Kristin L. Hannigan, Melissa L. Fortier, Nicholas Kertesz, Rachel Fore, Roger Paraison, Samantha Chierici, Sandra M. Winsted, Susan A. Welsh, Tara A. Reimer

all of the city of Chicago state of IL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of November, 2022.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 15th day of November, 2022 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 8th day of February, 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Chewy Wholesale, LLC — MDEG License # (if applicable): _____

Physical Address: 255 South 143rd Ave, Suite C

City: Goodyear — State: AZ — Zip: 85338

Mailing Address (if different from physical address): _____

City: _____ — State: _____ — Zip: _____

Telephone: (623) 932-8158 — Website: _____

Licensing Company Email: Pharmacylicensing@chewy.com

Section 2: Personal Information

First: Jill — Middle: Diane — Last: Mehrer

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]E Rafael Ave

City: Mesa — State: AZ — Zip: 85212

Telephone: [redacted] — Email: jmehrer@chewy.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed)

School Name		From - To (MM/YY – MM/YY)	
University of Arizona College of Pharmacy		08/98-05/02	
Address	City	State	Zip
1295 N. Martin Ave	Tucson	AZ	85721
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
fUniversity of Arizona		08/95-05/98	
Address	City	State	Zip
1200 E University Blvd.	Tucson	AZ	85721
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Mountain View High School		08/92-05/95	
Address	City	State	Zip
2700 E Brown Rd	Mesa	AZ	85213
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/12- Current	[redacted] E. Rafael Ave	Mesa	AZ	85212
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Chewy Wholesale LLC		05/21- Current	
Business Address	**City**	**State**	**Zip**
255 S. 143rd Ave Suite C	Goodyear	AZ	85338
Phone	**Title**	**Number of Employed Hours**	
623-932-8158	Designated Representative	3,440	

Description of Duties
Develop/Implement/Maintain P&P and SOP. Inventory Management. Responsible for distribution operations for a full-service drug distributor including vendor verification, receipt, and distribution of veterinary pharmacy products.

Business Name		From - To (MM/YY – MM/YY)	
Chewy Pharmacy		03/20-05/21	
Business Address	**City**	**State**	**Zip**
255 S. 143rd Ave Suite B	Goodyear	AZ	85338
Phone	**Title**	**Number of Employed Hours**	
623-850-3556	Staff Pharmacist	2,360	

Description of Duties
Drug utilization review of prescription orders. Verification of filled prescription orders.

Business Name		From - To (MM/YY – MM/YY)	
CVS Health		02/10-03/20	
Business Address	**City**	**State**	**Zip**
325 W. Apache Trail	Apache Junction	AZ	85120
Phone	**Title**	**Number of Employed Hours**	
480-932-1129	Pharmacy Manager	22,880	

Description of Duties
Responsible for all operations of a retail pharmacy including, inventory, compliance, regulatory and staffing.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.	✔	

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
04/14/2021	5/23/2021	AZ	Phoenix	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21-0185		Arizona Board of Pharmacy		
Reason/Charge				
Under reporting of continuing education hours required during a renewal				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Jill Diane Mehrer				
Name of Business/Industry/Entity				

Provide explanation below:

The Arizona Board of Pharmacy issued a disciplinary action against me for submitting my license renewal prior to completing my required CEs. On October 21, 2020, I submitted and paid for my Arizona pharmacist license renewal. At that time, I had completed 4.5 of the required 30 hours of CE. I mistakenly believed I had until October 31, 2021, to complete the remaining CEs to remain compliant with the regulation. Between October 21, 2020, and October 31, 2020, I completed 29 CEs, bringing me to a total of 33.5 CE hours for the two-year licensure period of 11/1/2018 to 10/31/2020. It was not my intent to deceive or mislead the Arizona Board of Pharmacy in any way. I truly believed I had until October 31, 2020, to complete the remaining required CEs.

As part of my consent agreement with the Arizona Board of Pharmacy I was fined $2,550.00 and required to complete 45 CEs for the next renewal period. I have paid the fine in full and completed the required CEs. The Arizona Board of Pharmacy has lifted all blocks to my next license renewal.

Jill Mehrer
Original Signature (electronic, copies or stamps not accepted)

2/28/2023
Date

I, Jill Mehrer Pharm D., **certify that as the MDEG Administrator for**

Chewy Wholesale, LLC,

that I (initial that you have read and meet the following requirements):

1. JM Have a high school diploma or its equivalent;
2. JM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jill Mehrer
Print Name (First, Last)

JillMehrer
Original Signature (electronic, copies or stamps not accepted)

2/28/2023
Date

Board Use Only	Date Received: 3.14.23

chewy | Health

Dear Board of Pharmacy,

The Arizona Board of Pharmacy issued a disciplinary action against me for submitting my license renewal prior to completing my required CEs. On October 21, 2020, I submitted and paid for my Arizona pharmacist license renewal. At that time, I had completed 4.5 of the required 30 hours of CE. I mistakenly believed I had until October 31, 2021, to complete the remaining CEs to remain compliant with the regulation. Between October 21, 2020, and October 31, 2020, I completed 29 CEs, bringing me to a total of 33.5 CE hours for the two-year licensure period of 11/1/2018 to 10/31/2020. It was not my intent to deceive or mislead the Arizona Board of Pharmacy in any way. I truly believed I had until October 31, 2020, to complete the remaining required CEs.

As part of my consent agreement with the Arizona Board of Pharmacy I was fined $2,550.00 and required to complete 45 CEs for the next renewal period. I have paid the fine in full and completed the required CEs. The Arizona Board of Pharmacy has lifted all blocks to my next license renewal.

To prevent this occurring in the future, I will not renew any licenses prior to completing all CEs for the licensure period.

Sincerely,

Jill Mehrer, RPh
Designated Representative of Chewy Wholesale, LLC
255 South 143rd Avenue, Suite C
Goodyear, AZ 85338

MARK BRNOVICH
Attorney General
(Firm State Bar No. 14000)

JEANNE M. GALVIN
Assistant Attorney General
State Bar No. 015072
SETH T. HARGRAVES
Assistant Attorney General
State Bar No. 020176
2005 N. Central Ave., SGD/LES
Phoenix, Arizona 85004-1592
Tel: (602) 542-7983
Tel: (602) 542-7672
Fax: (602) 364-3202

Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of **JILL DIANE MEHRER** Holder of License No. S013310 As A Licensed Pharmacist In the State of Arizona	Board Case No. 21-0185 **CONSENT AGREEMENT FOR CIVIL PENALTY, CONTINUING EDUCATION AND AUDIT**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.* Jill Diane Mehrer ("Respondent"), holder of license S013310 as a Pharmacist in the State of Arizona and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

RECITALS

1. Respondent has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Respondent understands that she has a right to a public administrative hearing concerning this matter at which hearing he could present evidence and cross examine witnesses. By entering into this Consent Agreement, Respondent knowingly and voluntarily relinquishes all right to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Respondent affirmatively agrees that this Consent Agreement shall be irrevocable.

4. Respondent understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against her.

5. Respondent understands this Consent Agreement deals with Case No. 21-0185 involving allegations of unprofessional conduct against Respondent. The investigation into these allegations against respondent shall be concluded upon the Board's adoption of this Consent Agreement.

6. Respondent acknowledges and agrees that the acceptance of this Consent Agreement is solely to settle this Board matter and does not preclude the Board from instituting other proceedings as may be appropriate now or in the future.

7. Respondent understands that this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

8. Furthermore, and notwithstanding any language in this Consent Agreement, this Consent Agreement does not preclude in any way any other state agency or officer or political subdivision of this state from instituting proceedings, investigating claims, or taking legal action as may be appropriate now or in the future relating to this matter other matters concerning Respondent, including violations of Arizona's Consumer Fraud Act.

Respondent acknowledges that, other than with respect to the Board, this Consent Agreement makes no representations, implied or otherwise, about the views or intended actions of any other state agency or officer or political subdivision of the state relating to this matter or other matters concerning Respondent.

9. Respondent acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, she may not revoke acceptance of the Consent Agreement or make any modifications to the document regardless of whether the Consent Agreement has been signed by the Executive Director. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

10. This Consent Agreement is subject to the approval of the Board and is effective only when accepted by the Board and signed by the Executive Director. In the event that the Board does not approve this Consent Agreement, it is withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that should the Board reject this Consent Agreement and this case proceeds to hearing, Respondent shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

11. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

12. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

13. The parties understand and agree that Portable Document Format and facsimile copies of this Consent Agreement including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

14. Respondent understands that any violation of this Consent Agreement constitutes unprofessional conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(B)(20) and A.R.S. §32-1927(A)(1).

15. Respondent agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

.

ACCEPTED AND AGREED BY RESPONDENT

_____ Dated: _____

Jill Diane Mehrer
Pharmacist

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Respondent is the holder of license S013310 as a Pharmacist.

3. On or about October 21, 2020, Respondent filed his application for license renewal. Respondent answered "YES" to question no. 4 asking "Have you complied with the continuing education requirements set forth in A.A.C R4-23-411?" thereby attesting that he had completed the required thirty (30) continuing education (CE) hours during the two year period preceding his renewal.

4. On or about April 14, 2021, the Board staff conducted a continuing education audit that included Respondent (licensees are selected at random).

5. Prior to reaching out to Respondent, the Board staff reviewed the CPE Monitor and discovered that Respondent had only completed 4.5 of the 30 hours of continuing education during the audit time period.

6. Board staff sent Respondent an email on April 14, 2021, asking that she provide additional information showing completion of the required CE.

7. On April 15, 2021, Respondent submitted an email with completed CE information. The information provided showed that Respondent had only completed 4.5 of the required CE during the audit time period.

8. Upon information and belief, Respondent was short twenty-five and one-half (25.5) CE hours required for renewal of a Pharmacist license.

CONCLUSIONS OF LAW

1. The Board possesses jurisdiction over the subject matter and over Respondent pursuant to A.R.S. § 32-1901 *et seq.*

2. The Board may discipline a Pharmacist who has engaged in unprofessional conduct. A.R.S. § 32-1927(A)(1).

3. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(B)(4) "Obtaining or attempting to obtain a license to practice pharmacy or a license renewal by fraud, by misrepresentation or by knowingly taking advantage of the mistake of another person or an agency."

4. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(B)(7) "Failing to comply with the mandatory continuing professional pharmacy education requirements of sections 32-1936 and 32-1937 and rules adopted by the board."

5. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(B)(17) "Knowingly filing with the board any application, renewal or other document that contains false or misleading information."

6. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(B)(18) "Providing false or misleading information or omitting material information in any communication to the board or the board's employees or agents."

7. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(B)(19) "Violating or attempting to violate, directly or indirectly, or assisting in or abetting in the violation of, or conspiring to violate, this chapter.", specifically as it relates to A.R.S. § 32-1936 and A.A.C. R4-23-204.

ORDER

Based upon the above Findings of Fact and Conclusions of Law, IT IS HEREBY ORDERED THAT:

1. Respondent shall pay to the Board as a civil penalty the sum of Two Thousand Five Hundred Fifty Dollars (**$2,550.00 [$100.00 per deficient CE hour]**). The civil penalty shall be paid in full to the Board within **ninety (90) days** of the effective date of this Consent Agreement and Order. The effective date of this Consent Agreement is the date it is signed by the Board's Executive Director.

2. In addition, Respondent shall complete a total of **forty-five (45) continuing education hours for the next renewal period ending October 31, 2022.**

3. Respondent is also subject to a mandatory audit of his continuing education requirements for the 2020-2022 renewal cycle.

4. **IF RESPONDENT FAILS TO TIMELY COMPLY WITH THIS CONSENT AGREMENT AND ORDER, THE MATTER SHALL BE REFERRED TO FORMAL HEARING FOR THE SUSPENSION OR REVOCATION OF HIS LICENSE.** Failing to abide by this Consent Agreement and Order is a violation of A.R.S. §32-1901.01(B)(20), which is violating a formal order, terms of probation, a consent agreement or a stipulation issued or entered into by the board it its executive director. The issue at such a hearing will be limited solely to whether this Order has been violated.

5. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action.

DATED this 3rd day of August, 2021.

ARIZONA STATE BOARD OF PHARMACY

By: _____
KAMLESH GANDHI, PharmD
Executive Director

ORIGINAL OF THE FORGOING FILED
this 3rd day of August, 2021 with:

Arizona State Board of Pharmacy
1616 W. Adams Street
Phoenix, Arizona 85007

EXECUTED COPY OF THE FOREGOING MAILED
BY CERTIFIED MAIL
this 3rd day of August, 2021, to:

Jill Diane Mehrer
[redacted] E Rafael Ave
Mesa, AZ 85212
jill.mehrer@gmail.com

EXECUTED COPY OF THE FOREGOING MAILED
Mail this 3rd day of August, 2021, to:

Jeanne Galvin
Seth T. Hargraves
Arizona Attorney General's Office
2005 N. Central Ave. – SGD/LES
Phoenix, AZ 85004
Attorneys for the Board

JMitchell

Doc #9473459

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

4

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Chewy Wholesale, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 255 South 143rd Ave, Suite C

City Goodyear State AZ Zip 85338

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (623) 932-8158 Website _____

Licensing Company Email Pharmacylicensing@chewy.com

Section 2: Personal Information

First Jill Middle _____ Last Mehrer

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] E Rafael Ave

City Mesa State AZ Zip 85212

Telephone [redacted] Email jmehrer@chewy.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Arizona College of Pharmacy		08/98-05/02	
Address	**City**	**State**	**Zip**
1295 N. Martin Ave	Tucson	AZ	85721
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Arizona		08/95-05/98	
Address	**City**	**State**	**Zip**
1200 E University Blvd.	Tucson	AZ	85721
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Mountain View High School		08/92-5/95	
Address	**City**	**State**	**Zip**
2700 E Brown Rd.	Mesa	AZ	85213
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/12-Current	[redacted] E Rafael Ave	Mesa	AZ	85212
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of and/or record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Chewy Wholesale LLC		05/21-Current	
Business Address	City	State	Zip
255 S. 143rd Ave Suite C	Goodyear	AZ	85338
Phone	Title	Number of Employed Hours	
623-932-8158	Designated Representative	3,440	
Description of Duties			
Develop/Implement/Maintain P&P and SOP. Inventory Management. Responsible for distribution operations for a full-service drug distributor including vendor verification, receipt, and distribution of veterinary pharmacy products.			

Business Name		From - To (MM/YY – MM/YY)	
Chewy Pharmacy		03/20-05/21	
Business Address	City	State	Zip
255 S. 143rd Ave Suite B	Goodyear	AZ	85338
Phone	Title	Number of Employed Hours	
623-850-3556	Staff Pharmacist	2,360	
Description of Duties			
Drug utilization review of prescription orders. Verification of filled prescription orders.			

Business Name		From - To (MM/YY – MM/YY)	
CVS Health		02/10-03/20	
Business Address	City	State	Zip
320 W. Apache Trail	Apache Junction	AZ	85120
Phone	Title	Number of Employed Hours	
480-983-1129	Pharmacy Manager	22,880	
Description of Duties			
Responsible for all operations of a retail pharmacy including, inventory, compliance, regulatory and staffing.			

Business Name		From - To (MM/YY – MM/YY)	
Walgreens Pharmacy		08/02-01/10	
Business Address	City	State	Zip
2345 E Baseline Rd	Gilbert	AZ	85234
Phone	Title	Number of Employed Hours	
480-982-4978	Staff Pharmacist	20,800	
Description of Duties			
Prescription order processing and verification.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
08/03/2021		AZ	Phoenix	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21-0185		Arizona Board of Pharmacy		
Reason/Charge				
Consent Agreement for Civil Penalty, Continuing Education and Audit.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

The Arizona Board of Pharmacy issued a disciplinary action against me and reported me to the National Practitioner Data Bank for submitting my license renewal prior to completing my required CEs. On October 21, 2020, I submitted and paid for my Arizona pharmacist license renewal. At that time, I had completed 4.5 of the required 30 hours of CE. I mistakenly believed I had until October 31, 2021, to complete the remaining CEs to remain compliant with the regulation. Between October 21, 2020, and October 31, 2020, I completed 29 CEs, bringing me to a total of 33.5 CE hours for the two-year licensure period of 11/1/2018 to 10/31/2020. It was not my intent to deceive or mislead the Arizona Board of Pharmacy in any way. I truly believed I had until October 31, 2020, to complete the remaining required CEs.

As part of my consent agreement with the Arizona Board of Pharmacy I was fined $2,550.00 and required to complete 45 CEs for the next renewal period. I have paid the fine in full and completed the required CEs. The Arizona Board of Pharmacy has lifted all blocks to my license renewal and I renewed my license 9/2022.

Original Signature (electronic, copies or stamps not accepted)

2/10/2023
Date

chewy | Health

Dear Board of Pharmacy,

The Arizona Board of Pharmacy issued a disciplinary action against me for submitting my license renewal prior to completing my required CEs. On October 21, 2020, I submitted and paid for my Arizona pharmacist license renewal. At that time, I had completed 4.5 of the required 30 hours of CE. I mistakenly believed I had until October 31, 2021, to complete the remaining CEs to remain compliant with the regulation. Between October 21, 2020, and October 31, 2020, I completed 29 CEs, bringing me to a total of 33.5 CE hours for the two-year licensure period of 11/1/2018 to 10/31/2020. It was not my intent to deceive or mislead the Arizona Board of Pharmacy in any way. I truly believed I had until October 31, 2020, to complete the remaining required CEs.

As part of my consent agreement with the Arizona Board of Pharmacy I was fined $2,550.00 and required to complete 45 CEs for the next renewal period. I have paid the fine in full and completed the required CEs. The Arizona Board of Pharmacy has lifted all blocks to my next license renewal.

To prevent this occurring in the future, I will not renew any licenses prior to completing all CEs for the licensure period.

Sincerely,

Jill Mehrer, RPh
Designated Representative of Chewy Wholesale, LLC
255 South 143rd Avenue, Suite C
Goodyear, AZ 85338

MARK BRNOVICH
Attorney General
(Firm State Bar No. 14000)

JEANNE M. GALVIN
Assistant Attorney General
State Bar No. 015072
SETH T. HARGRAVES
Assistant Attorney General
State Bar No. 020176
2005 N. Central Ave., SGD/LES
Phoenix, Arizona 85004-1592
Tel: (602) 542-7983
Tel: (602) 542-7672
Fax: (602) 364-3202

Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of **JILL DIANE MEHRER** Holder of License No. S013310 As A Licensed Pharmacist In the State of Arizona	Board Case No. 21-0185 **CONSENT AGREEMENT FOR CIVIL PENALTY, CONTINUING EDUCATION AND AUDIT**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.* Jill Diane Mehrer ("Respondent"), holder of license S013310 as a Pharmacist in the State of Arizona and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

RECITALS

1. Respondent has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Respondent understands that she has a right to a public administrative hearing concerning this matter at which hearing he could present evidence and cross examine witnesses. By entering into this Consent Agreement, Respondent knowingly and voluntarily relinquishes all right to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Respondent affirmatively agrees that this Consent Agreement shall be irrevocable.

4. Respondent understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against her.

5. Respondent understands this Consent Agreement deals with Case No. 21-0185 involving allegations of unprofessional conduct against Respondent. The investigation into these allegations against respondent shall be concluded upon the Board's adoption of this Consent Agreement.

6. Respondent acknowledges and agrees that the acceptance of this Consent Agreement is solely to settle this Board matter and does not preclude the Board from instituting other proceedings as may be appropriate now or in the future.

7. Respondent understands that this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

8. Furthermore, and notwithstanding any language in this Consent Agreement, this Consent Agreement does not preclude in any way any other state agency or officer or political subdivision of this state from instituting proceedings, investigating claims, or taking legal action as may be appropriate now or in the future relating to this matter other matters concerning Respondent, including violations of Arizona's Consumer Fraud Act.

Respondent acknowledges that, other than with respect to the Board, this Consent Agreement makes no representations, implied or otherwise, about the views or intended actions of any other state agency or officer or political subdivision of the state relating to this matter or other matters concerning Respondent.

9. Respondent acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, she may not revoke acceptance of the Consent Agreement or make any modifications to the document regardless of whether the Consent Agreement has been signed by the Executive Director. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

10. This Consent Agreement is subject to the approval of the Board and is effective only when accepted by the Board and signed by the Executive Director. In the event that the Board does not approve this Consent Agreement, it is withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that should the Board reject this Consent Agreement and this case proceeds to hearing, Respondent shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

11. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

12. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

13. The parties understand and agree that Portable Document Format and facsimile copies of this Consent Agreement including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

14. Respondent understands that any violation of this Consent Agreement constitutes unprofessional conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(B)(20) and A.R.S. §32-1927(A)(1).

15. Respondent agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

.

ACCEPTED AND AGREED BY RESPONDENT

_____ Dated: _____

Jill Diane Mehrer
Pharmacist

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Respondent is the holder of license S013310 as a Pharmacist.

3. On or about October 21, 2020, Respondent filed his application for license renewal. Respondent answered "YES" to question no. 4 asking "Have you complied with the continuing education requirements set forth in A.A.C R4-23-411?" thereby attesting that he had completed the required thirty (30) continuing education (CE) hours during the two year period preceding his renewal.

4. On or about April 14, 2021, the Board staff conducted a continuing education audit that included Respondent (licensees are selected at random).

5. Prior to reaching out to Respondent, the Board staff reviewed the CPE Monitor and discovered that Respondent had only completed 4.5 of the 30 hours of continuing education during the audit time period.

6. Board staff sent Respondent an email on April 14, 2021, asking that she provide additional information showing completion of the required CE.

7. On April 15, 2021, Respondent submitted an email with completed CE information. The information provided showed that Respondent had only completed 4.5 of the required CE during the audit time period.

8. Upon information and belief, Respondent was short twenty-five and one-half (25.5) CE hours required for renewal of a Pharmacist license.

CONCLUSIONS OF LAW

1. The Board possesses jurisdiction over the subject matter and over Respondent pursuant to A.R.S. § 32-1901 *et seq.*

2. The Board may discipline a Pharmacist who has engaged in unprofessional conduct. A.R.S. § 32-1927(A)(1).

3. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(B)(4) "Obtaining or attempting to obtain a license to practice pharmacy or a license renewal by fraud, by misrepresentation or by knowingly taking advantage of the mistake of another person or an agency."

4. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(B)(7) "Failing to comply with the mandatory continuing professional pharmacy education requirements of sections 32-1936 and 32-1937 and rules adopted by the board."

5. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(B)(17) "Knowingly filing with the board any application, renewal or other document that contains false or misleading information."

6. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(B)(18) "Providing false or misleading information or omitting material information in any communication to the board or the board's employees or agents."

7. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(B)(19) "Violating or attempting to violate, directly or indirectly, or assisting in or abetting in the violation of, or conspiring to violate, this chapter.", specifically as it relates to A.R.S. § 32-1936 and A.A.C. R4-23-204.

ORDER

Based upon the above Findings of Fact and Conclusions of Law, IT IS HEREBY ORDERED THAT:

1. Respondent shall pay to the Board as a civil penalty the sum of Two Thousand Five Hundred Fifty Dollars **($2,550.00 [$100.00 per deficient CE hour]).** The civil penalty shall be paid in full to the Board within **ninety (90) days** of the effective date of this Consent Agreement and Order. The effective date of this Consent Agreement is the date it is signed by the Board's Executive Director.

2. In addition, Respondent shall complete a total of **forty-five (45) continuing education hours for the next renewal period ending October 31, 2022.**

3. Respondent is also subject to a mandatory audit of his continuing education requirements for the 2020-2022 renewal cycle.

4. **IF RESPONDENT FAILS TO TIMELY COMPLY WITH THIS CONSENT AGREMENT AND ORDER, THE MATTER SHALL BE REFERRED TO FORMAL HEARING FOR THE SUSPENSION OR REVOCATION OF HIS LICENSE.** Failing to abide by this Consent Agreement and Order is a violation of A.R.S. §32-1901.01(B)(20), which is violating a formal order, terms of probation, a consent agreement or a stipulation issued or entered into by the board it its executive director. The issue at such a hearing will be limited solely to whether this Order has been violated.

5. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action.

DATED this 3rd day of August, 2021.

ARIZONA STATE BOARD OF PHARMACY

By: Kam Gandhi
KAMLESH GANDHI, PharmD
Executive Director

ORIGINAL OF THE FORGOING FILED
this 3rd day of August, 2021 with:

Arizona State Board of Pharmacy
1616 W. Adams Street
Phoenix, Arizona 85007

EXECUTED COPY OF THE FOREGOING MAILED
BY CERTIFIED MAIL
this 3rd day of August, 2021, to:

Jill Diane Mehrer
[redacted] E Rafael Ave
Mesa, AZ 85212
[redacted]

EXECUTED COPY OF THE FOREGOING MAILED
Mail this 3rd day of August, 2021, to:

Jeanne Galvin
Seth T. Hargraves
Arizona Attorney General's Office
2005 N. Central Ave. – SGD/LES
Phoenix, AZ 85004
Attorneys for the Board

JMitchell

Doc #9473459

I, Jill Mehrer, **certify that as the designated representative for**

Chewy Wholesale, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JM I am at least 21 years of age;
3. JM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jill Mehrer

Print Name (First, Last)

Jill Mehrer

Original Signature (electronic, copies or stamps not accepted)

2/10/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jill Mehrer

Print Name (First, Last)

Jill Mehrer

Original Signature (electronic, copies or stamps not accepted)

2/13/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Jill Diane Mehrer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jill Mehrer

Original Signature

2/13/2023

Date

Subscribed and Sworn to before me this 13th day of February 2023

Notary Public Signature

ZAIDA RUBIO NUNEZ
Notary Public, State of Arizona
Maricopa County
Commission # 601455
My Commission Expires
March 16, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Chewy Wholesale, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 255 South 143rd Avenue Suite C

City: Goodyear State: AZ Zip: 85338

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (623) 932-8158 Website:

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Ornel Middle: Last: Cotera

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] SE 12th Avenue

City: Deerfield Beach State: FL Zip: 33441

Telephone: Email: ocotera@chewy.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Mast Academy		06/96 - 05/00	
Address	City	State	Zip
3979 Rickenbacker Causeway	Miami	FL	33149
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Florida		06/00 - 08/06	
Address	City	State	Zip
205 Fletcher Dr	Gainesville	FL	32611
Diploma/Degree obtained, if any			
B.S. Economics			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19 - current	[redacted] SE 12th AVE	Deerfield Beach	FL	33441
10/09 - 05/19	[redacted] SE 11th AVE	Deerfield Beach	FL	33441
03/11 - 11/14	[redacted] Sutton Dr Apt [redacted]	Matawan	NJ	07747
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Chewy, Inc.			09/15 - current
Business Address	**City**	**State**	**Zip**
7700 W. Sunrise Blvd	Plantation	FL	33322
Phone	**Title**		
786 320 7111	VP, Category Management		
Description of Duties			
Monitoring & overseeing of Pharmacy, Compounding, OTC, Flea & tick and practice hub business teams.			

Business Name			From - To (MM/YY – MM/YY)
Office Depot			11/14 - 09/15
Business Address	**City**	**State**	**Zip**
6600 N. Military Trail	Boca Raton	FL	33487
Phone	**Title**		
561-438-4800	Sr. Category Manager		
Description of Duties			
Managed assortment for digital storage category.			

Business Name			From - To (MM/YY – MM/YY)
Hess Corp.			~~06/07~~ 06/07 - 11/14
Business Address	**City**	**State**	**Zip**
1 Hess Plaza	Woodbridge	NJ	07095
Phone	**Title**		
732-750-6888	Category Manager		
Description of Duties			
Managed center store assortment for convenience stores			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ornel Cotera

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/2/23

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, ORNEL COTERA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/2/23

Date

Subscribed and Sworn to before me this 2 day of August, 2023.

Notary Public Signature

BRITTNY KAREL ANNE RODRIGUEZ
Notary Public-State of Florida
Commission # GG 961625
My Commission Expires
February 24, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Chewy Wholesale, LLC

Physical Address 255 South 143rd Ave, Suite C

City Goodyear State AZ Zip 85338

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email PharmacyLicensing@chewy.com

Section 2: Personal Information

First Justin Middle _____ Last Mills

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] Watterson Trail

City Louisville State KY Zip 40299

Telephone _____ Email PharmacyLicensing@chewy.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials _____

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)		
University of Kentucky	08/04 - 05/10		
Address	City	State	Zip
789 S. Limestone	Lexington	KY	40508
Diploma/Degree obtained, if any			
Pharm. D			

School Name	From - To (MM/YY – MM/YY)		
Jefferson Community College	08/01 - 05/04		
Address	City	State	Zip
109 E. Broadway	Louisville	KY	40202
Diploma/Degree obtained, if any			
N/A			

School Name	From - To (MM/YY – MM/YY)		
Jeffersontown High School	08/97 - 05/01		
Address	City	State	Zip
9600 Old 6 Mile Ln.	Louisville	KY	40299
Diploma/Degree obtained, if any			
High School Diploma			

School Name	From - To (MM/YY – MM/YY)		
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name	From - To (MM/YY – MM/YY		
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/20 - current	[redacted] Gutenberg Rd.	Louisville	KY	40299
12/10 - 06/20	[redacted] Keeling Ridge Ct.	Louisville	KY	40291
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Chewy Inc.			06/18 - current
Business Address	**City**	**State**	**Zip**
2815 Watterson Trail	Louisville	KY	40299
Phone	**Title**		
877-977-3879	Director / Vice President		
Description of Duties			
Director of pharmacy and wholesale operations.			

Business Name			From - To (MM/YY – MM/YY)
Pet360			11/12 - 6/18
Business Address	**City**	**State**	**Zip**
2815 Watterson Trail	Louisville	KY	40299
Phone	**Title**		
877-977-3879	PIC		
Description of Duties			
Pharmacist in Charge			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Applicant's initials JM

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials _____

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Justin Mills

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-28-23

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Jefferson

I, Justin M. Mills, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5-2-23

Date

Subscribed and Sworn to before me this 2 day of May 2023.

Victoria Kenney

Notary Public Signature

VICTORIA ELIZABETH KENNEY
Notary Public
Commonwealth of Kentucky
Commission Number KYNP54238
My Commission Expires Jun 24, 2026

(Seal)

Applicant's initials

chewy | Health

Chewy Wholesale, LLC located at 255 South 143rd Ave, Suite C, Goodyear AZ employee's one employee, Jill Mehrer who is the Designated Representative.

4P

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Chewy Wholesale, LLC

Physical Address: 370 Research Drive

City: Pittston State: PA Zip: 18640

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 570-569-4666 Website: _____

Name of Designated Representative (DR): Elizabeth Shipula

Licensing Company Email: PharmacyLicensing@chewy.com DR Email: eshipula@chewy.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☒ Veterinarians		☒ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 1950 W. Oak Circle City: 1950 W. Oak Circle State: GA Zip: 30062
Name: Elanco
Address: 2500 Innovation Way City: Greenfield State: IN Zip: 46140
Name: PetIQ
Address: 530 Fentress Blvd City: Daytona Beach State: FL Zip: 32114
Name: The Harvard Drug Group
Address: 5960 E SHELBY DR City: MEMPHIS State: TN Zip: 38141

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Chewy, Inc.
Corporation/Organization Name: Chewy Wholesale, LLC
Mailing Address: 7700 West Sunrise Blvd, Plantation FL 33322
City: State: FL Zip: 33322
Telephone: 617-755-0591 Email: PharmacyLicensing@chewy.com
Contact Person Name: Melissa Curry

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Chewy Wholesale, LLC

Facility Name

Elizabeth Shipula

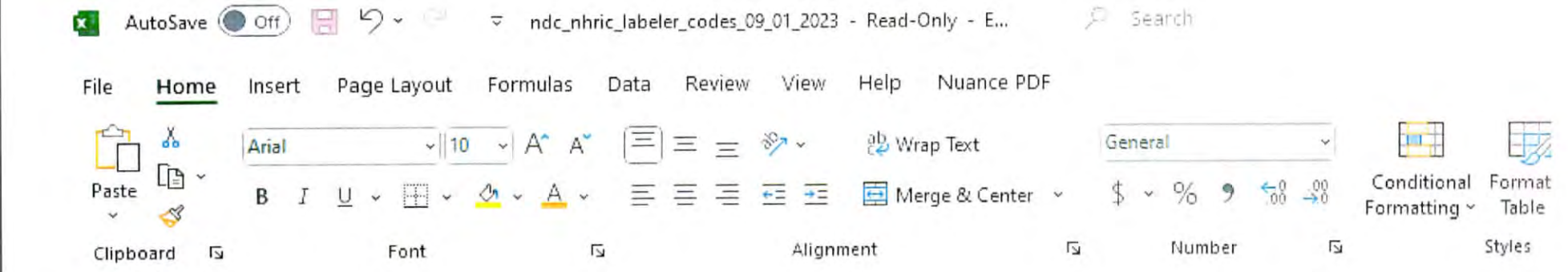
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/13/23

Date

Board Use Only	Date Received: 3-16-23	Amount: 1000.00 CC



	A	B
1	**NDC/NHRIC Labeler**	**Firm Name**
4674	0182	Teva Pharmaceuticals Development, Inc.
4675	62670	Bath & Body Works, Inc.
4676	74489	UbiQD, Inc.
4677	72769	BioCryst Pharmaceuticals, Inc.
4678	73845	Lost & Found Distillery, Inc
4679	66394	Sandoz Private Limited
4680	0799	Calmoseptine Inc.
4681	50452	Phoenix Research Industries, Inc.
4682	66829	Novartis Ringaskiddy Limited
4683	73536	Pharmaessentia Usa Corporation
4684	73231	Skin Innovations LLC
4685	51942	Jiangxi Dadi Pharmaceutical Limited Liability Company
4686	13298	ALFA VITAMINS LABORATORIES INC
4687	86109	Chewy, Inc.
4688	69559	MARYHELEN ORIENTAL MEDICINE RESEARCH
4689	82966	Blip Products, Inc.
4690	55676	SHANDONG HELI DAILY NECESSITIES CO.,LTD

✓ Updated 9/1/23

Chewy Wholesale, LLC Officers List and Corporate Shareholder Information:

Name	Title/ Percent of Ownership	Business Address
Chewy Wholesale, LLC	Owner, 100%	7700 West Sunrise Blvd, Plantation FL 33322
Aseemita Malhotra	President, 0%	7700 West Sunrise Blvd, Plantation FL 33322
Justin Mills	Vice President, 0%	2815 Watterson Trail, Louisville, KY 40299

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CHEWY WHOLESALE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF APRIL, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

7115452 8300

SR# 20193028943

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication:

202682438 Date: 03-22-23

Certificate of Licensure

Certificate No. 8000003081
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Wholesaler/Distributor

Drug & Device Registration
555 WALNUT ST-FORUM PLACE
SUITE 701
HARRISBURG, PA 17101
(717) 787-4779

CHEWY WHOLESALE, LLC
370 RESEARCH DRIVE
PITTSTON, PA 18640

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: September 09, 2021
Expiration Date: The Last Day of September, 2023

Susan Coble
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

K Klinepeter
Keara Klinepeter
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

Certificate of Registration

Certificate No. 3000010299
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Drug & Device Registration
555 WALNUT ST-FORUM PLACE
SUITE 701
HARRISBURG, PA 17101
(717) 787-4779

Category:

Distributor (Prescription)

CHEWY WHOLESALE, LLC
370 RESEARCH DRIVE
PITTSTON, PA 18640

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: September 09, 2021
Expiration Date: The Last Day of September, 2023

Susan Coble
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

K Klinepeter
Keara Klinepeter
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
12/15/2021

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Insurance Services West, Inc.
Phoenix AZ Office
2555 East Camelback Rd.
Suite 700
Phoenix AZ 85016 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Safety National Casualty Corp	15105
INSURER B:	XL Specialty Insurance Co	37885
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Chewy, Inc.
1855 Griffin Road, Suite B-428
Dania Beach FL 33004 USA

COVERAGES **CERTIFICATE NUMBER:** 570090631836 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE / X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY / PRO-JECT / LOC OTHER:			GL4064502 SIR applies per policy terms & conditions	02/12/2023	02/12/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $500,000 Excluded $1,000,000 $5,000,000 $4,000,000
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY / X SCHEDULED AUTOS X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY			CA6675895	02/12/2023	02/12/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
B	X UMBRELLA LIAB / X OCCUR EXCESS LIAB / CLAIMS-MADE DED / X RETENTION $10,000			US00107790LI21A	02/12/2023	02/12/2024	EACH OCCURRENCE AGGREGATE	$10,000,000 $10,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N / N/A If yes, describe under DESCRIPTION OF OPERATIONS below			LDS4064501	02/12/2023	02/12/2024	X PER STATUTE / OTH- E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Western Veterinary Conference, Mandalay Corp., Mandalay Bay Resort and Casino and Freeman and their respective directors, officers, employees, agents, representatives, parent companies, subsidiaries and affiliates and any additional entities as required by Mandalay Corp., the "Insured Entities" are included as Additional Insured in accordance with the policy provisions of the General Liability and Automobile Liability policies. General Liability evidenced herein is Primary & Non Contributory to other insurance available to an Additional Insured, but only in accordance with the policy provisions.

CERTIFICATE HOLDER

WVC
dba Viticus Group
2425 E. Oquendo Rd.
Las Vega NV 89120 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Insurance Services West, Inc.

Holder Identifier :

Certificate No : 570090631836

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AGENCY CUSTOMER ID: 570000080467

LOC #:

ADDITIONAL REMARKS SCHEDULE

Page _ of _

AGENCY	NAMED INSURED
Aon Risk Insurance Services West, Inc.	Chewy, Inc.
POLICY NUMBER: See Certificate Number: 570090631836	
CARRIER: See Certificate Number: 570090631836 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insured Listing

The following are included as Named Insureds under the referenced policies:

Chewy, Inc.
American Journey, LLC
Chewy Pharmacy, LLC
Chewy Promotions LLC
Chewy Wholesale, LLC
CF Services LLC
Dania Pet Goods, LLC
Dr. Lyon's, LLC
Lab 11, LLC
Spot 11, LLC
Onguard Pet Products, LLC
Paw & Parcel Food Co, LLC
Tiny Tiger, LLC
Tylee's, LLC

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 285071852

Application/License No. _____

CHEWY WHOLESALE LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 370 Research Drive Pittston, PA 18640 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 1, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 8th day of February, 2023.

APPLICANT/PRINCIPAL
CHEWY WHOLESALE LLC

COMPANY

Authorized Representative

SURETY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Derek J. Elston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Ricky Casas

Witness Ann Formhals

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8209007-285057

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aerie Walton, Bartlomiej Siepierski, Christina L. Sandoval, Christopher P. Troha, Corinne Chapman, Dartonya Wright, Derek J. Elston, James B. McTaggart, Jean Torres, Jennifer L. Jakaitis, Jennifer Williams, Jessica B. Dempsey, Judith A. Lucky-Eftimov, Kristin L. Hannigan, Melissa L. Fortier, Nicholas Kertesz, Rachel Fore, Roger Paraison, Samantha Chierici, Sandra M. Winsted, Susan A. Welsh, Tara A. Reimer

all of the city of Chicago state of IL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of November, 2022.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 15th day of November, 2022 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 8th day of February, 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Chewy Wholesale, LLC MDEG License # (if applicable) _____

Physical Address 370 Research Drive

City Pittston State PA Zip 18640

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 570-569-4666 Website _____

Licensing Company Email Pharmacylicensing@chewy.com

Section 2: Personal Information

First Elizabeth Middle Lee Last Shipula

Alias(es, nicknames, name changes, etc.) Elizabeth Lee Garner

Date of Birt[redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]Spruce Street

City Mountain Top State PA Zip 18707

Telephone [redacted] Email eshipula@chewy.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wilkes University		08/06 - 05/12	
Address	**City**	**State**	**Zip**
84 W. South Street	Wilkes-Barre	PA	18766
Diploma/Degree obtained, if any			
Pharm D.			

School Name		From - To (MM/YY – MM/YY)	
St. Thomas More Academy		08/02 - 05/06	
Address	**City**	**State**	**Zip**
133 Thomas More Drive	Magnolia	DE	19962
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/15 - Present	[redacted]pruce Street	Mountatin Top	PA	18707
01/14 - 03/15	1[redacted]S Main Street	Hanover Township	PA	18706
08/01 - 01/14	[redacted]Persimmon Tree Lane	Dover	DE	19901

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Chewy Wholesale, LLC			08/21 - Present
Business Address	**City**	**State**	**Zip**
370 Research Drive	Pittston	PA	18640
Phone	**Title**	**Number of Employed Hours**	
570-569-4666	Designated Representative	3,120	
Description of Duties			
Designated Representative overseeing daily wholesale operations, receiving and managing inventory.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/28/23
Date

I, Elizabeth Shipula, **certify that as the MDEG Administrator for**

Chewy Wholesale, LLC,

that I (initial that you have read and meet the following requirements):

1. EJS Have a high school diploma or its equivalent;
2. EJS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. EJS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. EJS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Elizabeth Shipula
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/28/23
Date

Board Use Only	Date Received: 3-14-23

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Chewy Wholesale, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 370 Research Drive

City Pittston State PA Zip 18640

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 570-569-4666 Website _____

Licensing Company Email PharmacyLicensing@chewy.com

Section 2: Personal Information

First Elizabeth Middle Lee Last Shipula

Alias(es, nicknames, name changes, etc.) Elizabeth Lee Garner

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address [redacted] Spruce Street

City Mountain Top State PA Zip 18707

Telephone [redacted] Email eshipula@chewy.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wilkes Universiity		08/06 - 05/12	
Address	**City**	**State**	**Zip**
84 W. South Street	Wilkes-Barre	PA	18766
Diploma/Degree obtained, if any			
Pharm D.			

School Name		From - To (MM/YY – MM/YY)	
St. Thomas More Academy		08/02 - 05/06	
Address	**City**	**State**	**Zip**
133 Thomas More Drive	Magnolia	DE	19962
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/15 - Present	[redacted] Spruce Street	Mountain Top	PA	18707
01/14 - 03/15	[redacted] S Main Street	Hanover Township	PA	18706
08/01 - 01/14	[redacted] Persimmon Tree Lane	Dover	DE	19901

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Chewy Wholesale, LLC			08/21 - Present
Business Address	**City**	**State**	**Zip**
370 Research Drive	Pittston	PA	18640
Phone	**Title**	**Number of Employed Hours**	
(570) 569-4666	Designated Representative	2,880 †	
Description of Duties			
Designated Representative			

Business Name			From - To (MM/YY – MM/YY)
Pennsylvania Dispensary Solutions, LLC			06/19 - 08/21
Business Address	**City**	**State**	**Zip**
1146 S Main Ave	Scranton	PA	18504
Phone	**Title**	**Number of Employed Hours**	
570-800-6760	Pharmacy Manager/Pharmacist	4,160	
Description of Duties			
Dispensary manager and pharmacist.			

Business Name			From - To (MM/YY – MM/YY)
Alliance Medication Services, LLC			10/17 - 06/19
Business Address	**City**	**State**	**Zip**
88 Mahanoy Ave	Tamaqua	PA	18252
Phone	**Title**	**Number of Employed Hours**	
866-929-8500	Pharmacist in Charge	3,200	
Description of Duties			
Pharmacist in charge			

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			04/14 - 10/17
Business Address	**City**	**State**	**Zip**
330 S Main Ave	Scranton	PA	18504
Phone	**Title**	**Number of Employed Hours**	
570-341-1429	Pharmacist in Charge	6,720	
Description of Duties			
Pharmacist in charge			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/13/23
Date

I, Elizabeth Shipula, **certify that as the designated representative for**

Chewy Wholesale, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ELS I am at least 21 years of age;
3. ELS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ELS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ELS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ELS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ELS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Elizabeth Shipula
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/13/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Elizabeth Shipula

Print Name (First, Last).

Original Signature (electronic, copies or stamps not accepted)

3/13/23

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Luzerne

I, Elizabeth Shipula, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/13/23

Date

Subscribed and Sworn to before me this 13 day of MARCH.

Notary Public Signature

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
JOHN MINETOLA, NOTARY PUBLIC
WYOMING BORO., LUZERNE COUNTY
MY COMMISSION EXPIRES AUG 26, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Chewy Wholesale, LLC

Physical Address 370 Research Drive

City Pittston State PA Zip 18640

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 570-569-4666 Website _____

Licensing Company Email PharmacyLicensing@chewy.com

Section 2: Personal Information

First Elizabeth Middle Lee Last Shipula

Alias(es, nicknames, name changes, etc.) Elizabeth Lee Garner

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address [redacted] Spruce Street

City Mountain Top State PA Zip 18707

Telephone [redacted] Email eshipula@chewy.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Applicant's initials ELS

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wilkes University		08/06 - 05/12	
Address	**City**	**State**	**Zip**
84 W. South Street	Wilkes-Barre	PA	18766
Diploma/Degree obtained, if any			
Pharm D.			

School Name		From - To (MM/YY – MM/YY)	
St. Thomas More Academy		08/02 - 05/06	
Address	**City**	**State**	**Zip**
133 Thomas More Drive	Magnolia	DE	19962
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/15 - Present	[redacted] Spruce Street	Mountain Top	PA	18707
01/14 - 03/15	[redacted]S Main Street	Hanover Township	PA	18706
08/01 - 01/14	[redacted]Persimmon Tree Lane	Dover	DE	19901

Applicant's initials ELS

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Chewy Wholesale, LLC			08/21 - Present
Business Address	**City**	**State**	**Zip**
370 Research Drive	Pittston	PA	18640
Phone	**Title**		
570-569-4666	Designated Representative		
Description of Duties			
Designated Representative			

Business Name			From - To (MM/YY – MM/YY)
Pennsylvania Dispensary Solutions, LLC			06/19 - 8/21
Business Address	**City**	**State**	**Zip**
1146 S Main Ave	Scranton	PA	18504
Phone	**Title**		
570-800-6760	Pharmacy Manager/Pharmacist		
Description of Duties			
Dispensary manager and pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Alliance Medication Services, LLC			10/17 - 6/19
Business Address	**City**	**State**	**Zip**
88 Mahanoy Ave	Tamaqua	PA	18252
Phone	**Title**		
866-929-8500	Pharmacist in Charge		
Description of Duties			
Pharmacist in Charge			

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			04/14 - 10/17
Business Address	**City**	**State**	**Zip**
330 S Main Ave	Scranton	PA	18504
Phone	**Title**		
570-341-1429	Pharmacist in Charge		
Description of Duties			
Pharmacist in Charge			

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			04/13 - 01/14
Business Address	**City**	**State**	**Zip**
17248 S Dupont Highway	Harrington	DE	19952
Phone	**Title**		
570-398-1200	Pharmacist in Charge		
Description of Duties			
Pharmacist in Charge			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			07/12 - 04/13
Business Address	**City**	**State**	**Zip**
Various Locations			
Phone	**Title**		
	Pharmacist		
Description of Duties			
Floating pharmacist covering locations in Delaware and Maryland.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/13/23
Date

Applicant's initials ELS

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Elizabeth Shipula

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/3/23

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Luzerne

I, Elizabeth Shipula, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/3/23

Date

Subscribed and Sworn to before me this 3rd day of March 2023.

Notary Public Signature

Commonwealth Of Pennsylvania
- Notary Seal -
JOSHUA MINETOLA, Notary Public
Luzerne County
My Commission Expires July 20, 2026
Commission Number 1256984

(Seal)

Applicant's initials ELS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Chewy Wholesale, LLC

Physical Address 370 Research Drive

City Pittston State PA Zip 18640

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email PharmacyLicensing@chewy.com

Section 2: Personal Information

First Justin Middle _____ Last Mills

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] Watterson Trail

City Louisville State KY Zip 40299

Telephone _____ Email PharmacyLicensing@chewy.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials JM

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Kentucky		08/04 - 05/10	
Address	City	State	Zip
789 S Limestone	Lexington	KY	40508
Diploma/Degree obtained, if any			
Pharm.D			
School Name		From - To (MM/YY – MM/YY)	
Jefferson Community College		08/01 - 05/04	
Address	City	State	Zip
109 E Broadway	Louisville	KY	40202
Diploma/Degree obtained, if any			
NA			
School Name		From - To (MM/YY – MM/YY)	
Jeffersontown High School		08/97 - 05/01	
Address	City	State	Zip
9600 Old 6 Mile Ln	Louisville	KY	40299
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/20 - current	[redacted]Gutenberg Rd	Louisville	KY	40299
12/10 - 06/20	[redacted]Keeling Ridge Ct	Louisville	KY	40291
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials JM

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Chewy Inc.			06/18 - current	
Business Address		**City**	**State**	**Zip**
2815 Watterson Trail		Louisville	KY	40299
Phone	**Title**			
877-977-3879	Director			
Description of Duties				
Director of pharmacy and wholesale operations.				

Business Name			From - To (MM/YY – MM/YY)	
Pet360			11/12 - 6/18	
Business Address		**City**	**State**	**Zip**
2815 Watterson Trail		Louisville	KY	40299
Phone	**Title**			
877-977-3879	PIC			
Description of Duties				
Pharmacist in Charge				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials JM

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials JM

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Justin Mills

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-28-23

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Jefferson

I, Justin Mills, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2-28-23

Date

Subscribed and Sworn to before me this 28th day of February 2023

Notary Public Signature

Dathan A Echols
Notary Public, ID KYNP50686
State at Large, Kentucky
(Seal)
My Commission Expires on May 12, 2026

Applicant's initials JM

chewy | Health

Chewy Wholesale, LLC located at 370 Research Drive, Pittston, PA 18640 employe's Elizabeth Shipula as their only employee who is the Designated Representative.

4Q

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Coloplast Corp.

Physical Address: 4495 E Wall Street, Suite 101

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 909-229-9861 Website: https://www.coloplast.us/

Name of Designated Representative (DR): Francisco Gonzalez Guzman

Licensing Company Email: N/A DR Email: usfgg@coloplast.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: DMEs		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - Coloplast Corp. does not distribute drugs or controlled substances.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Coloplast A/S

Corporation/Organization Name: Coloplast Corp.

Mailing Address: 1601 West River Road North

City: Minneapolis State: MN Zip: 55411

Telephone: 1-800-788-0293 Email: uslegal@coloplast.com

Contact Person Name: General Counsel, Stephen Froehle

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration Enclosed 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. Enclosed		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** Enclosed	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** Noted in cover letter		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** Enclosed	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ Enclosed		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ Noted in cover letter		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** Enclosed	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** Enclosed	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ Enclosed	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). Enclosed	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Coloplast Corp.

Facility Name

Stephen G. Froehle

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

June 27, 2023

Date

Board Use Only	Date Received: 7/10/23	Amount: 1000 - CC 7/11/23

CITY OF ONTARIO

2023 - 2024

BUSINESS LICENSE

TO BE POSTED IN A CONSPICUOUS PLACE AND NOT TRANSFERABLE OR ASSIGNABLE.

The party shown is granted this certificate pursuant to License and Permit Provisions of the Municipal Code. This is not an endorsement of the activity, nor certification of compliance with other laws. This license is issued without verification that the licensee is subject to or exempt from licensing by the State of California.

Business Name COLOPLAST MANUFACTURING US, LLC

Business Location 4495 E WALL ST STE 101
ONTARIO, CA 91761-8186

Business Owner(s) COLOPLAST MANUFACTURING US LLC
NARINDER DHALIWAL

MIKE HODGSON
COLOPLAST MANUFACTURING US, LLC
4495 E WALL ST STE 101
ONTARIO, CA 91761-8186

License Number 12415209

Business Type WAREHOUSE

Effective Date February 01, 2023

Expiration Date January 31, 2024

Conditions Warehouse Distribution of medical devices, some packaging of some products prior to shipment.

COLOPLAST MANUFACTURING US, LLC :

Thank you for your payment on your City of Ontario Business License. **ALL LICENSES MUST BE AVAILABLE FOR INSPECTION UPON REQUEST.** If you have questions concerning your business license, contact the Business Support Center via email at: Ontario@HDLgov.com or by telephone at: (909) 395-2022.

Contact the Business Registration Division at (909) 395-2022 if the business closes prior to the expiration date of the certificate. Please notify this office within ten (10) days of any change of business name, ownership, address location or activity.

Starting January 1, 2021, Assembly Bill 1607 requires the prevention of gender-based discrimination of business establishments. A full notice is available in English or other languages by going to: https://www.dca.ca.gov/publications/.

CITY OF ONTARIO SOUTHERN CALIFORNIA

LICENSING DIVISION
303 EAST B STREET
ONTARIO, CA. 91764-4196

City of Ontario
BUSINESS LICENSE

MIKE HODGSON
COLOPLAST MANUFACTURING US, LLC
4495 E WALL ST STE 101
ONTARIO, CA 91761-8186

License Number: **12415209**

Date of Issue: **02/01/2023**

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "COLOPLAST CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF MAY, A.D. 2023.

Jeffrey W. Bullock, Secretary of State

4408961 8300

SR# 20232279556

Authentication: 203402238

Date: 05-23-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

COLOPLAST CORP.
CORPORATE GOVERNANCE SUMMARY

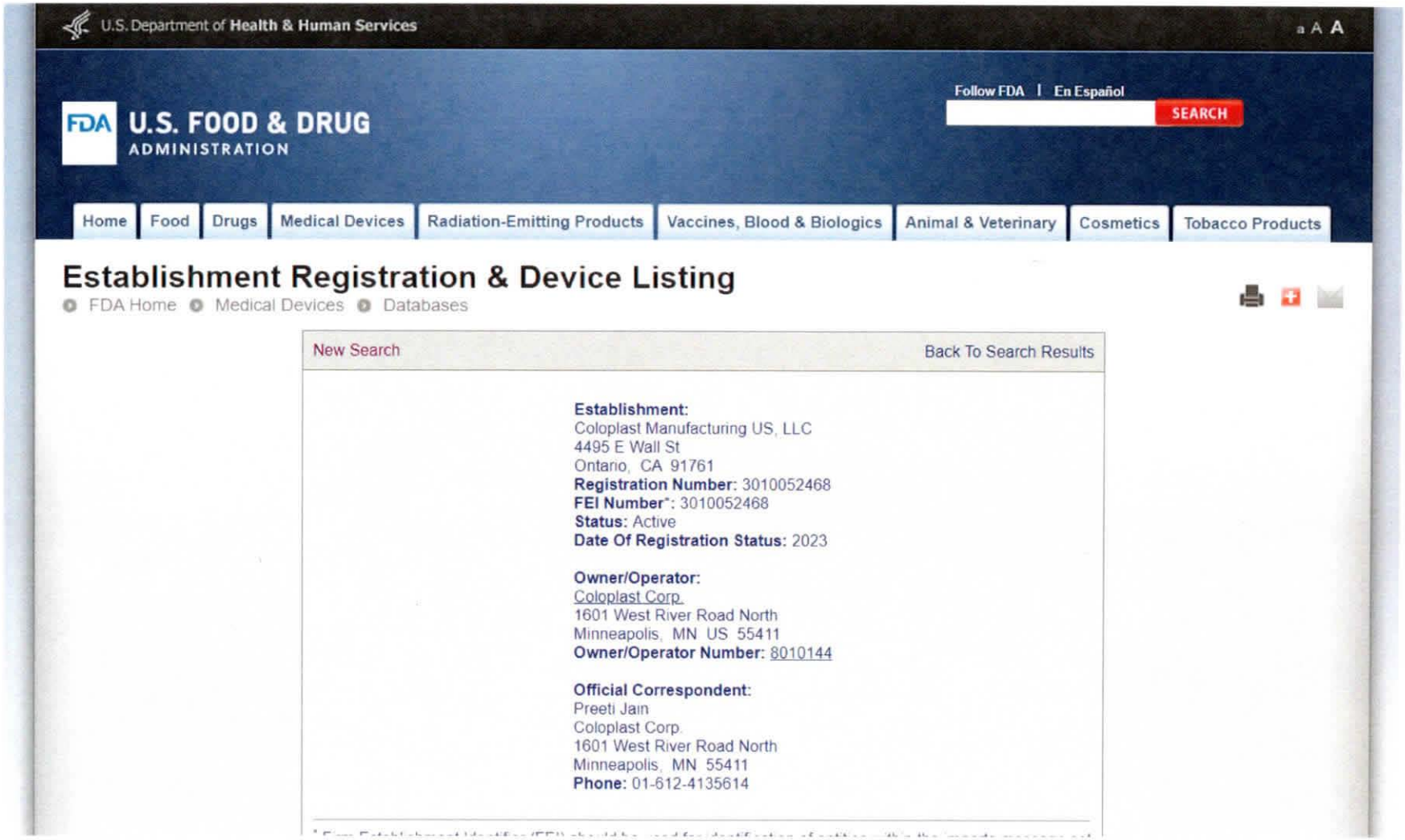
Coloplast Corp.

Directors:

Henrik Deneke
Manu Varma
Thomas NP Johns, Jr.

Officers:

Manu Varma, Chief Executive Officer
Thomas NP Johns, Jr., Vice President
Kimberly Ditter, Vice President
Shelley Mueller, Treasurer
Stephen G. Froehle, Secretary



U.S. Department of Health & Human Services

a A A

FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

New Search | Back To Search Results

Establishment:
Coloplast Manufacturing US, LLC
4495 E Wall St
Ontario, CA 91761
Registration Number: 3010052468
FEI Number*: 3010052468
Status: Active
Date Of Registration Status: 2023

Owner/Operator:
Coloplast Corp.
1601 West River Road North
Minneapolis, MN US 55411
Owner/Operator Number: 8010144

Official Correspondent:
Preeti Jain
Coloplast Corp.
1601 West River Road North
Minneapolis, MN 55411
Phone: 01-612-4135614

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/14/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Marsh USA Inc.
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400
Attn: Minneapolis.CertRequest@marsh.com Fax 212-948-0114

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : XL Insurance America, Inc.	24554
INSURER B : The Charter Oak Fire Insurance Company	25615
INSURER C : Phoenix Insurance Company	25623
INSURER D : QBE Insurance Corporation	39217
INSURER E :	
INSURER F :	

INSURED
Coloplast Corp.
1601 West River Road
Minneapolis, MN 55411

COVERAGES **CERTIFICATE NUMBER:** CHI-009560485-08 **REVISION NUMBER:** 8

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			US00011271LI22A	10/01/2022	10/01/2023	EACH OCCURRENCE	$	5,000,000
	X CLAIMS-MADE ☐ OCCUR			SIR: See Attached			DAMAGE TO RENTED PREMISES (Ea occurrence)	$	100,000
							MED EXP (Any one person)	$	5,000
							PERSONAL & ADV INJURY	$	5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	5,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$	5,000,000
	OTHER:							$	
B	AUTOMOBILE LIABILITY			8102G274522	10/01/2022	10/01/2023	COMBINED SINGLE LIMIT (Ea accident)	$	2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$	
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$	
	☐ DED ☐ RETENTION $							$	
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			UB0L9954032212E	10/01/2022	10/01/2023	X PER STATUTE ☐ OTH-ER		
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? Y	N/A					E.L. EACH ACCIDENT	$	1,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
D	CYBER LIABILITY			QPL0769038	10/01/2022	10/01/2023	EACH OCCURRENCE		1,000,000
	(Claims Made)			SIR Value: $10,000,000			AGGREGATE		1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance

CERTIFICATE HOLDER

Coloplast Corp.
1601 West River Road N.,
Minneapolis, MN 55411

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

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AGENCY CUSTOMER ID: CN102734708
LOC #: Minneapolis

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Marsh USA Inc.	Coloplast Corp. 1601 West River Road Minneapolis, MN 55411
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

GENERAL LIABILITY SIR
$79,500 (500,000 DKK) per claim - non implant products and premises
$1,590,000 (10m DKK) per claim - all implants products (excluding penile implants)
$1,590,000 (10m DKK) per claimant - penile implants
Non-ranking deductible - each and every claim $5,963

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 20BSBJB5095

Application/License No. _____

Coloplast Manufacturing US, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4495 E Wall Street, Ontario, CA 91761 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1111 Northshore Drive Knoxville, TN 37919 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 23, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

20BSBJB5095

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 23rd day of June, 2023.

APPLICANT/PRINCIPAL

Coloplast Manufacturing US, LLC

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Bonnie Rice, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Lori Wright

Witness Andrea Allman

Countersigned by:

N/A
Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: MARSH USA LLC
Agency Code: 20-246454

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint Bonnie Rice

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 20BSBJB5095
Naming Coloplast Manufacturing US, LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of June 23, 2023.

Signed and sealed in Lake Mary, Florida.

Keith Dozois

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Coloplast Corp. MDEG License # (if applicable) _____

Physical Address 4495 E Wall Street, Suite 101

City Ontario State CA Zip 91761

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 909-229-9861 Website https://www.coloplast.us/

Licensing Company Email N/A

Section 2: Personal Information

First Francisco Middle J. Last Gonzalez Guzman

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Addres[redacted] Ebony PL

City Fontana State CA Zip 92335

Telephone[redacted] Email usfgg@coloplast.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Riverside City Collage		08/06 - 05/07	
Address	**City**	**State**	**Zip**
4800 Magnolia Ave.	Riverside	CA	92506
Diploma/Degree obtained, if any			
No			
School Name		**From - To (MM/YY – MM/YY)**	
Henry J. Kaiser High School		08/02-05/06	
Address	**City**	**State**	**Zip**
11155 Almond Ave	Fontana	CA	92337
Diploma/Degree obtained, if any			
Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Sequoia Middle School		11/00 - 05/02	
Address	**City**	**State**	**Zip**
9452 Hemlock Ave	Fontana	CA	92337
Diploma/Degree obtained, if any			
Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/17 - Present	[redacted] Ebony Pl	Fontana	CA	92335
09/14 - 03/17	[redacted] Carob ST	Fontana	CA	92335
02/00 - 08/14	[redacted] Ebony Pl	Fontana	CA	92335
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Coloplast Corp.			10/14 - Present	
Business Address		**City**	**State**	**Zip**
4495 E Wall Street, Suite 101		Ontario	CA	91761
Phone	**Title**		**Number of Employed Hours**	
909-229-9861	Warehouse Lead		18,000+	
Description of Duties				
Responsible for distribution and warehouse management.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

07/05/2023
Date

I, Francisco Gonzalez Guzman, **certify that as the MDEG Administrator for**

Coloplast Corp.,

that I (initial that you have read and meet the following requirements):

1. FGG Have a high school diploma or its equivalent;
2. FGG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. FGG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. FGG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Francisco Gonzalez Guzman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/05/2023
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Coloplast Corp.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 4495 E Wall Street, Suite 101

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 909-229-9861 Website: https://www.coloplast.us/

Licensing Company Email: N/A

Section 2: Personal Information

First: Francisco Middle: J. Last: Gonzalez Guzman

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Ebony PL

City: Fontana State: CA Zip: 91761

Telephone: [redacted] Email: usfgg@coloplast.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Riverside City Collage		08/06 - 05/07	
Address	City	State	Zip
4800 Magnolia Ave.	Riverside	CA	92506
Diploma/Degree obtained, if any			
No			

School Name		From - To (MM/YY – MM/YY)	
Henry J. Kaiser High School		08/02-05/06	
Address	City	State	Zip
11155 Almond Ave	Fontana	CA	92337
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Sequoia Middle School		11/00 - 05/02	
Address	City	State	Zip
9452 Hemlock Ave	Fontana	CA	92335
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/17 - Present	[redacted] Ebony Pl	Fontana	CA	92335
From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/14 - 03/17	[redacted]Carob ST	Fontana	CA	92335
From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/00 - 08/14	[redacted]Ebony Pl	Fontna	CA	92335
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Coloplast Corp.			10/14 - Present	
Business Address		**City**	**State**	**Zip**
4495 E Wall Street, Suite 101		Ontario	CA	91761
Phone	**Title**		**Number of Employed Hours**	
	Warehouse Lead		18,000+	
Description of Duties				
Responsible for distribution and warehouse management.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

07/05/2023
Date

I, Francisco Gonzalez Guzman, **certify that as the designated representative for**

Coloplast Corp.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. FGG I am at least 21 years of age;
3. FGG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. FGG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. FGG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. FGG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. FGG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Francisco Gonzalez Guzman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/05/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Francisco Gonzalez Guzman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/05/2023

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Bernardino

I, Francisco J. Gonzalez Guzman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/5/23

Date

Subscribed and Sworn to before me this 5 day of July 2023.

Notary Public Signature

CHARISMA MARTINEZ
Notary Public - California
San Bernardino County
Commission # 2439101
My Comm. Expires Feb 24, 2027

(Seal)


Michael Hodgson
Warehouse Manager
Carlos Rodriguez Vences
Shipper
Francisco Gonzalez Guzman
Warehouse Lead
Gustavo Rodriguez Vences
Shipper
Jesus Cordova Ibarra
Shipper
Joshua Barragan
Shipper
Rogelio Loreto
Shipper
Mario Vazquez
Shipper

Coloplast

June 30, 2023

Aaron Rodriquez
Senior Legal Counsel, North America
Mobile: 612-889-0672
Mail: usarodr@coloplast.com

Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411
United States

Tel: 612.372.7400
Toll Free Number
1.800.788.0293
www.coloplast.us

Executive Secretary Dave Wuest
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

RE: Coloplast Corp. Wholesaler Application

To Whom It May Concern:

By this letter, Coloplast Corp. is requesting a temporary wholesaler license for the Coloplast Corp. facility listed below. We are making this request at the same time as we are providing to the Nevada State Board of Pharmacy (BOP) our wholesaler application as discussed on a June 6, 2023 teleconference with me, Tara Farrington and from the BOP, Mr. Zunino, Mr. Wuest and Mr. Cedars. At the conclusion of that call, you sent me an email indicating that I should submit this request for Temporary Licensure on Coloplast letterhead and addressed to you. It is my understanding that, if approved, BOP staff will issue the "temp" license valid until the board meeting date which will be assigned to this application.

This request for temporary licensure is made for Coloplast Corp. (Coloplast) at this facility:

4495 E Wall Street, Suite 101
Ontario, CA 91761

Sincerely,

Aaron Rodriquez
Senior Legal Counsel, North America

Coloplast

June 28, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Aaron Rodriquez
Senior Legal Counsel, North America
Mobile: 612-889-0672
Mail: usarodr@coloplast.com

Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411
United States

Tel: 612.372.7400
Toll Free Number:
1.800.788.0293
www.coloplast.us

RE: Coloplast Corp. Wholesaler Application – Ontario, CA Facility

To Whom It May Concern:

By this letter, Coloplast Corp. is providing to the Nevada State Board of Pharmacy (BOP) its wholesaler application as discussed on a June 6, 2023 teleconference with me, Tara Farrington and from the BOP, Mr. Zunino, Mr. Wuest and Mr. Cedars. This wholesaler application is made for Coloplast Corp. (Coloplast) at 4495 E Wall Street facility in Ontario, CA 91761 (CA Application).

I am providing the following information to supplement the CA Application.

Coloplast Corp. (Applicant) is a Delaware Corporation and a wholly owned subsidiary of Coloplast A/S which, in turn, is a Danish company that is publicly traded on the Danish stock exchange. Applicant is the U.S. based operating company and is based at the address shown above and in the CA Application. Coloplast A/S and Applicant are medical device manufacturers operating in the U.S (principally through Applicant) and globally, principally through Coloplast A/S. Neither Coloplast A/S nor Applicant manufactures or distributes drugs or controlled substances. The information in this paragraph may be helpful for Sectian 9. Page 5, of the CA Application in bullet three ("all corporation shareholders" for Coloplast Corp).

Coloplast Manufacturing US, LLC is a wholly owned subsidiary and operating unit of Coloplast Corp., the Applicant. Coloplast Manufacturing US, LLC operates a facility in Ontario, CA. The information in this paragraph may be helpful for Section 8, page 5 of the CA Application as Coloplast Manufacturing US, LLC is listed with the Applicant, Coloplast Corp., on the public FDA registration website and in the FDA registration materials included in the CA Application. The information in this paragraph may also be helpful for Section 9 of the CA Application, bullet 11 (license in the city where wholesaler is located).

Coloplast has included a list of the management and leadership employees at the Applicant's CA address, rather than listing every involved employee's name and other information in detail. The management and leadership employees that are identified in the CA Application are responsible for the Applicant's activities at the address set out in this letter. The information in this paragroph may be helpful for Section 9 of the CA Application in bullet 10 ("list containing each employee").

Coloplast

The Personal Record History Record Application described in bullet 7 of CA Application Section 9 is not applicable to Coloplast Corp.

In a separate letter, copy attached, Coloplast is requesting, as discussed in a June 6, 2023 email from Mr. Cedars to me, a temporary license for CA Applicant's facility.

Sincerely,

Aaron Rodriquez
Senior Legal Counsel, North America

CC: Executive Secretary Dave Wuest, Nevada BOP

Enclosures:
1) Wholesaler Application Package with Check Payment

Coloplast

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

June 28, 2023

Aaron Rodriquez
Senior Legal Counsel, North America
Mobile: 612-889-0672
Mail: usarodr@coloplast.com

Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411
United States

Tel: 612.372.7400
Toll Free Number:
1.800.788.0293
www.coloplast.us

RE: Coloplast Corp. Wholesaler Application – Ontario, CA Facility

To Whom It May Concern:

By this letter, Coloplast Corp. is providing to the Nevada State Board of Pharmacy (BOP) its wholesaler application as discussed on a June 6, 2023 teleconference with me, Tara Farrington and from the BOP, Mr. Zunino, Mr. Wuest and Mr. Cedars. This wholesaler application is made for Coloplast Corp. (Coloplast) at 4495 E Wall Street facility in Ontario, CA 91761 (CA Application).

I am providing the following information to supplement the CA Application.

Coloplast Corp. (Applicant) is a Delaware Corporation and a wholly owned subsidiary of Coloplast A/S which, in turn, is a Danish company that is publicly traded on the Danish stock exchange. Applicant is the U.S. based operating company and is based at the address shown above and in the CA Application. Coloplast A/S and Applicant are medical device manufacturers operating in the U.S (principally through Applicant) and globally, principally through Coloplast A/S. Neither Coloplast A/S nor Applicant manufactures or distributes drugs or controlled substances. The information in this paragraph may be helpful for Section 9. Page 5, of the CA Application in bullet three ("all corporation shareholders" for Coloplast Corp).

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Coloplast has included a list of the management and leadership employees at the Applicant's CA address, rather than listing every involved employee's name and other information in detail. The management and leadership employees that are identified in the CA Application are responsible for the Applicant's activities at the address set out in this letter. The information in this paragraph may be helpful for Section 9 of the CA Application in bullet 10 ("list containing each employee").

Coloplast

The Personal Record History Record Application described in bullet 7 of CA Application Section 9 is not applicable to Coloplast Corp.

In a separate letter, copy attached, Coloplast is requesting, as discussed in a June 6, 2023 email from Mr. Cedars to me, a temporary license for CA Applicant's facility.

Sincerely,

Aaron Rodriquez
Senior Legal Counsel, North America

CC: Executive Secretary Dave Wuest, Nevada BOP

Enclosures:
1) Wholesaler Application Package with Check Payment

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 01534	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Diamond Animal Health, Inc.

Physical Address: 2538 SE 43rd Street

City: Des Moines State: IA Zip: 50327

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (515)263-8600 Website: www.heska.com

Name of Designated Representative (DR): Laurie E. Peterson

Licensing Company Email: john.davidson@heska.com DR Email: laurie.peterson@heska.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Veterinary Legend Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Distributors		■ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA **. Provide all the following *where applicable*:** NA

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

July 11, 2023
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Diamond Animal Health, Inc.
Address: 2538 SE 43rd Street City: Des Moines State: IA Zip: 50327
Name: Nova Tech, Inc.
Address: 4705 Gold Core Road City: Grand Island State: NE Zip: 68801
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Iowa - Diamond Animal Health, Inc.
Parent Company (if any): Heska Corporation - Incorporated in Delaware
Corporation/Organization Name: Heska Corporation, a wholly owned subsidiary of Antech, Inc.
Mailing Address: 3760 Rocky Mountain Avenue
City: Loveland State: CO Zip: 80538
Telephone: (800)464-3752 Email: laurie.peterson@heska.com
Contact Person Name: Laurie E. Peterson

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Diamond Animal Health, Inc.

Facility Name

Laurie E. Peterson

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

July 10, 2023

Date

Board Use Only	Date Received: 7/12/23	Amount: 1000-CK-143765

2538 S.E. 43RD STREET
DES MOINES, IOWA 50327
U.S.A.

TELEPHONE: (515) 263-8600
FAX: (515) 263-8661

DIAMOND®
A subsidiary of Heska Corporation

July 11, 2023

List of All Corporation Shareholders and Their Percent Ownership

Diamond Animal Health, Inc. (Diamond), a wholly owned subsidiary of Heska Corporation (Heska), is notifying the Nevada Board of Pharmacy that Heska Corporation has been acquired by Mars, Incorporated (Mars). Diamond remains a wholly owned subsidiary of Heska Corporation. Heska Corporation is now a wholly owned subsidiary of Antech Diagnostics, Incorporated (Antech), who is a wholly owned subsidiary of Mars. The acquisition of Heska was consummated June 13, 2023.

CORPORATE OFFICER LIST

DIAMOND ANIMAL HEALTH, INC.

CONFIDENTIAL
INFORMATION PROVIDED WILL NOT BE DISCLOSED TO THE PUBLIC

PRESIDENT	Name:	Christopher Sveen
	Home Address:	[redacted] Chestnut Place Apt. [redacted] Denver, Colorado 80202
	Date of Birth:	[redacted]
	Soc. Sec. No.:	
VICE PRESIDENT, GENERAL MANAGER	Name:	Laurie E. Peterson
	Home Address:	[redacted] Boulder Drive West Des Moines, IA 50266
	Date of Birth:	[redacted]
	Soc. Sec. No.:	
VICE PRESIDENT, CHIEF FINANCIAL OFFICER and TREASURER	Name:	Catherine Grassman
	Home Address:	[redacted] Marshall Street Fort Collins, CO 80525
	Date of Birth:	[redacted]
	Soc. Sec. No.:	

2020

IOWA SECRETARY OF STATE
PAUL D. PATE

CERTIFICATE OF EXISTENCE

Issue Date: 7/5/2023

Name: DIAMOND ANIMAL HEALTH, INC. (490 DP - 170088)
Date of Incorporation: 10/14/1993
Duration: PERPETUAL

I, Paul D. Pate, Secretary of State of the State of Iowa, custodian of the records of incorporations, certify the following for the corporation named on this certificate:

a. The entity is in existence and duly incorporated under the laws of Iowa.

b. All fees required under the Iowa Business Corporation Act due the Secretary of State have been paid.

c. The most recent biennial report required has been filed with the Secretary of State.

d. Articles of dissolution have not been filed.

Certificate ID: **CS271518**

To validate certificates visit:
sos.iowa.gov/ValidateCertificate

Paul D. Pate, Iowa Secretary of State

IOWA BOARD OF PHARMACY
400 S.W. EIGHTH STREET, SUITE E
DES MOINES, IA 50309-4688
515/281-5944 FAX 515/281-4609
https://pharmacy.iowa.gov

2023

Limited Distributor License No. 40014

Veterinary Drug Distributor

ISSUED 12/02/2022

EXPIRES 12/31/2023

LICENSE STATUS: Current/Active

MAILING ADDRESS
Diamond Animal Health Inc
2538 SE 43rd St
Des Moines,IA 50327

LICENSED LOCATION
Diamond Animal Health Inc
2538 SE 43rd St
Des Moines, IA 50327

Facility Manager: Laurie Eileen Peterson

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0514958	06-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N	EXPORTER	05-31-2023

DIAMOND ANIMAL HEALTH, INC.
2538 SE 43RD ST
DES MOINES, IA 503271538

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0514958	06-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N	EXPORTER	05-31-2023

DIAMOND ANIMAL HEALTH, INC.
2538 SE 43RD ST
DES MOINES, IA 503271538

CONTROLLED SUBSTANCE/REGULATED CHEMICAL REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
7295 2271

COPY

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0514946	06-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N	IMPORTER	05-31-2023

DIAMOND ANIMAL HEALTH, INC.
2538 SE 43RD ST
DES MOINES, IA 503271538

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
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SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N	IMPORTER	05-31-2023

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DES MOINES, IA 503271538

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3N	IMPORTER	05-31-2023

DIAMOND ANIMAL HEALTH, INC.
2538 SE 43RD ST
DES MOINES, IA 503271538

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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P.O. Box 2639
Springfield, VA 22152-2639

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You have been registered to handle the following chemical/drug codes:

Drug Codes
7295

COPY

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0224888	06-30-2024	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2N,3N	MANUFACTURER	05-30-2023

DIAMOND ANIMAL HEALTH
2538 SE 43RD ST
DES MOINES, IA 503271538

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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RD0224888	06-30-2024	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2N,3N	MANUFACTURER	05-30-2023

DIAMOND ANIMAL HEALTH
2538 SE 43RD ST
DES MOINES, IA 503271538

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SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
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DIAMOND ANIMAL HEALTH
2538 SE 43RD ST
DES MOINES, IA 503271538

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DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
2270 2271

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Diamond Animal Health**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Diamond Animal Health, Inc.	1910093	102913878	ANALYSIS; LABEL; MANUFACTURE; PACK;	2538 SE 43rd St, Des Moines, Iowa (IA) 50327, United States (USA)	12/31/2023

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Monday, Oct 10, 2022

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Diamond Animal Health, Inc.

Pharmacy/Wholesaler License # (if applicable) WH01534

Physical Address 2538 SE 43rd Street

City Des Moines State IA Zip 50327

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (515)263-8600 Website www.heska.com

Licensing Company Email laurie.peterson@heska.com

Section 2: Personal Information

First Laurie Middle E. Last Peterson

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Boulder Drive

City West Des Moines State IA Zip 50266

Telephone (515)263-8600 Email laurie.peterson@heska.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
South Dakota State University		08/1987-12/1991	
Address	**City**	**State**	**Zip**
1451 Stadium Rd.	Brookings	SD	57007
Diploma/Degree obtained, if any			
M.S. Microbiology			

School Name		From - To (MM/YY – MM/YY)	
South Dakota State University		12/1991-05/1994	
Address	**City**	**State**	**Zip**
1451 Stadium Rd.	Brookings	SD	57007
Diploma/Degree obtained, if any			
B.S. Microbiology and Biology; Minor Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Aberdeen Central High		08/1984-05/1987	
Address	**City**	**State**	**Zip**
2200 Roosevelt Street	Aberdeen	SD	57401
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/1999-Present	[redacted]Boulder	West Des Moines	IA	50266
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

SURETY RIDER

Old Republic Surety Company
PO BOX 1635
Milwaukee, WI 53201-1635

TO BE ATTACHED TO AND FORM PART OF

Pharmaceutical Wholesaler (Type of bond) Bond Number B150026786

IN FAVOR OF NV State Board of Pharmacy (Obligee)

ON BEHALF OF Laurie Peterson Diamond Animal House (Principal)

EFFECTIVE July 11, 2023 (Original Effective Date)

IT IS AGREED THAT, in consideration of the original premium charged for this bond, and any additional premium that may be properly chargeable as a result of this rider,

1. The Surety hereby gives its consent to:

☑ CHANGE THE NAME OF THE PRINCIPAL

☐ CHANGE THE ADDRESS OF THE PRINCIPAL

(of) the above referenced bond FROM: Diamond Animal House

TO: Diamond Animal Health Inc

EFFECTIVE: July 11, 2023

2. PROVIDED, however, that this bond shall be subject to all of its agreements, limitations, and considerations except as herein expressly modified, and that the liability of the Surety under this bond and under this bond as changed by this rider shall not be cumulative.

3. Signed and sealed this 12th day of July, 2023.

ACCEPTED BY: Old Republic Surety Company (SURETY)

Attorney-in-Fact (TITLE) By: Kimberly Charles ATTORNEY-IN-FACT

ORSC 22381 (5/08)

OLD REPUBLIC SURETY COMPANY

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That OLD REPUBLIC SURETY COMPANY, a Wisconsin stock insurance corporation, does make, constitute and appoint: Kimberly Charles Of LAS VEGAS, Nevada

its true and lawful Attorney(s)-in-Fact, with full power and authority, not exceeding $10,000,000, for and on behalf of the company as surety, to execute and deliver and affix the seal of the company thereto (if a seal is required), bonds, undertakings, recognizances or other written obligations in the nature thereof, ***(other than bail bonds, bank depository bonds, mortgage deficiency bonds, mortgage guaranty bonds, guarantees of installment paper and note guaranty bonds, self-insurance workers compensation bonds guaranteeing payment of benefits, asbestos abatement contract bonds, waste management bonds, hazardous waste remediation bonds or black lung bonds),*** as follows: Effective Date of Change: 07/11/2023

Bond Number:	B150026786	Bond Amount:	Twenty-Five Thousand Dollars	$ 25,000.00
Principal Name:	Laurie Peterson		Diamond Animal House	
Obligee Name:	NV State Board of Pharmacy, Nevada			

and to bind OLD REPUBLIC SURETY COMPANY thereby, and all of the acts of said Attorneys-in-Fact, pursuant to these presents, are ratified and confirmed. This appointment is made under and by authority of the board of directors at a special meeting held on February 18, 1982.

This Power of Attorney is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the board of directors of the OLD REPUBLIC SURETY COMPANY on February 18,1982.

RESOLVED that the president, any vice president or assistant vice president, in conjunction with the secretary or any assistant secretary, may appoint attorneys-in-fact or agents with authority as defined or limited in the instrument evidencing the appointment in each case, for and on behalf of the company to execute and deliver and affix the seal of the company to bonds, undertakings, recognizances, and suretyship obligations of all kinds; and said officers may remove any such attorney-in-fact or agent and revoke any Power of Attorney previously granted to such person.

RESOLVED FURTHER that any bond, undertaking, recognizance, or suretyship obligation shall be valid and binding upon the Company

(i) when signed by the president, any vice president or assistant vice president, and attested and sealed (if a seal be required) by any secretary or assistant secretary; or

(ii) when signed by the president, any vice president or assistant vice president, secretary or assistant secretary, and countersigned and sealed (if a seal be required) by a duly authorized attorney-in-fact or agent; or

(iii) when duly executed and sealed (if a seal be required) by one or more attorneys-in-fact or agents pursuant to and within the limits of the authority evidenced by the Power of Attorney issued by the company to such person or persons.

RESOLVED FURTHER that the signature of any authorized officer and the seal of the company may be affixed by facsimile to any Power of Attorney or certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the company; and such signature and seal when so used shall have the same force and effect as though manually affixed.

IN WITNESS WHEREOF, OLD REPUBLIC SURETY COMPANY has caused these presents to be signed by its proper officer, and its corporate seal to be affixed this 12th day of July, 2023.

OLD REPUBLIC SURETY COMPANY

Karen J. Haffner
Assistant Secretary

Alan Pavlic
President

STATE OF WISCONSIN, COUNTY OF WAUKESHA - SS

On this 12th day of July, 2023, personally came before me, Alan Pavlic and Karen J. Haffner, to me known to be the individuals and officers of the OLD REPUBLIC SURETY COMPANY who executed the above instrument, and they each acknowledged the execution of the same, and being by me duly sworn, did severally depose and say: that they are the said officers of the corporation aforesaid, and that the seal affixed to the above instrument is the seal of the corporation, and that said corporate seal and their signatures as such officers were duly affixed and subscribed to the said instrument by the authority of the board of directors of said corporation.

Kathryn R. Pearson
Notary Public

My Commission Expires: 09/28/2026
(Expiration of notary's commission does not invalidate this instrument)

CERTIFICATE

I, the undersigned, assistant secretary of the OLD REPUBLIC SURETY COMPANY, a Wisconsin corporation, CERTIFY that the foregoing and attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolutions of the board of directors set forth in the Power of Attorney, are now in force.

0515130

Signed and sealed at the City of Brookfield, WI this 12th day of July, 2023.

Karen J. Haffner
Assistant Secretary

ORSC 22262 (3-06)

ALL N ONE BONDING & INS INC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. B150026786

Application/License No. WH01534

Laurie Peterson Diamond Animal House (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2538 SE 43rd St, Des Moines, IA 50327-1538 (Address of Applicant/Principal), as PRINCIPAL, and Old Republic Surety Company (Surety Company), a corporation organized under the laws of the state of Wisconsin (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 18500 W Corporate Dr, Ste 170, Brookfield, WI 53045 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 7/11/2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th day of July, 20 23.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Kimberly Charles, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Andrew Renshaw

OLD REPUBLIC SURETY COMPANY

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That OLD REPUBLIC SURETY COMPANY, a Wisconsin stock insurance corporation, does make, constitute and appoint: Kimberly Charles Of LAS VEGAS, Nevada

its true and lawful Attorney(s)-in-Fact, with full power and authority, not exceeding $10,000,000, for and on behalf of the company as surety, to execute and deliver and affix the seal of the company thereto (if a seal is required), bonds, undertakings, recognizances or other written obligations in the nature thereof, ***(other than bail bonds, bank depository bonds, mortgage deficiency bonds, mortgage guaranty bonds, guarantees of installment paper and note guaranty bonds, self-insurance workers compensation bonds guaranteeing payment of benefits, asbestos abatement contract bonds, waste management bonds, hazardous waste remediation bonds or black lung bonds),*** as follows: Effective Date of Change: 07/11/2023

Bond Number:	B150026786	Bond Amount:	Twenty-Five Thousand Dollars	$ 25,000.00
Principal Name:	Laurie Peterson		Diamond Animal House	
Obligee Name:	NV State Board of Pharmacy, Nevada			

and to bind OLD REPUBLIC SURETY COMPANY thereby, and all of the acts of said Attorneys-in-Fact, pursuant to these presents, are ratified and confirmed. This appointment is made under and by authority of the board of directors at a special meeting held on February 18, 1982.

This Power of Attorney is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the board of directors of the OLD REPUBLIC SURETY COMPANY on February 18,1982.

RESOLVED that the president, any vice president or assistant vice president, in conjunction with the secretary or any assistant secretary, may appoint attorneys-in-fact or agents with authority as defined or limited in the instrument evidencing the appointment in each case, for and on behalf of the company to execute and deliver and affix the seal of the company to bonds, undertakings, recognizances, and suretyship obligations of all kinds; and said officers may remove any such attorney-in-fact or agent and revoke any Power of Attorney previously granted to such person.

RESOLVED FURTHER that any bond, undertaking, recognizance, or suretyship obligation shall be valid and binding upon the Company

(i) when signed by the president, any vice president or assistant vice president, and attested and sealed (if a seal be required) by any secretary or assistant secretary; or

(ii) when signed by the president, any vice president or assistant vice president, secretary or assistant secretary, and countersigned and sealed (if a seal be required) by a duly authorized attorney-in-fact or agent; or

(iii) when duly executed and sealed (if a seal be required) by one or more attorneys-in-fact or agents pursuant to and within the limits of the authority evidenced by the Power of Attorney issued by the company to such person or persons.

RESOLVED FURTHER that the signature of any authorized officer and the seal of the company may be affixed by facsimile to any Power of Attorney or certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the company; and such signature and seal when so used shall have the same force and effect as though manually affixed.

IN WITNESS WHEREOF, OLD REPUBLIC SURETY COMPANY has caused these presents to be signed by its proper officer, and its corporate seal to be affixed this 11th day of July, 2023.

OLD REPUBLIC SURETY COMPANY

Karen J. Haffner
Assistant Secretary

Alan Pavlic
President

STATE OF WISCONSIN, COUNTY OF WAUKESHA - SS

On this 11th day of July, 2023, personally came before me, Alan Pavlic and Karen J. Haffner, to me known to be the individuals and officers of the OLD REPUBLIC SURETY COMPANY who executed the above instrument, and they each acknowledged the execution of the same, and being by me duly sworn, did severally depose and say: that they are the said officers of the corporation aforesaid, and that the seal affixed to the above instrument is the seal of the corporation, and that said corporate seal and their signatures as such officers were duly affixed and subscribed to the said instrument by the authority of the board of directors of said corporation.

Kathryn R. Pearson
Notary Public

My Commission Expires: 09/28/2026
(Expiration of notary's commission does not invalidate this instrument)

CERTIFICATE

I, the undersigned, assistant secretary of the OLD REPUBLIC SURETY COMPANY, a Wisconsin corporation, CERTIFY that the foregoing and attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolutions of the board of directors set forth in the Power of Attorney, are now in force.

0515130

Signed and sealed at the City of Brookfield, WI this 11th day of July, 2023.

Karen J. Haffner
Assistant Secretary

ORSC 22262 (3-06)

ALL N ONE BONDING & INS INC

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Diamond Animal Health, Inc.			09/08-Present
Business Address	**City**	**State**	**Zip**
2538 SE 43rd Street	Des Moines	IA	50327
Phone	**Title**	**Number of Employed Hours**	
(515)263-8600	General Manager	Full Time	
Description of Duties			
Responsible for the overall management of the operations based in Des Moines including: manufacturing, inventory, distribution, R&D, Quality, Regulatory, Finance, HR, Business Development, IT, and Safety			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

July 10, 2023
Date

I, Laurie E. Peterson, **certify that as the designated representative for**

Diamond Animal Health, Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LEP I am at least 21 years of age;
3. LEP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LEP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LEP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LEP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LEP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Laurie E. Peterson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 10, 2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Laurie E. Peterson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 10, 2023
Date

Please have this section completed in the presence of a Notary Public.

State of Iowa, ss. County of Polk

I, Laurie E. Peterson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

July 11, 2023
Date

Subscribed and Sworn to before me this 11 (~~10~~) day of July. KD 7-11-2023

Notary Public Signature

KAITLYN BROOKE DUDDING
Commission Number 835555
My Commission Expires
November 4, 2024

(Seal)

Full Time Employees and Contractors

Legal Last Name	Legal First Name	Home Department Description
Anderson	Alicia	Immunotherapy ZUV
Andrews	Joshua	Validation/Calibration ZUV
Ayersman	Erin	Plant Administration ZUV
Baltzell	Paige	Bio Regulatory Affairs ZUV
Barfield	Kara	Heska Distribution ZUV
Bedord	Michael	Plant Administration ZUV
Betterley	Margaret	Bio Regulatory Affairs ZUV
Boyce	Linda	Packaging ZUV
Bradshaw	Leslie	Warehouse ZUV
Bradshaw	Randy	Heska Distribution ZUV
Branca	John	Validation/Calibration ZUV
Bruere	Jessica	Bio Regulatory Affairs ZUV
Burnett	Duncan	Chemical Control ZUV
Carlson	Lucas	Heska Distribution ZUV
Carre	Bradley	Maintenance ZUV
Carre	Brandon	Tablets/Powder Production ZUV
Chapman	Brett	Heska Distribution ZUV
Chiri	Gregory	Tablets/Powder Production ZUV
Christensen	Jack	Warehouse ZUV
Cool	Marc	Information Systems ZUV
Crabtree	David	Farm ZUV
Cronk	Angela	Bio Regulatory Affairs ZUV
Dang	Einsteen	Plant Administration ZUV
Davidson	Allyson	Heska Distribution ZUV
Davidson	Isabelle	Heska Distribution ZUV
Davidson	John	Plant Administration ZUV
DeRoos	Jennifer	Quality Control ZUV
Dirks	Michael	Maintenance ZUV
Downing	Mark	Tablets/Powder Production ZUV
Dudding	Kaitlyn	Bio Regulatory Affairs ZUV
Ellis	Alexandria	Quality Assurance/Warehouse ZUV
Erickson	Daniel	Maintenance ZUV
Espinoza	Manolo	Warehouse ZUV
Exline	Paula	Research/Development ZUV
Garth	JB	Sterile Fill ZUV
Geery	Zachary	Immunotherapy ZUV
Gill	Eric Daniel	Packaging ZUV
Goddard	Carl	Sterile Fill ZUV
Hagwood	Kelly	Quality Control ZUV
Halter	Steven	Central Services ZUV
Hamm	Vanessa	Bio Regulatory Affairs ZUV
Hansen	Thomas	Central Services ZUV
Heckman	Andrew	Chemical Control ZUV
Henning	Eric	Solutions ZUV
Hofer	Shane	Maintenance ZUV

Hook	Spencer	Quality Assurance/Warehouse ZUV
Illg	Michael	Plant Administration ZUV
Inman	Richard	Information Systems ZUV
Johnson	Bradley	Heska Distribution ZUV
Keeney	Tiffany	Quality Control ZUV
Kenne	Danielle	Quality Control ZUV
Klechee	Harry	Tablets/Powder Production ZUV
Knight	Jeffery	Plant Administration ZUV
Krogman	Christine	Plant Administration ZUV
Kurtz	Lindsey	Immunotherapy ZUV
Lawrence	Nathan	Instrumentation ZUV
Leach	Brandon	Maintenance ZUV
Little	Michelle	Biological Production ZUV
Lord	MaKayla	Animal Care ZUV
Lovan	Khamla	Plant Administration ZUV
Matthew	Etaslon	Immunotherapy ZUV
McKenzie	Kyla	Immunotherapy ZUV
Miller	Kevin	Biological Production ZUV
Miller	Tracy	Packaging ZUV
Moeller	Kenidy	Plant Administration ZUV
Moreno Islas	Omar	Quality Assurance/Warehouse ZUV
Murillo	Bernardino	Tablets/Powder Production ZUV
Musselman	Debbie	Quality Control ZUV
Naffziger	Nathaniel	Central Services ZUV
Neal	Richard	Instrumentation ZUV
Nguyen	Daniel	Quality Assurance/Warehouse ZUV
Ortiz	Bobby	Central Services ZUV
Ortiz	Gabrielle	Heska Distribution ZUV
Pacheco-Loredo	Sianna	Immunotherapy ZUV
Patricio	Antonio	Chemical Control ZUV
Peterson	Laurie	Plant Administration ZUV
Plum	Tim	Biological Production ZUV
Podraza	Amy	Quality Assurance/Warehouse ZUV
Pollard	Kathryn	Quality Assurance/Warehouse ZUV
Prevo	Cassandra	Immunotherapy ZUV
Rettkowski	Mindelyn	Animal Care ZUV
Rice	Henry	Quality Assurance/Warehouse ZUV
Sithonnorath	Anoma	Instrumentation ZUV
Sloan	Julie	Plant Administration ZUV
Smith	Dorinda	Heska Distribution ZUV
Smith	Kathleen	Heska Distribution ZUV
Son	Nadia	Finance ZUV
Steenhoek	Justin	Chemical Control ZUV
Stegg	Kristi	Chemical Control ZUV
Steichen	Christopher	Research/Development ZUV
Steil	Sarah	Validation/Calibration ZUV
Stephens	Dustin	Maintenance ZUV

Sunkle	Blake	Serial Assembly ZUV
Teav	Thomas	HES ZUV
Thilges	Charles	Biological Production ZUV
Thompson	Steve	Farm ZUV
Thurlby	Matthew	Maintenance ZUV
Tran	Don	Tablets/Powder Production ZUV
Van Sickle	Jennifer	Finance ZUV
Vansice	Jeremy	Maintenance ZUV
Volker	Alexandra	Chemical Control ZUV
Walton	Trent	Sterile Fill ZUV
Ware	Rachelle	Quality Assurance/Warehouse ZUV
White	Tariq	Immunotherapy ZUV
Wilcoxson	Michael	Heska Distribution ZUV
Willoughby	Lary	Sterile Fill ZUV
Yeakel	Paige	Quality Control ZUV

Contractors

Aguilar	Linda	Quality Assurance/Warehouse ZUV
Cunningham	Amanda	Tablets/Powder Production ZUV
Dunn	Kary	Tablets/Powder Production ZUV
Kevin	Kirkendall	Sterile Fill ZUV
Jenna	Moore	Immunotherapy ZUV
Valentino	Orrai	Tablets/Powder Production ZUV
Andrew	Roland	Sterile Fill ZUV
Charles	Snyder	Sterile Fill ZUV
Donna	Williamson	Heska Distribution ZUV
Madelyn	Write	Biological Production ZUV

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: DJO, LLC

Physical Address: 3151 Scott Street

City: Vista State: CA Zip: 92081

Mailing Address (if different from physical address): 7000 Cardinal Pl, Attn: QRA

City: Dublin State: OH Zip: 43017

Telephone: 737-228-5760 Website: www.djoglobal.com

Name of Designated Representative (DR): ~~Matthew Osborn~~ Juan Villanueva juan.villanueva @enovis.com

4/25/2023 CA

Licensing Company Email: licensure@cardinalhealth.com DR Email: ~~matt.osborn@enovis.com~~

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Domex Technology Corp.
Address: No 6, Hsin Ann RD. Hsinchu City: _____ State: Taiwan Zip: _____
Name: South Dakota Partners Inc.
Address: 205 HWY 22 E. City: Clear Lake State: SD Zip: 57226
Name: Mitsubishi Chemical Carbon Fiber and Composites Inc.
Address: 1822 Reynolds Ave City: Irvine State: CA Zip: 92614
Name: Parker Hannifin Corporation
Address: 26 Clinton Dr. #103 City: Hollis State: NH Zip: 03049

Section 4: Publicly Traded Corporation

State of Incorporation: _____
Parent Company (if any): _____
Corporation Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): DJO Finance, LLC
Corporation/Organization Name: _____
Mailing Address: 5919 Sea Otter Place, Ste. 200
City: Carlsbad State: CA Zip: 92010
Telephone: 800-321-9549 Email: licensure@cardinalhealth.com
Contact Person Name: Jeanette Peat

Section 6: Partnership

Partnership Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____
Business Name: _____
Business Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
✓ **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
✓ **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
✓ **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
✓ **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
✓ **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** NOT APPLICABLE	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
✓ **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
✓ **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
✓ [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
✓ **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form at:** http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

DJO, LLC

Facility Name

Keegan Chamberlain

Print Name of Authorized Person Submitting Application

K

Original signature of Authorized Person (copies or stamps not accepted)

1/11/2023

Date

Board Use Only	Date Received: 5/23/23	Amount: $1000 CC ✓ 6/1/23

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
DJO, LLC
3151 Scott St
Vista, CA 92081
Registration Number: 3012446970
FEI Number*: 2020737
Status: Active
Date Of Registration Status: 2023

Owner/Operator:
DJO, LLC[6]
5919 Sea Otter Place
Suite 200
Carlsbad, CA US 92010
Owner/Operator Number: 9015378[7]

Official Correspondent:
Dave Hunter
5919 Sea Otter Place
Suite 200
Carlsbad, CA 92010
Phone: 1-858-2458747

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9015378&
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9015378&

Page Last Updated: 11/14/2022

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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4. https://www.fda.gov/Medical-Devices

DJO Global Ownership Structure
(after acquisition by Colfax Corporation)

Colfax Corporation
TIN: 54-1887631
420 National Business Parkway

Owner of 100% of:

Motion Parent, Inc.
TIN: 83-2819343
420 National Business Parkway
Annapolis Junction, MD 20701

Owner of 100% interest in:

DJO Global, Inc.
TIN: 65-0572565
1430 Decision St. Vista, CA 92081

Owner of 100% of:

DJO Holdings LLC
TIN: 20-5654205
1430 Decision St. Vista, CA 92081

Owner of 100% of:

DJO Finance LLC
TIN: 20-5653965
1430 Decision St. Vista, CA 92081

Owner of 100% of:

DJO, LLC
TIN: 52-2165554
1430 Decision St. Vista, CA 92081

3151 Scott Street
Vista, California 92081

Officer Name	Title	Percentage of Ownership
Brady Rodgers Shirley	President and CEO	0
Bradley J. Tandy	Executive Vice President and General Counsel	0%

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The above two named individuals are Corporate Officers for DJO, LLC.

Juan Villanueva is the Designated Representative for the facility.

DJO, LLC - Corporate Officers

Officer Name	Title	Company
Brady Rodgers Shirley	President and CEO	DJO, LLC
Bradley J. Tandy	Executive Vice President and General Counsel	DJO, LLC

DJO, LLC is a privately owned entity.

Parent Company with 100% ownership is DJO Finance, LLC (also privately held).

DJO Finance, LLC is located at 5919 Sea Otter Place, Ste. 200 Carlsbad, CA 92010.

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

DJO, LLC.
3151 Scott Street
Vista, CA 92081

LICENSE NUMBER: 57600
EXPIRATION DATE: 4/2/2025

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 2/22/2023

OSP 07 102308

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

DJO, LLC.
3151 Scott Street
Vista, CA 92081

LICENSE NUMBER: 57600
EXPIRATION DATE: 11/5/2023

The person named herein is licensed to operate a Home Medical Device Retail Facility through the expiration date of this license. This annual license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to Home Medical Device Retail Facilities.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 10/13/2022

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 07/14/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA, LLC.
445 SOUTH STREET
MORRISTOWN, NJ 07962-1966
Attn: morristown.certrequest@marsh.com Fax 212-948-0979

CN101292797-DJO.-GAWUX-22-24

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B : Travelers Prop. Casualty Co. Of America	25674
INSURER C : N/A	N/A
INSURER D : See Attached Acord 101	
INSURER E :	
INSURER F :	

INSURED
DJO, LLC
1430 Decision St.
Vista, CA 92081

COVERAGES **CERTIFICATE NUMBER:** NYC-011652003-01 **REVISION NUMBER:** 5

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			OGL G2570132A	05/31/2023	05/31/2024	EACH OCCURRENCE	$	5,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	100,000
							MED EXP (Any one person)	$	
							PERSONAL & ADV INJURY	$	5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	10,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$	EXCLUDED
	OTHER:							$	
B	AUTOMOBILE LIABILITY			TC2JCAP-2H532302-TIL-23	01/01/2023	01/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$	2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	$	
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$	
	DED [ ] RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			UB-1W929206-23-51-K (AOS)	01/01/2023	01/01/2024	X PER STATUTE [ ] OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] (Mandatory in NH)		N/A	UB-1W92950A-23-51-R (AZ,MA,NE,WI)	01/01/2023	01/01/2024	E.L. EACH ACCIDENT	$	1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
D	PRODUCTS LIABILITY			LSR-PCO-00451-22	08/15/2022	08/15/2023	EACH OCC / AGGREGATE		10,000,000
				SIR: $1M EA EVENT / $2.5M AGG					

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
RE: DJO, LLC, 5919 Sea Otter Place, Suite 200, Carlsbad, CA 92010

CERTIFICATE HOLDER

National Supplier Clearinghouse
P O Box 100236
Columbia, SC 29202-3236

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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AGENCY CUSTOMER ID: CN101292797
LOC #: Morristown

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA, LLC.	DJO, LLC 1430 Decision St. Vista, CA 92081
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

EXCESS AUTO LIABILITY:
CARRIER: TRAVELERS PROPERTY CASUALTY COMPANY OF AMERICA
POLICY NO: EX-9S191122-23-NF
EFFECTIVE: 01/01/2023 - 01/01/2024
COMBINED SINGLE LIMIT: $3,000,000

Product Coverage Carriers:
Underwriters:
47.50% Underwriters at Lloyd's
20.00% AXA XL Insurance Company UK Limited
12.50% Arch Specialty Insurance Company
20.00% Scottsdale Insurance Company

Name Insured Schedule:

Enovis Corporation
DJO Consumer LLC
DJO LLC
Elastic Therapy LLC
LiteCure LLC
Surgi-Care Inc.
Trilliant Surgical LLC
Ortho Pros Xpress Inc
Stoody Company
E6259-Central NA
Encore Medical
DJO Consumer LLC
DJO UK Limited
Elastic Therapy LLC
ENCORE MEDICAL, L.P. dba DJO SURGICAL
Matrix Orthopedics Surgical Devices
Apex Health Solutions, LLC
CalSurg. Inc
CP Medical, LLC
Dr. Comfort

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Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DJO, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF AUGUST, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "DJO, LLC" WAS FORMED ON THE TWENTY-SECOND DAY OF MARCH, A.D. 1999.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3019890 8300

SR# 20233307207

Authentication: 204012932

Date: 08-22-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	DJO, LLC
Entity No.:	199916310078
Registration Date:	06/11/1999
Entity Type:	Limited Liability Company - Out of State
Formed In:	DELAWARE
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of August 21, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 139194843

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

LICENSE OR
PERMIT BOND

Bond K41709108

LICENSE OR PERMIT BOND

KNOW ALL BY THESE PRESENTS, That we, DJO LLC
3151 Scott Street, Vista, CA 92081
as Principal, and the Federal Insurance Company, a Indiana corporation,
as Surety, are held and firmly bound unto Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206, Reno, NV 89521, as Obligee,
in the sum of Twenty-five Thousand & 00/100
Dollars ($25,000.00)
for which sum, well and truly to be paid, we bind ourselves, our heirs, executors, administrators, successors and assigns, jointly and severally, firmly by these presents.

Signed and sealed this 1st day of August, 2023.

THE CONDITION OF THIS OBLIGATION IS SUCH, That WHEREAS, the Principal has been or is about to be granted a license or permit to do business as Medical Devices, Equipment & Gases Supplier Warehouse Distribution Center by the Obligee.

NOW, Therefore, if the Principal well and truly comply with applicable local ordinances, and conduct business in conformity therewith, then this obligation to be void; otherwise to remain in full force and effect.

PROVIDED, HOWEVER; 1. This bond shall continue in force:

☐ Until _____, _____, or until the date of expiration of any Continuation Certificate executed by the Surety

OR

☑ Until canceled as herein provided.

2 This bond may be canceled by the Surety by the sending of notice in writing to the Obligee, stating when, not less than thirty days thereafter, liability hereunder shall terminate as to subsequent acts or omissions of the Principal.

DJO LLC

Principal

By _____

Federal Insurance Company

By _____
April D. Perez Attorney-in-Fact
NV Non-Resident License #722132

LMS-10908 10/06

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Wisconsin corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

April D. Perez

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **10th** day of **March, 2020**.

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

Steven M Haney

Stephen M. Haney, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **10th** day of **March, 2020** before me, a Notary Public of New Jersey, personally came Dawn M. Chloros and Stephen M. Haney, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Dawn M. Chloros and Stephen M. Haney, being by me duly sworn, severally and each for herself and himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

KATHERINE J. ADELAAR
NOTARY PUBLIC OF NEW JERSEY
No. 2316685
Commission Expires July 16, 2024

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Dawn M. Chloros, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this August 1, 2023

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

FEDERAL INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2022

(in thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash and Short Term Investments	$ 123,147	Outstanding Losses and Loss Expenses	$ 9,263,034
United States Government, State and Municipal Bonds	3,769,695	Reinsurance Payable on Losses and Expenses	1,723,798
Other Bonds	5,864,508	Unearned Premiums	2,632,590
Stocks	245,498	Ceded Reinsurance Premiums Payable	380,182
Other Invested Assets	1,979,194	Other Liabilities	471,528
TOTAL INVESTMENTS	12,082,042	TOTAL LIABILITIES	14,471,130
Investments in Affiliates			
Great Northern Ins. Co.	422,405	Capital Stock	20,880
Vigilant Ins. Co	381,723	Paid-In Surplus	2,711,474
Chubb Indemnity Ins. Co.	185,044	Unassigned Funds	1,545,403
Chubb National Ins. Co.	194,379		
Other Affiliates	124,046	SURPLUS TO POLICYHOLDERS	4,277,857
Premiums Receivable	1,859,933		
Other Assets	3,519,415		
TOTAL ADMITTED ASSETS	$ 18,748,987	TOTAL LIABILITIES AND SURPLUS	$ 18,748,987

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners. At December 31, 2022, investments with a carrying value of $512,747,632 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Federal Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2022.

Sworn before me this March 16, 2023

Senior Vice President

Notary Public

September 19, 2023
My commission expires

Commonwealth of Pennsylvania - Notary Seal
Jaime L. Yates, Notary Public
Philadelphia County
My commission expires September 19, 2023
Commission number 1357070
Member, Pennsylvania Association of Notaries

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG DJO, LLC MDEG License # (if applicable) _____

Physical Address 3151 Scott Street

City Vista State CA Zip 92081

Mailing Address (if different from physical address) 7000 Cardinal Pl - QRA

City Dublin State OH Zip 43017

Telephone 800-321-9549 Website djoglobal.com

Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First Juan Middle Ramon Last Villanueva

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Scott Street

City Vista State CA Zip 92081

Telephone 800-321-9549 Email juan.villanueva@enovis.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Palomar college		4/2016 – Present	
Address	**City**	**State**	**Zip**
1140 W Mission Rd	San Marcos	CA	92069
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Escondido adult School		2015	
Address	**City**	**State**	**Zip**
220 W Crest St.	Escondido	CA	92025
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016 - Present	[redacted] White Oak Pl Unit 3	Escondido	CA	92027
09/2014 - 12/2015	[redacted] Rock Springs Rd	San Marcos	CA	92069
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
DJO, LLC			09/14 - Present
Business Address	**City**	**State**	**Zip**
3151 Scott Street	Vista	CA	92081
Phone	**Title**		**Number of Employed Hours**
800-321-9549	Supervisor		Approx 19k
Description of Duties			
Implemented operational process improvements to increase efficiency in material ordering, inventory management, and data management.			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name N/A		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/17/2023
Date

I, Juan Villanueva, **certify that as the MDEG Administrator for**

DJO, LLC,

that I (initial that you have read and meet the following requirements):

1. JV Have a high school diploma or its equivalent;
2. JV Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JV Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JV Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Juan Villanueva
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/17/2023
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler DJO, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 3151 Scott Street

City Vista State CA Zip 92081

Mailing Address (if different from physical address) 7000 Cardinal Pl - QRA

City Dublin State OH Zip 43017

Telephone 800-321-9549 Website djoglobal.com

Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First Juan Middle Ramon Last Villanueva

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Scott Street

City Vista State CA Zip 92081

Telephone 800-321-9549 Email juan.villanueva@enovis.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Palomar College			4/2016 - Present	
Address		**City**	**State**	**Zip**
1140 W Mission Rd		San Marcos	CA	92069
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Escondido adult School			2015	
Address		**City**	**State**	**Zip**
220 W Crest St		Escondido	CA	92025
Diploma/Degree obtained, if any				
GED				

School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
N/A				
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016-Present	[redacted] White Oak Pl Unit [redacted]	Escondido	CA	92027
09/2014-12/2015	[redacted] Rock Springs Rd	San Marcos	CA	92069
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
DJO, LLC			09/14 - Present
Business Address	**City**	**State**	**Zip**
3151 Scott Street	Vista	CA	92081
Phone	**Title**		**Number of Employed Hours**
800-321-9549	Supervisor		Approx 19k
Description of Duties			
Implemented operational process improvements to increase efficiency in material ordering, inventory management, and data management.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/18/2023
Date

I, Juan Villanueva, **certify that as the designated representative for**

DJO, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JV I am at least 21 years of age;
3. JV I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JV I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JV I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JV I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JV I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Juan Villanueva

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/17/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Juan Villanueva

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/17/2023

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Diego

I, Juan Villanueva, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/17/2023

Date

Subscribed and Sworn to before me this 17 day of April, 23.

Notary Public Signature

MARIBEL FRANCO
Comm. #2334732-Mfc. #NNA1
Notary Public
CALIFORNIA
San Diego County
My Comm. Exp. Oct 30, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler DJO, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable)

Physical Address ~~3300 Eagle Parkway~~ 3151 Scott Street

City ~~Fort Worth~~ Vista State ~~TX~~ CA Zip ~~76177~~ 92081

4/25/2023 KA

Mailing Address (if different from physical address) 7000 Cardinal Pl, Attn: QRA

City Dublin State OH Zip 43017

Telephone 737-228-5760 Website www.djoglobal.com

Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First Juan Middle Ramon Last Villanueva

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 3151 Scott Street

City Vista State CA Zip 92081

Telephone 800-321-9549 Email juan.villanueva@enovis.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
Palomar College	4/2016 - Present

Address	City	State	Zip
1140 W Mission Rd	San Marcos	CA	92069

Diploma/Degree obtained, if any

School Name	From - To (MM/YY – MM/YY)
Escondido adult School	2015

Address	City	State	Zip
220 W Crest St.	Escondido	CA	92025

Diploma/Degree obtained, if any
GED

School Name	From - To (MM/YY – MM/YY)
N/A	

Address	City	State	Zip

Diploma/Degree obtained, if any

School Name	From - To (MM/YY – MM/YY)
N/A	

Address	City	State	Zip

Diploma/Degree obtained, if any

School Name	From - To (MM/YY – MM/YY)
N/A	

Address	City	State	Zip

Diploma/Degree obtained, if any

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016-Present	[redacted] White Oak Pl Unit 3	Escondido	CA	92027
09/2014 - 12/2015	[redacted] Rock Springs Rd	San Marcos	CA	92069
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: DJO, LLC			From - To (MM/YY – MM/YY): 09/14 - Present	
Business Address: 3151 Scott Street	City: Vista		State: CA	Zip: 92081
Phone: 800-321-9549	Title: Supervisor			
Description of Duties: Implemented operational process improvements to increase efficiency in material ordering, inventory management, and data management.				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/17/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Juan Villanueva

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/17/2023

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Diego

I, Juan Villanueva, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/17/2023

Date

Subscribed and Sworn to before me this 17 day of April, 23.

Notary Public Signature

MARIBEL FRANCO
Comm. #2334732-Mfr. #NNA1
Notary Public
CALIFORNIA
San Diego County
My Comm. Exp. Oct 30, 2024

(Seal)

Employee list for the Vista, CA application for DJO, LLC

Legal Name	Business Title	Worker Type	Location	State
Carlos Eduardo Zepeda Martinez	Manager, Process Engineering	Employee	DJO Vista Manufacturing Center	California
Brian Phan	Senior Buyer	Employee	DJO Vista Manufacturing Center	California
Leticia Nunez	Precision Operator 2	Employee	DJO Vista Manufacturing Center	California
Jaime Corona	Maintenance Technician 4	Employee	DJO Vista Manufacturing Center	California
Patty Sonevongxay	Precision Operator 2	Employee	DJO Vista Manufacturing Center	California
Jose Villa	Bldg. Maintenance Technician 3	Employee	DJO Vista Manufacturing Center	California
Jesse Lemus	Precision Operator - 2	Employee	DJO Vista Manufacturing Center	California
JOSE ZUNIGA	Electrical Engineering Technician	Employee	DJO Vista Manufacturing Center	California
Rosa Gutierrez Andrade	Precision Operator 2	Employee	DJO Vista Manufacturing Center	California
Laura Reyes	Precision Operator-2	Employee	DJO Vista Manufacturing Center	California
Felipa Rodriguez	Precision Operator 2	Employee	DJO Vista Manufacturing Center	California
Maria Ortega	Material Handler 2	Employee	DJO Vista Manufacturing Center	California
Refugio Cazares	Precision Operator 2	Employee	DJO Vista Manufacturing Center	California
Kwang Lee	Lead - Electronics	Employee	DJO Vista Manufacturing Center	California
Lucila Hall	Precision Operator 2	Employee	DJO Vista Manufacturing Center	California
Maria De Velazquez	Precision Operator 2	Employee	DJO Vista Manufacturing Center	California
Angeles Palencia	Precision Operator-2	Employee	DJO Vista Manufacturing Center	California
Arcelia Garcia	EGX Engineer - 2	Employee	DJO Vista Manufacturing Center	California
Areli Maya	Precision Operator 2	Employee	DJO Vista Manufacturing Center	California
Robert Seale	Quality Control Technician 3	Employee	DJO Vista Manufacturing Center	California
Pierre Millan Penaloza	Quality Control Technician - 3	Employee	DJO Vista Manufacturing Center	California
Juan Villanueva	Supervisor Shipping and Planning	Employee	DJO Vista Manufacturing Center	California
Lorena Jauregui	Quality Control Inspector-2	Employee	DJO Vista Manufacturing Center	California
Veronica Ontiveros	Quality Technician - 2	Employee	DJO Vista Manufacturing Center	California
Jose Luis Torres Coronado	Manager, Quality Assurance	Employee	DJO Vista Manufacturing Center	California
Veronica Arcos	Material Handler - 3	Employee	DJO Vista Manufacturing Center	California
Lemuel Cadsap	Quality Control Inspector-2	Employee	DJO Vista Manufacturing Center	California
Matthew Osborn	Manufacturing Manager-3	Employee	DJO Vista Manufacturing Center	California
Ester Cruz	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
J De Jesus Rodriguez Portillo	Product Assembler-3	Employee	DJO Vista Manufacturing Center	California
Alejo Garcia	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Margarita Olivera	Product Assembler-3	Employee	DJO Vista Manufacturing Center	California

Isabel Contreras	Product Assembler 2	Employee	DJO Vista Manufacturing Center	California
Hilda Martinez	Product Assembler-3	Employee	DJO Vista Manufacturing Center	California
Ursulina Leon	Precision Operator - 1	Employee	DJO Vista Manufacturing Center	California
Jean Morales	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Sara Lopez	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Juan Delgado-candia	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Anastacia Canseco	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Maria Meza	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Maria Cisneros	Product Assembler-3	Employee	DJO Vista Manufacturing Center	California
Margarita Alejandre	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Laura Garcia	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Maria Flores	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Maria Ortega	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Maria De Haro	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Esperanza Ramirez	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Rosina Gonzalez	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Eugene Bongato	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Juana Barrios	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Cecilia Venegas	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Jose Amador	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Jova Mendez	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Ricarda Canseco	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Pravinkumar Patel	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Luis Flores	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Alma Cedillo	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Lorena Mercado	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Fernando Castaneda	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Carmen Magana	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Javier Moreno Llamas	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Hector Rodriguez Banuelos	Product Assembler-3	Employee	DJO Vista Manufacturing Center	California
Mylene Custodio	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Ernesto Chavez Diaz	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Ramona Rodriguez De Guerrero	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Reyna Galvan Ramirez	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California

Norma Castro Valencia	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Jacquiline Doeing	Manufacturing Lead	Employee	DJO Vista Manufacturing Center	California
Noemi Navarro Garcia	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Jose Resendiz Mendieta	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Hildegarda Morales-sanchez	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Paulina Morales	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Yesica Sanchez	Manufacturing Lead	Employee	DJO Vista Manufacturing Center	California
Juan Sanchez	Material Handler - 1	Employee	DJO Vista Manufacturing Center	California
Leonel Mora	Sr. Procurement Analyst	Employee	DJO Vista Manufacturing Center	California
Jaime Contreras Castro	Maintenance Technician-1	Employee	DJO Vista Manufacturing Center	California
Dung Ngo	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Cesar Flores	Product Assembler-2	Employee	DJO Vista Manufacturing Center	California
Elizabeth Alejandra Pelayo Rojas	QA Engineer - 2	Employee	DJO Vista Manufacturing Center	California
Diana Ochoa	Material Handler - 1	Employee	DJO Vista Manufacturing Center	California
Jessica Arcos	Material Handler - 1	Employee	DJO Vista Manufacturing Center	California
Richard Clifford	Director, Manufacturing	Employee	DJO Vista Manufacturing Center	California
Maria Rubio	Assembler - 1	Employee	DJO Vista Manufacturing Center	California
Ana Ortiz	Value Stream Manager	Employee	DJO Vista Manufacturing Center	California
Maria Nava	Assembler - 1	Employee	DJO Vista Manufacturing Center	California
Dolores Cervantes	Assembler - 1	Employee	DJO Vista Manufacturing Center	California
RAMON VEGA CASTRO	Process Engineer - 3	Employee	DJO Vista Manufacturing Center	California
Benjamin Montes	Assembler - 1	Employee	DJO Vista Manufacturing Center	California
Marbella Sanchez	Assembler - 1	Employee	DJO Vista Manufacturing Center	California
Martha Torres	Assembler - 1	Employee	DJO Vista Manufacturing Center	California
Joanna Michell Galvan	Material Handler - 1	Employee	DJO Vista Manufacturing Center	California
Paula Mott	Assembler - 2	Employee	DJO Vista Manufacturing Center	California
Jennifer Gomez	Quality Technician - 2	Employee	DJO Vista Manufacturing Center	California
Amanda Timm	Quality Control Technician - 1	Employee	DJO Vista Manufacturing Center	California
Aaron Tei	Material Handler - 1	Employee	DJO Vista Manufacturing Center	California
Najib Gull	Process Engineer - 1	Employee	DJO Vista Manufacturing Center	California
Julia Fundora	QC Inspector - 1	Employee	DJO Vista Manufacturing Center	California
Joseline Zamora	Assembler - 1	Employee	DJO Vista Manufacturing Center	California
Hector Esteban Rodriguez García	Assembler - 1	Employee	DJO Vista Manufacturing Center	California
Maria de Lourdes Avila	Assembler - 1	Employee	DJO Vista Manufacturing Center	California

Marisela Garay	Supplier Quality Engineer	Employee	DJO Vista Manufacturing Center	California
Thuan Diep	Director, Manufacturing Operations	Employee	DJO Vista Manufacturing Center	California
Rene Cruz	Facilities Technician - 2	Employee	DJO Vista Manufacturing Center	California
Nicholas Greene	Process Engineer - 2	Employee	DJO Vista Manufacturing Center	California
James Nguyen	Technical Buyer - 1	Employee	DJO Vista Manufacturing Center	California
Paloma Fernanda Corral Heredia	Human Resources Business Partner	Employee	DJO Vista Manufacturing Center	California

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

y

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: GlaxoSmithKline LLC

Physical Address: 410 Blackwell St.

City: Durham State: NC Zip: 27701

Mailing Address (if different from physical address): 410 Blackwell St. Crowe Fowler Bld.

City: Durham State: NC Zip: 27701

Telephone: 919-302-9227 Website: N/A

Name of Designated Representative (DR): Donna Melton

Licensing Company Email: gsklicensing@iqvia.com DR Email: donna.s.melton@gsk.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Physicians, Government		■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
17-Mar-2023	15-May-2023	FL	Tallahassee	Leon County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2023-001069 / 2023-001081	State of Florida, Dept. of Buiness & Professional Regulations, Div. of Drugs, Devices

Reason/Charge
Notifying Florida Board of change of address associated with existing permit for GlaxoSmithKline corporate office

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
	Settlement agreement

Name of Business/Industry/Entity
GlaxoSmithKline LLC

Provide explanation below:

In association with GlaxoSmithKline relocating its corporate headquarters from Research Triangle Park, North Carolina to Durham, North Carolina the state of North Carolina of was notified of the change who then coordinated the on site inspection and issued the updated home state license. After receiving the updated home state license, subsequent notification was initiated with the state of Florida to notify them of the change in address. System limitations that coincided with trying to process annual license renewal and change of address at the same time along with extended dialogue with representatives wtihin the Department of Business & Professional Regulations prevented the change of address from being processed in a timely manner.

Original Signature (electronic, copies or stamps not accepted)

03-Jun-2023

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06-Feb-2019	13-Mar-2019	CA	Sacramento	Sacramento County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2017-79707		California State Board of Pharmacy		
Reason/Charge				
Notifying California Board of Pharmacy of change with desigated representative-in-charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				
GlaxoSmithKline LLC				

Provide explanation below:
Alleged GSK did not notify the California Board in writing within 30 days of the date when Mark Bullard, designated representative-in-charge, left the organization and Stacey Wise became the new designated representative.

Original Signature (electronic, copies or stamps not accepted)

03-Jun-2023
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05-Jul-2017	14-Aug-2017	FL	Tallahassee	Leon County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2016-008682	State of Florida, Dept. of Buiness & Professional Regulations, Div. of Drugs, Devices

Reason/Charge
Disprecancy with address noted on packing list for GlaxoSmithKline

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
	Settlement agreement

Name of Business/Industry/Entity
GlaxoSmithKline LLC

Provide explanation below:
Alleged GSK did not reference the proper address for GlaxoSmithKline as the Seller on the packing list. Discrepancy with how the address for GlaxoSmithKline was referenced on the license that was issued versus what was listed on the Florida Department of Business & Professional Regulation website.

Original Signature (electronic, copies or stamps not accepted)

03-Jun-2023
Date

Appendix 1

GlaxoSmithKline LLC

In July 2012, GSK LLC entered into a global settlement of three separate federal investigations with the US federal government and many state governments. As part of the settlement, GSK LLC pled guilty to three counts of misdemeanor violations of the Federal Food Drug & Cosmetic Act, one count each for the misbranding of Paxil and Wellbutrin and one count for failing to include information about the initiation and status of certain Avandia studies to the FDA:

(1) From April 1998 to August 2003, there were some occasions when GSK sales representatives promoted the use of Paxil to physicians for patients under age 18, an unapproved use of the drug;

(2) From January 1999 to December 2003, there were some occasions when GSK sales representatives, physician speakers, and consultants discussed certain uses of Wellbutrin that were not approved by FDA; and

(3) From 2001-2007 GSK inadvertently failed to include information about the initiation or status of certain Avandia studies in Periodic and Annual Reports submitted to the FDA.

GSK LLC has not been convicted or entered a guilty plea in any criminal proceeding where there has been a finding or admission of fraud. The misdemeanors to which GSK pleaded guilty required no finding of fraudulent intent to establish a violation, unlike felony violations, which require a finding of "intent to defraud or mislead." These no-intent misdemeanor violations do not constitute convictions for fraud GSK denies the government's allegations to the extent they go beyond the admissions in the plea as summarized above.

As part of the global settlement, GSK LLC entered into civil settlement agreements with the federal government and many states to resolve all allegations related to Avandia, Paxil and Wellbutrin as well as additional products. GSK denies all allegations described in the civil settlement agreements and the related civil complaints other than the admissions, summarized above, which were made as part of the no-intent misdemeanor guilty plea.

GSK LLC was not excluded from participation in any US federal or state health care programs as a result of this settlement. GSK LLC was not and is not currently on probation. GSK LLC entered into a Plea Agreement with the US Department of Justice, which contains certain compliance and reporting obligations to the US Department of Justice, and a 5-year Corporate Integrity Agreement with the Office of Inspector General for the US Department of Health and Human Services.

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

v. **Case No.: 2016-008682**

GLAXOSMITHKLINE LLC,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (this "agreement") as disposition of the alleged violations described in the Second Amended Notice of Violation in case number 2016-008682 (the "allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereafter, "Department" or "Petitioner") is charged with regulating drugs, devices, and cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. GlaxoSmithKline LLC (hereafter, "Respondent"), is permitted as a nonresident prescription drug manufacturer by the Department, having been issued permit number 26:444.

2. Respondent's address of record is 5 Moore Drive, Research Triangle Park, North Carolina 27709.

3. Respondent was issued a Second Amended Notice of Violation on or about July 5, 2017, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent, by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent neither admits nor denies the allegations set forth in the Second Amended Notice of Violation, but is entering into this settlement to resolve the issues raised by the Department.

SETTLEMENT TERMS

6. Respondent affirms that the violations alleged in the Second Amended Notice of Violation issued in case number 2016-008682, if they existed, have been corrected.

7. Respondent agrees to pay a settlement amount of Four Thousand Five Hundred Dollars ($4,500). **Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida, 32399-1047, Attention: Tammy Shaw, Senior Legal Assistant.** Respondent acknowledges that payment is enclosed with this

agreement. The payment and execution of this agreement by Respondent are absolute conditions precedent to Petitioner's execution of this agreement.

8. The Department agrees that this agreement will not be deemed to constitute discipline against Respondent within the meaning of Section 499.066, Florida Statutes, and Rule 61N-1.024, Florida Administrative Code, and that this agreement will not be considered in any future claim, action, or proceeding against Respondent by the Department. Nothing herein shall be construed to limit, restrict, or otherwise affect the Department's rights to: (i) inspect under Section 499.051, Florida Statutes; (ii) examine, sample, test, embargo, seize, detain, condemn, or destroy any drug, device, or cosmetic in accordance with Sections 499.06, 499.062, and 499.065, Florida Statutes; or (iii) seek injunctions or take any other action authorized by Sections 499.066 and 499.0661, Florida Statutes, in the event of a public health emergency or any immediate and substantial threat, hazard, or danger to the public health.

STANDARD PROVISIONS

9. It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

10. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. **The final order shall operate to close case number 2016-008682. The final order shall be final disposition in this proceeding, and shall constitute final agency action with respect thereto.**

11. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Settlement Agreement and the final order in which the agreement is incorporated.

12. Respondent waives the right to seek any attorney's fees or costs from the Department in connection with this proceeding.

13. This agreement may be executed in any number of counterparts including, without limitation, telecopies, and facsimile transmission copies, all of which together shall constitute a single document.

14. The parties agree that this agreement represents a fair, appropriate, and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

15. The terms and provisions of this agreement are severable, and if any term or provision is declared or deemed void, invalid, illegal, or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

16. It is expressly understood that this Settlement Agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts the settlement and adopts it in a final order.

17. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals, and as duly designated representatives, to fully bind such principals.

GLAXOSMITHKLINE LLC

By: _____

Name: ROBERT J. COYLE

Title: VP, NA SUPPLY CHAIN

Date: 14-AUG-2017

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS

By: _____

Name: _____

Title: _____

Date: _____

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 06, 2019

DATED MATERIAL ENCLOSED

GLAXOSMITHKLINE
ATTN: JOHN BAILEY, PRS
1704 MID PARK DR
KNOXVILLE, TN 37921

RE: CI 2017 79707
GLAXOSMITHKLINE
OSD 4105

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- March 08, 2019: Unless the Citation is contested payment of fine(s) must be received by the Board.
- February 20, 2019: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- March 08, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Joshua Monforte, Citation and Fine Analyst at (916) 574-7903.

Sincerely

Anne Sodergren

Anne Sodergren
Interim Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **March 08, 2019.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than February 20, 2019 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than March 08, 2019 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Associate Enforcement Analyst, at (916) 574-7924.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2017 79707	GLAXOSMITHKLINE, OSD 4105

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (j)	A nonresident wholesaler or non resident third-party logistics provider shall identify and notify the board of a new designated representative in charge ceases to be the designated representative in charge	$400.00
Bus. & Prof. Code § 4161 subd. (j)	A nonresident wholesaler or non resident third-party logistics provider shall identify and notify the board of a new designated representative in charge ceases to be the designated representative in charge	$400.00

CONDUCT:

GlaxoSmithKline violated Business and Professions Code section 4161(j) in that it failed to notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge (DRIC) ceased to act as the DRIC. Specifically, on Feb. 16, 2018, GlaxoSmithKline notified the board 329 days after the date Mark S. Bullard (EXC 12292) ceased to act as DRIC on March 24, 2017.

Business and Professions Code section 4161(j) requires every non-resident wholesaler to be managed by a licensed designated representative-in-charge (DRIC). Specifically, GlaxoSmithKline operated for 168 days without a DRIC, between the date Mark S. Bullard (EXC 12292) ceased to act as DRIC on March 24, 2017, and the date Stacey Lea Wise (EXC 24362) took over as DRIC on Sep. 8, 2017.

CITATION ISSUED ON: February 08, 2019 | **TOTAL AMOUNT OF FINE(S): $800.00**

PAYMENT OF FINE(S) DUE BY: March 08, 2019

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

COPY

Citation Number	Name, License No
CI 2017 79707	GLAXOSMITHKLINE, OSD 4105

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

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CONDUCT:

GlaxoSmithKline violated Business and Professions Code section 4161(j) in that it failed to notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge (DRIC) ceased to act as the DRIC. Specifically, on Feb. 16, 2018, GlaxoSmithKline notified the board 329 days after the date Mark S. Bullard (EXC 12292) ceased to act as DRIC on March 24, 2017.

Business and Professions Code section 4161(j) requires every non-resident wholesaler to be managed by a licensed designated representative-in-charge (DRIC). Specifically, GlaxoSmithKline operated for 168 days without a DRIC, between the date Mark S. Bullard (EXC 12292) ceased to act as DRIC on March 24, 2017, and the date Stacey Lea Wise (EXC 24362) took over as DRIC on Sep. 8, 2017.

CITATION ISSUED ON: February 06, 2019 | **TOTAL AMOUNT OF FINE(S): $800.00**

PAYMENT OF FINE(S) DUE BY: March 08, 2019

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: GLAXOSMITHKLINE

License No: OSD 4105

Citation Number : CI 2017 79707

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

☐ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

_____

_____

_____

_____

_____

_____

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Telephone: (Business) (___) _____ Residence: (___) _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
Attn: Jennifer Sevilla
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7925

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against: GLAXOSMITHKLINE OSD 4105 Respondent	Citation Case No : CI 2017 79707 NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: GLAXOSMITHKLINE, OSD 4105
Citation and Fine CI 2017 79707

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On February 06, 2019, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
GLAXOSMITHKLINE ATTN: JOHN BAILEY, PRS 1704 MID PARK DR KNOXVILLE, TN 37921	7018 0680 0000 1183 0427

I declare under penalty of perjury that the forgoing is true and correct.

Executed on February 06, 2019, at Sacramento, California.

DECLARANT
Joshua Monforte
Citation and Fine Analyst

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 13, 2019

GLAXOSMITHKLINE
ATTN: STACEY LEA WISE, EIC
1704 MID PARK DR
KNOXVILLE, TN 37921

RE: CI 2017 79707
GLAXOSMITHKLINE
OSD 4105

This is in response to the administrative fine provided to the board for the above referenced citation. The payment has been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Citation and Fine Analyst, Joshua Monforte at (916) 574-7903.

Sincerely

Joshua Monforte
Citation and Fine Analyst
Board of Pharmacy

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

Case Nos.: 2023-001069
2023-001081

v.

GLAXOSMITHKLINE, LLC,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (hereinafter, "this agreement") as disposition of the alleged violations described in the Notice of Violation in case numbers 2023-001069 and 2023-001081 (hereinafter, "the allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereinafter, "the Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. GlaxoSmithKline, LLC (hereinafter, "Respondent") currently holds non-resident prescription drug manufacturer permit 26:444 and complimentary drug distributor permit number 40:8.

2. Respondent's address of record is 410 Blackwell Street, Durham, North Carolina 27701.

3. Respondent was issued a Notice of Violation on March 17, 2023, alleging that it

committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent, by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent neither admits nor denies the allegations in the Notice of Violation issued in case numbers 2023-001069 and 2023-001081, but enters into this agreement for the purpose of resolving the issues raised by the Department.

SETTLEMENT TERMS

6. Respondent affirms that it is currently in compliance with Chapter 499, Florida Statutes.

7. Respondent agrees to pay a settlement amount of five thousand dollars ($5,000.00). **Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047, Attention: Kimberley Johnson, Senior Legal Assistant**. Respondent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Respondent are absolute conditions precedent to the Department's execution of this agreement.

8. The Department agrees that this agreement **will not** be deemed to constitute disciplinary action against Respondent within the meaning of Section 499.066, Florida Statutes, and Rule 61N-1.024, Florida Administrative Code.

STANDARD PROVISIONS

9. It is expressly understood that a violation of the terms of this agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

10. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. **The final order shall operate to close case numbers 2023-001069 and 2023-001081. The final order shall be the final disposition in this proceeding and shall constitute final agency action with respect thereto.**

11. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this agreement and the final order in which this agreement is incorporated, provided the final order does not conflict with this agreement.

12. Each party waives the right to seek any attorney's fees or costs from the other party in connection with this proceeding.

13. This agreement may be executed in any number of counterparts including, without limitation, telecopies and facsimile transmission copies, all of which together shall constitute a single document.

14. The parties agree that this agreement represents a fair, appropriate, and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

15. The terms and provisions of this agreement are severable and, if any term or provision is declared or deemed void, invalid, illegal, or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

16. It is expressly understood that this agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts this

agreement and adopts it in a final order.

17. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals and, as duly designated representatives, to fully bind such principals.

GLAXOSMITHKLINE, LLC,

By: Brian Vetter

Name: Brian Vetter

Title: Vice President

Date: 15-May-2023

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION DIVISION OF DRUGS, DEVICES, AND COSMETICS,

By: _____

Name: Walter Copeland

Title: Division Director

Date: _____

Prepared by:

Anthony Coniglio
DDC Legal Chief
Division of Drugs, Devices, and Cosmetics

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: GlaxoSmithKline LLC - Zebulon
Address: 1011 N. Arendell Ave. City: Zebulon State: NC Zip: 27597
Name: GlaxoSmithKline Vaccines
Address: 325 North Bridge St. City: Marietta State: PA Zip: 17547
Name: Glaxo Operations UK Ltd.- Barnard Castle
Address: Harmire Rd. City: Barnard Castle, Durham State: GBR Zip: DL12 8DT
Name: Glaxo Operations UK Ltd. - Ware
Address: Priory St. City: Ware, Hertfordshire State: GBR Zip: SD12 0DJ

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): GlaxoSmithKline Holdings (Americas) Inc.
Corporation/Organization Name: GlaxoSmithKline LLC
Mailing Address: 410 Blackwell St. Crowe Fowler Bld.
City: Durham State: NC Zip: 27701
Telephone: 919-302-9227 Email: gsklicensing@iqvia.com
Contact Person Name: Donna Melton

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

GlaxoSmithKline LLC
Facility Name

Brian Vetter
Print Name of Authorized Person Submitting Application

Brian Vetter
Original signature of Authorized Person (copies or stamps not accepted)

03-Jun-2023
Date

Board Use Only	Date Received: 7/31/23	Amount: 1000 - CK-652917

GlaxoSmithKline LLC
ADDENDUM TO CERTIFICATION

The officer responsible for the submission of this application is responding to all questions only to the best of his or her knowledge as it relates to GlaxoSmithKline LLC (GSK). GSK is one of numerous GSK-operating companies located in over 115 countries around the world as part of a global, science-led organization that researches, develops, manufactures, markets, and sells pharmaceutical, vaccines, and consumer healthcare products. The officer is not making any representations with respect to any GSK companies other than GSK.

While every endeavor has been made to ensure the statements, representations, and attestations ("Statements") provided in this application are accurate and correct, we would like to clarify the limitations in the due diligence that can reasonably be conducted in order to make such Statements. The Statements have been made in good faith on the basis of the information available to and known by the officer of GSK at the time of submission.

In relation to any questions that refer to employees and/or agents, please note that GSK employs many thousands of people and has extensive data protection processes which precludes obtaining and reviewing the records of every employee. Therefore, while the officer cannot have personal knowledge of every GSK employee and/or agent, GSK does have employee policies imposing strict compliance with applicable laws, a comprehensive employee training curriculum that covers a wide range of employee behaviors and compliance topics and pre-employment corporate security vetting. In addition, there is a GSK initiative that encourages and safeguards employees reporting illegal or unethical behavior within the company.

In relation to any questions that refer specifically to GSK and/or any corporate officers, the officer was given confirmation that there was no information available to indicate that a different answer be given than the one provided in the Statements, however, for additional transparency, please note the details below in Appendix 1.

Submission of this application by the officer reflects this reasonable care and diligence to be expected of a properly qualified and competent member of a large corporate organization providing Statements similar in scope and character to those provided.

To Whom it May Concern,

This is to confirm that the below labeler codes are active and in use in FDA systems.

Company	Labeler Name	Included Labeler Codes
GlaxoSmithKline LLC	GlaxoSmithKline LLC	0173, 49401, 69656
	GlaxoSmithKline Biologicals SA	58160
	ID Biomedical Corporation of Quebec	19515
ViiV Healthcare Company	ViiV Healthcare Company	49702
	Agouron	63010

Please be aware that the FDA does not issue any form of official documentation for labeler codes. FDA does maintain a list of active labeler codes, but it takes you to an excel document which does not contain anything identifying the source of the information. The link to this is below.

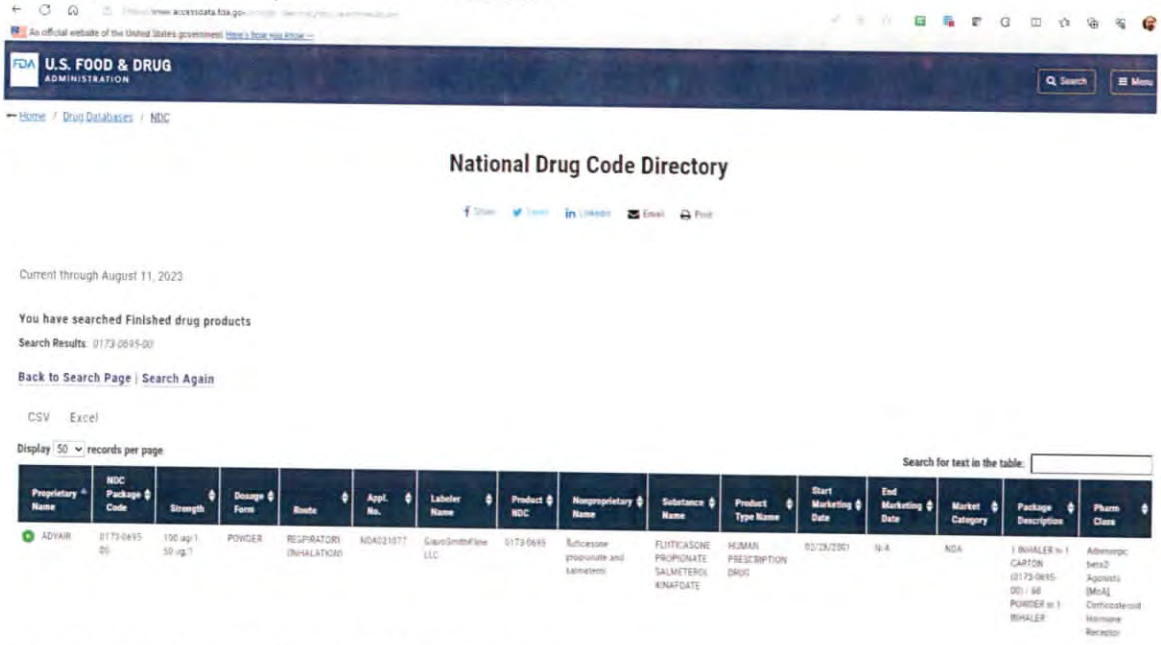
NDC/NHRIC Labeler Codes | FDA

To demonstrate that the labeler codes are active you will find below screengrabs from the FDA's National Drug Code Directory website with an example of active NDC for each of the above labeler codes. I have provided directly below the link to the FDA website that was used.

National Drug Code Directory (fda.gov)

To verify any of this, go the FDA website, for the Select Type field, choose NDC code and type in the respective NDC you wish to verify.

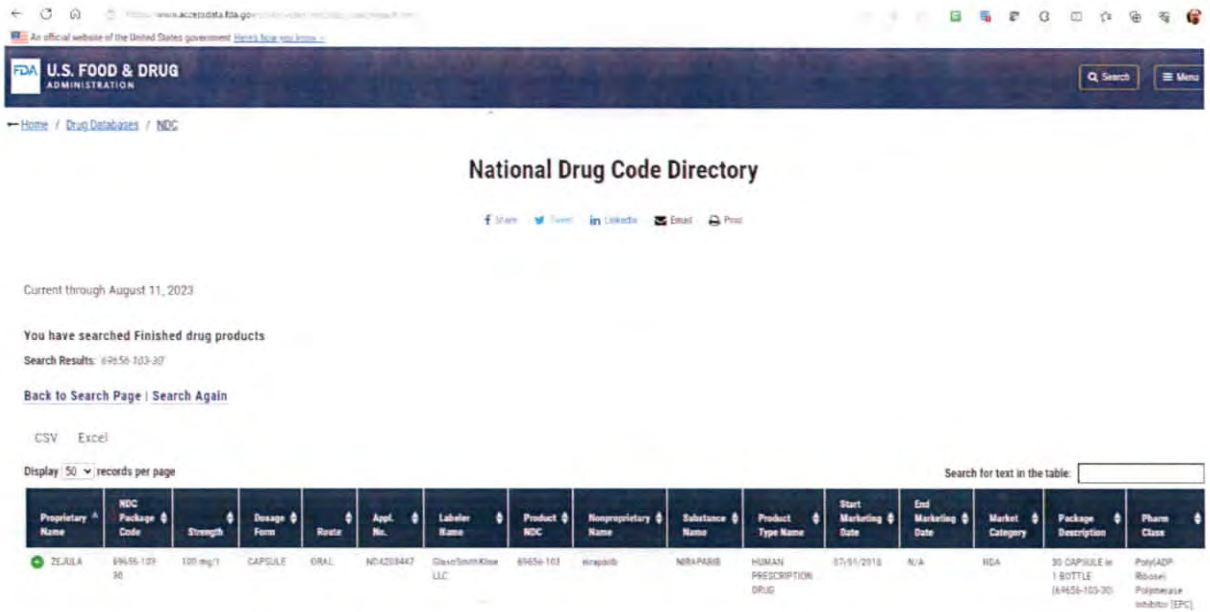
Screen grab of an example for labeler code 0173



Screen grab of an example for labeler code 49401:



Screen grab of an example for labeler code 69656:



U.S. FOOD & DRUG ADMINISTRATION

Home / Drug Databases / NDC

National Drug Code Directory

Current through August 11, 2023

You have searched Finished drug products

Search Results: 69656-103-30

Back to Search Page | Search Again

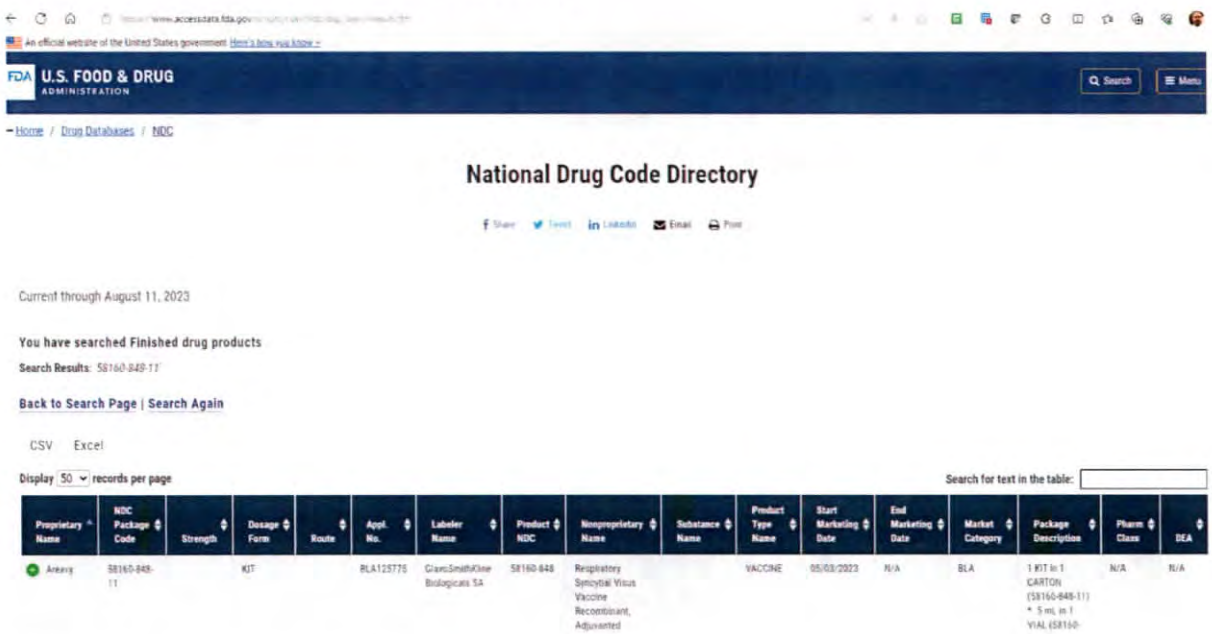
CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
ZEJULA	69656-103-30	100 mg/1	CAPSULE	ORAL	NDA208447	GlaxoSmithKline LLC	69656-103	niraparib	NIRAPARIB	HUMAN PRESCRIPTION DRUG	03/01/2018	N/A	NDA	30 CAPSULE in 1 BOTTLE (69656-103-30)	Poly(ADP-Ribose) Polymerase Inhibitor [EPC]

Screen grab of an example for labeler code 58160:



U.S. FOOD & DRUG ADMINISTRATION

Home / Drug Databases / NDC

National Drug Code Directory

Current through August 11, 2023

You have searched Finished drug products

Search Results: 58160-848-11

Back to Search Page | Search Again

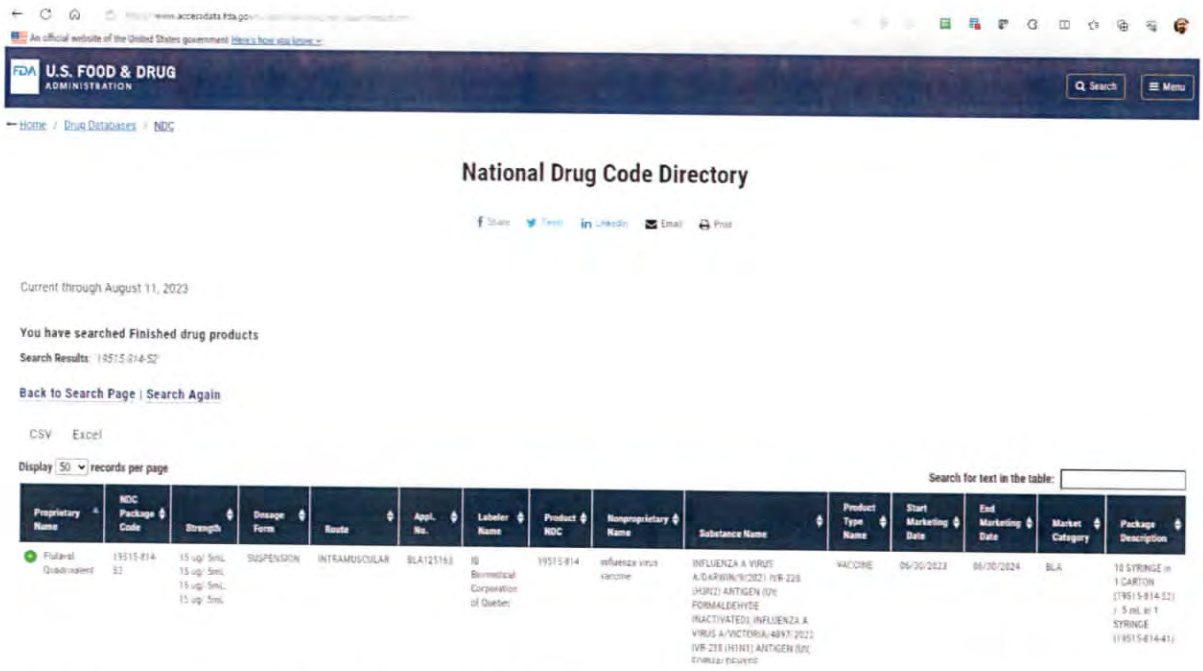
CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
Arexvy	58160-848-11		KIT		BLA125775	GlaxoSmithKline Biologicals SA	58160-848	Respiratory Syncytial Virus Vaccine Recombinant, Adjuvanted		VACCINE	05/03/2023	N/A	BLA	1 KIT in 1 CARTON (58160-848-11) * 5 mL in 1 VIAL (58160-	N/A	N/A

Screen grab of an example for labeler code 19515:



U.S. FOOD & DRUG ADMINISTRATION

Home / Drug Databases / NDC

National Drug Code Directory

Current through August 11, 2023

You have searched Finished drug products

Search Results: *19515-814-52*

Back to Search Page | Search Again

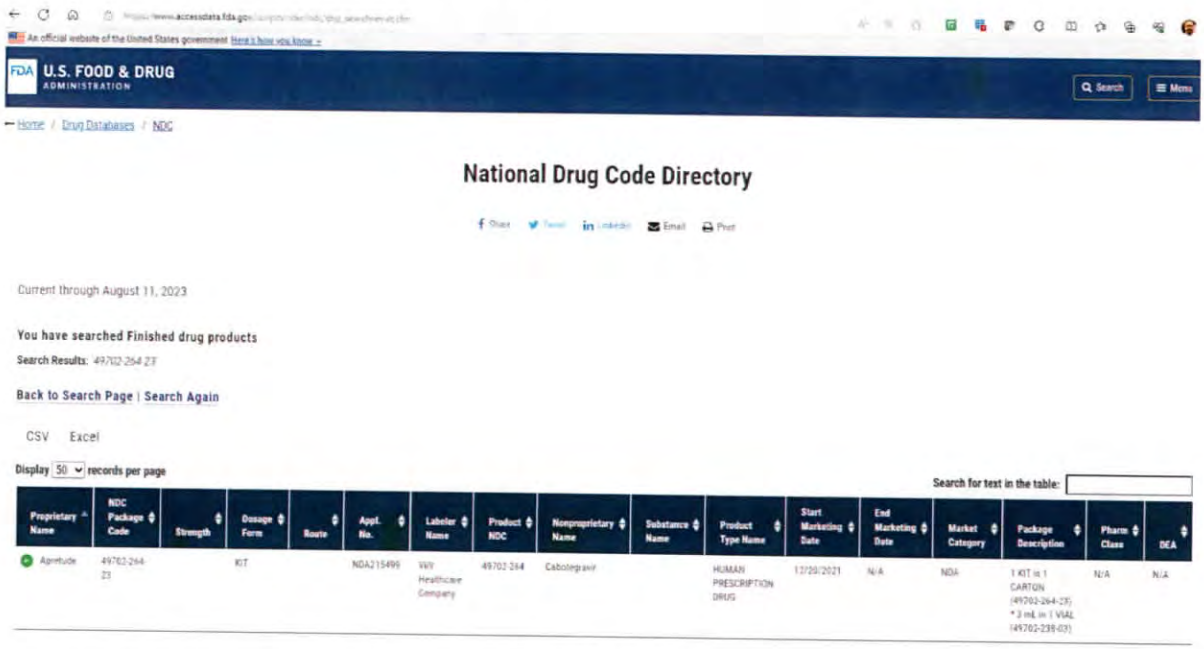
CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Flulaval Quadrivalent	19515-814-52	15 ug/ 5mL; 15 ug/ 5mL; 15 ug/ 5mL; 15 ug/ 5mL	SUSPENSION	INTRAMUSCULAR	BLA125163	ID Biomedical Corporation of Quebec	19515-814	influenza virus vaccine	INFLUENZA A VIRUS A/DARWIN/9/2021 (IVR-228 (H3N2) ANTIGEN (UV-FORMALDEHYDE INACTIVATED); INFLUENZA A VIRUS A/VICTORIA/4897/2022 IVR-238 (H1N1) ANTIGEN (UV-[illegible]	VACCINE	06/30/2023	06/30/2024	BLA	10 SYRINGE in 1 CARTON (19515-814-52) > 5 mL in 1 SYRINGE (19515-814-41)

Screen grab of an example for labeler code 49702:



U.S. FOOD & DRUG ADMINISTRATION

Home / Drug Databases / NDC

National Drug Code Directory

Current through August 11, 2023

You have searched Finished drug products

Search Results: *49702-264-23*

Back to Search Page | Search Again

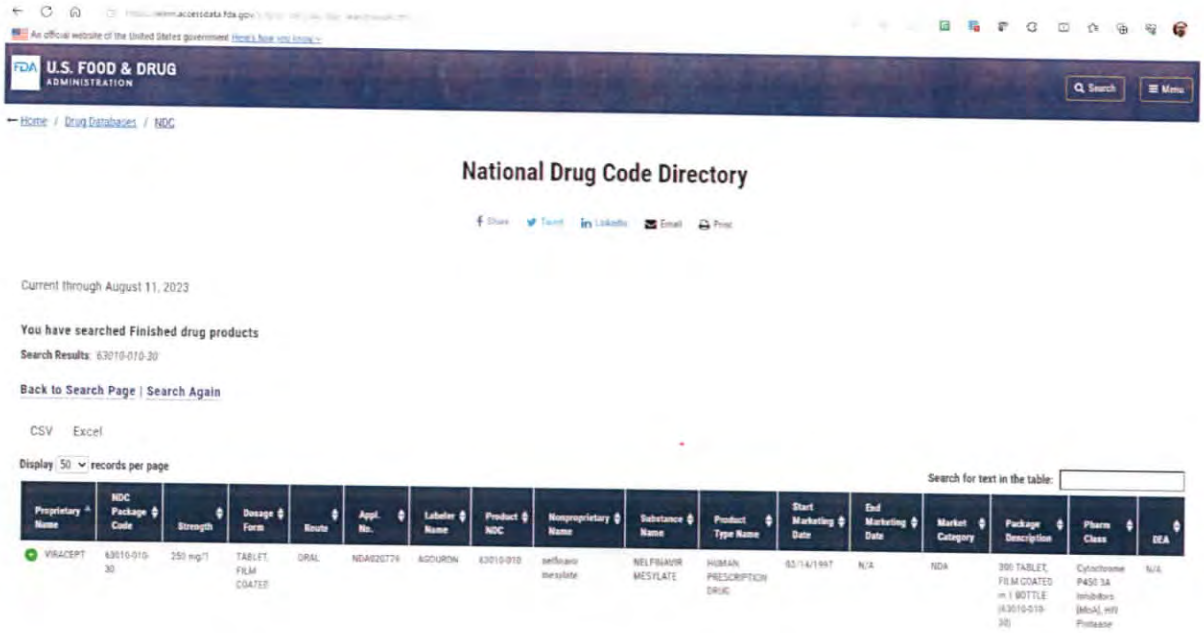
CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
Apretude	49702-264-23		KIT		NDA215499	ViiV Healthcare Company	49702-264	Cabotegravir		HUMAN PRESCRIPTION DRUG	12/20/2021	N/A	NDA	1 KIT in 1 CARTON (49702-264-23) * 3 mL in 1 VIAL (49702-238-03)	N/A	N/A

Screen grab of an example for labeler code 63010-010-30:



An official website of the United States government

U.S. FOOD & DRUG ADMINISTRATION

Search | Menu

Home / Drug Databases / NDC

National Drug Code Directory

Share | Tweet | LinkedIn | Email | Print

Current through August 11, 2023

You have searched Finished drug products

Search Results: *63010-010-30*

Back to Search Page | Search Again

CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
VIRACEPT	63010-010-30	250 mg/1	TABLET, FILM COATED	ORAL	NDA020779	AGOURON	63010-010	nelfinavir mesylate	NELFINAVIR MESYLATE	HUMAN PRESCRIPTION DRUG	03/14/1997	N/A	NDA	300 TABLET, FILM COATED in 1 BOTTLE (63010-010-30)	Cytochrome P450 3A Inhibitors [MoA], HIV Protease	N/A

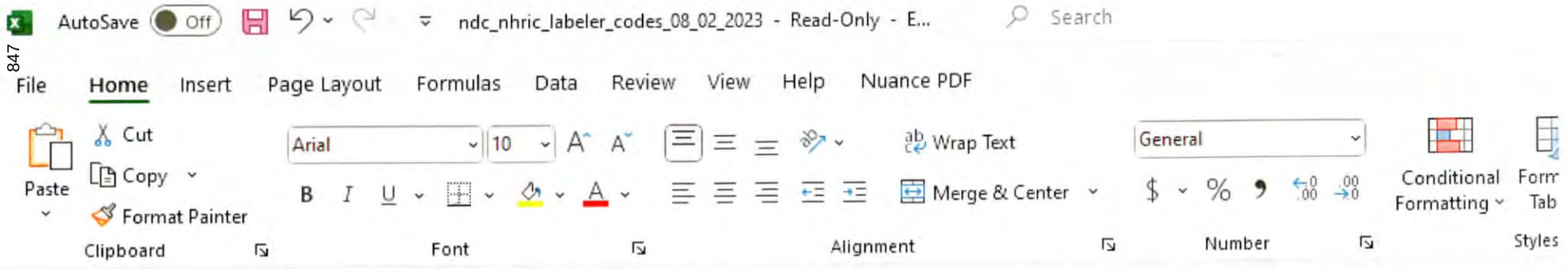
Kind regards,

Ben Harpster

QA Compliance Manager Drug Listing/ U.S. Agent

GSK US Market Supply Distribution and Quality

gsk do more feel better live longer



E913

	A	B
1	NDC/NHRIC Labeler	Firm Name
893	78134	ChemCeed
894	83132	KidneyAide LLC
895	23631	CRB SA
896	63660	Huzhou Zhanwang Pharmaceutical Co., Ltd.
897	79021	Positive Promotions Inc.
898	79811	EPONINE LABS LLC
899	57353	DENTOVATIONS INC
900	74306	GPS Associates
901	67560	HSI Health Care of America Inc.
902	72691	PILLAR HEALTH SYSTEMS LLC
903	76275	Polymer Surfaces Group LLC dba Advanced Home Actives
904	54129	Minitube of America, Inc.
905	77179	Y. SA, INC
906	68371	The Pharmacy Counter, LLC dba ProMedica Home Medical Equipment
907	0631	DONNA LO LABORATORIES
908	70641	White Girl Sunscreen
909	43655	GNC Holdings LLC
910	75404	Cloud Nine Vapor LLC
911	86003	Albaad Massuot Yitzhak Ltd
912	61045	PureCore Wellness
913	58437	GlaxoSmithKline LLC
914	69932	Blue Earth Diagnostics Limited
915	79628	Hunter Amenities (Shantou) Co., Ltd.
916	47784	Galsor S.r.l.

√verified
8/2/23

Owner and Officer List
GlaxoSmithKline LLC

Maria Martinez - President
Address: 410 Blackwell Street, Durham, NC 27701
Telephone: [redacted]

James R. MacRae - Senior Vice President, Legal Operations - US
Address: 410 Blackwell Street, Durham, NC 27701
Telephone: [redacted]

Kevin Ryan - Treasurer
Address: 410 Blackwell Street, Durham, NC 27701
Telephone: [redacted]

Brian Vetter - Vice President
Address: 410 Blackwell Street, Durham, NC 27701
Telephone: [redacted]

Justin Huang - Secretary
Address: 410 Blackwell Street, Durham, NC 27701
Telephone: [redacted]

GlaxoSmithKline Holdings (Americas) Inc. – Owner – 100% ownership
Address: 1100 North Market Street, 4th Floor, Wilmington, Delaware 19890

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "GLAXOSMITHKLINE LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTEENTH DAY OF NOVEMBER, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "GLAXOSMITHKLINE LLC" WAS FORMED ON THE TWENTY-SEVENTH DAY OF OCTOBER, A.D. 2009.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4746253 8300

SR# 20224029293

Authentication: 204867362

Date: 11-16-22

You may verify this certificate online at corp.delaware.gov/authver.shtml



2023

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO
1223

NOT TRANSFERABLE
STATUTE G.S. 81 106.119

LICENSE/CERTIFICATE TYPE: Virtual Manufacturer

Expiration Date 12/31/2023

LICENSEE OR CERTIFICATOR: GlaxoSmithKline LLC
410 BLACKWELL ST
DURHAM NC 27701

LICENSED
2023
NORTH CAROLINA

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

STEVE TROXLER, COMMISSIONER

NC Dept. of Agriculture & Consumer Services

Food & Drug Protection Division

Firm Name: GlaxoSmithKline LLC

Address: 410 BLACKWELL ST DURHAM, NC 27701

License Type: Virtual Manufacturer

License Number: 1223

Status: Active - in good standing

Discipline: No

Issue Date: 12/19/2022

Original Issue: 9/26/2016

Expiration Date: 12/31/2023

North Carolina Department of Agriculture
and Consumer Services
Food and Drug Protection Division

Inspection Report

GlaxoSmithKline LLC
410 Blackwell St.
Durham, NC 27701
(919) 368-0633

Inspected 09/29/2022
By: Bob Braswell
Drug Specialist

Steven W. Troxler
Commissioner

North Carolina Department of Agriculture
and Consumer Services
Food and Drug Protection Division

Christina L. Waggett
Assistant Commissioner
for Consumer Protection

Anita MacMullan
Director

Inspection Report

GlaxoSmithKline LLC
410 Blackwell St.
Durham, NC 27701
(919) 368-0633

Inspected 09/29/2022
By: Bob Braswell

History of Business

Glaxo, Inc. began operations in 1992 at Five Moore Drive in Research Triangle Drive. Glaxo merged with Burroughs Wellcome & Co. in 1995 to form GlaxoWellcome and merged again with SmithKlineBeecham in 2000 to form GlaxoSmithKline, a limited liability corporation created in Delaware and one of numerous GSK operating companies located globally. Corporate headquarters were transferred to the current location in July 2022.

Corporate Address

GlaxoSmithKline LLC
410 Blackwell St.
Durham, NC 27701

Corporate Officers

Maria Martinez	President
Richard Latchford	Vice President
Brian S. Vetter	Vice President

Person(s) Interviewed and Individual Responsibility

Credentials were presented to and Notice of Inspection issued to Ms. Donna Melton, Director, Compliance & Risk Management. She accompanied me during a limited visual inspection of the designated storage area, provided requested written procedures for review, and answered all questions regarding operations.

Background

This visit was a limited inspection of this virtual manufacturer of prescription drugs following a move to a new location. The purpose of this inspection was to verify compliance with NCGS §106 Article 12 (Food, Drugs and Cosmetics) and Article 12A (Wholesale Prescription Drug Distributors). GlaxoSmithKline maintains Prescription Drug Manufacturer (Virtual) registration #092-1223 with NCDA&CS.

There were no significant objectionable conditions noted during the previous NCDA&CS inspection at the previous location conducted on 11/04/2021, and an observation sheet was not issued.

Operations

GlaxoSmithKline, a global research-based pharmaceutical company headquartered in the UK and with operations based in the US, produces a broad range of prescription and over-the-counter drugs. This location serves as the corporate headquarters for GlaxoSmithKline LLC (GSK), one of multiple GSK operating companies. GSK currently occupies 74,899 square feet of administrative space on two levels of this multi-occupant office building located on the American Tobacco Campus in downtown Durham. Entry is limited to employees and escorted visitors, and security personnel are continuously on-site.

GSK does not manufacture, receive, or store any prescription drug products for distribution at this location; GSK registered this location with NCDA&CS to meet licensing/registration requirements of other states. GSK drug products are supplied by other manufacturing sites and distributed by Exel, Inc. d/b/a DHL Supply Chain, a third-party logistics provider with licensed facilities in multiple states.

In order to demonstrate the ability to comply with NCDA&CS registration/licensing requirements, GSK has designated a storage area and established a written procedure for the disposition of any drug products that may be shipped to this location in error. An unused file cabinet drawer in an office area has been designated as the drug storage area; this cabinet contains a locking storage container with keys controlled by designated personnel, and a thermometer is available for temperature monitoring and documentation. The written procedure outlines a method to receive and securely store these drug products and maintain adequate inventory controls; according to the procedure, any drug product returned to this location will be turned over to appropriate personnel for destruction.

The absence of any prescription drug products in the designated storage area was visually confirmed during this inspection.

Observations

There were no significant objectionable conditions identified during this inspection, and an observation sheet was not issued; the license/registration will be revised with the new address.

Compliance

This firm will be re-inspected on a routine or as-needed basis.

Attachments

Notice of Inspection

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107654559

Application/License No. _____

GlaxoSmithKline LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 410 Blackwell Street, Suite 300, Durham, NC 27701 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square, Hartford, Connecticut 061863 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 1, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of June, 20 23.

APPLICANT/PRINCIPAL

COMPANY

GlaxoSmithKline LLC

Authorized Representative

Brian Vetter

CINDY L STANSBURY NOTARY PUBLIC WAKE COUNTY, NC

My Commission Expires 1/28/2026

SIGNED and SEALED in the presence of:

Witness Cindy L. Stansbury

Witness

Donna Melton

SURETY

Travelers Casualty and Surety Company of America

Surety Company's Representative

Sandra Parker, print name, Attorney-in-fact

SIGNED and SEALED in the presence of:

Witness Tiffany Parker

Witness Melissa Haddick

Countersigned by:

Not Required

Nevada Resident Agent

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **SANDRA PARKER** of **HOUSTON**, **Texas**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April**, **2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April**, **2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June**, **2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **1st** day of **June**, **2023**.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler GlaxoSmithKline LLC

Pharmacy/Wholesaler License # (if applicable) Initial

Physical Address 410 Blackwell St.

City Durham State NC Zip 27701

Mailing Address (if different from physical address) 410 Blackwell St. Crowe Fowler Bld.

City Durham State NC Zip 27701

Telephone 919-302-9227 Website N/A

Licensing Company Email gsklicensing@iqvia.com

Section 2: Personal Information

First Donna Middle S. Last Melton

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address 410 Blackwell St. Crowe Fowler Bld.

City Durham State NC Zip 27701

Telephone 919-302-9227 Email gsklicensing@iqvia.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Selective Service (ref: 922.230)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Child Support Requirement (NRS 422.320, 425.520)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

[redacted] additional space is needed)

School Name		From - To (MM/YY – MM/YY)	
East Carolina University		12/08	
Address	City	State	Zip
901 E 5th St	Greenville	NC	27858
Diploma/Degree obtained, if any			
Master of Science Technology Systems, Industrial Distribution and Logistics concentration			

School Name		From - To (MM/YY – MM/YY)	
North Carolina Wesleyan University		12/99	
Address	City	State	Zip
3400 N Wesleyan Blvd	Rocky Mount	NC	27804
Diploma/Degree obtained, if any			
Bachelor of Science Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Louisburg College		05/92	
Address	City	State	Zip
501 N Main St	Louisburg	NC	27549
Diploma/Degree obtained, if any			
Associate of Arts Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Wake Forest-Rolesville High School		05/86	
Address	City	State	Zip
420 Stadium Dr	Wake Forest	NC	27587
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

[redacted] to all residences you have had for the last 10 years. Start with your present address. Attach separate sheet if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/07 - Present	[redacted] Shingleback Dr.	Wake Forest	NC	27587
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

[redacted]

Business Name		From - To (MM/YY – MM/YY)	
GlaxoSmithKline LLC		07/13 - Present	
Business Address	**City**	**State**	**Zip**
410 Blackwell St.	Durham	NC	27701
Phone	**Title**	**Number of Employed Hours**	
919-302-9227	Director SC/Risk Management	18,800	
Description of Duties			
See attached resume			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

[redacted]	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Donna Melton

Original Signature (electronic, copies or stamps not accepted)

31-May-2023

Date

I, Donna Melton, **certify that as the designated representative for**

GlaxoSmithKline LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DM I am at least 21 years of age;
3. DM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Donna Melton

Print Name (First, Last)

Donna Melton

Original Signature (electronic, copies or stamps not accepted)

31-May-2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Donna Melton

Print Name (First, Last)

Donna Melton — 31-May-2023

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Wake

I, Paige Cashwell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Donna Melton — 31-May-2023

Original Signature — **Date**

Subscribed and Sworn to before me this 31 day of May.

Paige Cashwell

Notary Public Signature

PAIGE CASHWELL NOTARY PUBLIC WAKE COUNTY, NC Commission Expires: Mar. 29, 2026

(Seal)

Donna S. Melton

[redacted] [redacted]

SUMMARY HIGHLIGHTS

Leadership Team member with excellent interpersonal skills to create team cohesion and strong cross departmental relationships

Development and Implementation of Compliance and **Risk Management Strategies**

Experienced history in **Compliance** role working closely with LOC Quality and in working in **regulated spaces** (GMP, FDA, EPA, DEA)

CAREER EXPERIENCE

GlaxoSmithKline

Director, US Customer Supply Chain Compliance and Risk Management, July 2013 - present

- Establish, develop, and lead the implementation and execution of all departmental compliance strategies in accordance with GSK requirements and applicable federal and state regulatory and legal requirements.
- Direct team in risk management related activities to effectively manage business risks and internal controls and to support compliant business solutions with a focus on risk management and compliance activities.
- Provide direction and facilitation to appropriately address risks, audit findings, and any other internal or external issues as they arise and ensure compliance with applicable regulations and company commitments.
- As the senior compliance and risk management leader, function as an independent and objective member of the Leadership Team that reviews and evaluates compliance issues/concerns and risk management issues within the region.
- Oversee and ensure GSK state licenses are submitted, maintained and renewed per individual state regulations for all product manufacturing and wholesale distribution in a fully compliant manner. Management oversight for VAWD (Verified Accredited Wholesale Distributor) accreditation with the NABP (National Association of Boards of Pharmacy).
- Lead the implementation of training and communication crucial to fully embedding the desired compliance and risk management culture within the organization.
- Lead the Risk Management Compliance Board for the Specialty Supply Chain Head. As the Risk Management Process Owner, ensure competent risk teams are assigned to address risks. Review the effectiveness of the overall risk management process and determine if changes are needed. Ensure appropriate reporting and escalation of red risks. Lead team in risk identification discussion sessions.
- Maintain a constant audit ready state at US Pharma Distribution Centers. Provide leadership around audit and deviation investigations and appropriate development of corrective and preventive actions. Lead and coordinate all internal and external audit requests. Liaise with auditors to clarify expectations and objectives and ensure all preliminary audit requests are fulfilled. Operate as primary audit contact and prepare audit responses to management.
- Responsible for overall Quality Management System administration, governance and compliance within USCSC.
- Lead the implementation of training and communication crucial to fully embedding the desired compliance and risk management culture within the organization.
- Ensure compliance with environmental regulations and reporting as related to US Distribution Operations (Spill Prevention, Control and Countermeasure Plans (SPCC), Resource Conservation Act (RCA) for hazardous waste disposal, including annual hazardous waste training, Emergency Personnel and Community Right to Know Act (EPCRA), as well as air and water permits). Establish hazardous waste process for US Distribution Operations and ensure ongoing compliance with hazardous and universal waste and associated documentation practices.
- Embed ABAC (Anti-Bribery, Anti-Corruption) policy including log for documenting interactions with government officials. Direct other compliance initiatives related to: DEA Schedule V licensing and requirements management, Sarbanes Oxley, Level 1 Self Assessment Program, training plan adherence, on-time training completion metrics, deviation and CAPA management, and CAPA trending and on-time closure.
- Act as Security Champion for US Supply Chain which includes governance to ensure processes in place and roles and responsibilities identified to protect our people and our places.

Donna S. Melton

[redacted] [redacted]

Compliance Manager, US Logistics, March 2006 – July 2013

- Develop, establish, and execute compliance strategy for US Logistics in accordance with internal GSK policies as well as federal and state regulatory requirements.
- Ensure successful Quality Management System deployment through gap analysis, action plans, and incorporation of QMS policies in local operations.
- Drive process consistency through operational audits while promoting continuous improvement opportunities.
- Conduct operational audits of Third Party Distribution Vendors.
- Develop role map for department training matrix to track all required training such as QMS, SOPs, etc.

Manager, US Packaging Services Design & Analysis Pkg Brand Mgmt, November 2004 – March 2006

- Manage the creation of commercial brand identities from logo to graphical pack design and ensure corporate standards are followed.
- Manage anti-counterfeiting strategies for US marketed products. Oversee selection and implementation of anti-counterfeiting solutions.
- Manage change control for US market pack changes.
- Review and approve write off costs for US pack changes and negotiate issues with supply sites.
- Oversee US market artwork production schedule to ensure product launches and FDA mandated changes are implemented in an expedient manner and to ensure first to market, critical product supply, and overall regulatory compliance.

Manager, N. America Critical Documentation & Label Changes, March 2001–November 2004

- Provide leadership, organization, and consultation on label changes for US market as well as international markets supported by North American packaging sites.
- Oversee Regulatory copy related changes for all printed components for US market.
- Manage department of 30-plus professional staff in 2 geographic sites.
- Manage department budget of 1.2MM. Reduced overall budget to $800K through cost saving initiatives.
- Member of the SAP International Labeling Team for developing requirements for labeling design and standardization.
- Manage production artwork for all US marketed products to ensure on time completion for all pack changes – including new product launches and line extensions.
- Project manager for team to develop new document management specification system.

EDUCATION AND ACHIEVEMENTS

East Carolina University

- Master of Science Technology Systems, Industrial Distribution and Logistics concentration

North Carolina Wesleyan College

- Bachelor of Science Business Administration

Certified Compliance & Ethics Professional (CCEP) (since 2013)

Lean Sigma Green Belt Certified

Employee List
GlaxoSmithKline LLC

- Maria Martinez
- Richard Latchford
- James R. MacRae
- Kevin Ryan
- Brian Vetter
- Justin Huang
- Donna Melton

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Luye Pharma USA, Ltd.

Physical Address: 502 Carnegie Center, Suite 100

City: Princeton State: NJ Zip: 08540

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 609-799-7600 Website: www.luye.cn

Name of Designated Representative (DR): Antoinette Succhetti

Licensing Company Email: compliance.luyepharma@gmail DR Email: antoniasacchetti@luye.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Virtual Manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Antonio Sacchetti
Original Signature (electronic, copies or stamps not accepted)

6/27/2023
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Please see attached list

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Luye Pharma Group, Ltd

Corporation/Organization Name: Luye Pharma USA, Ltd

Mailing Address: 502 Carnegie Center, Suite 100

City: Princeton State: NJ Zip: 08540

Telephone: 609-799-7600 Email: compliance.luyepharma@gmailcom

Contact Person Name: Yehong Zhang

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Luye Pharma USA, Ltd

Facility Name

Antoinette Sacchetti

Print Name of Authorized Person Submitting Application

Antoinette Sacchetti

Original signature of Authorized Person (copies or stamps not accepted)

6/27/2023

Date

Board Use Only	Date Received: 7/31/23	Amount: 1000-CK-11897

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through June 26, 2023

You have searched Finished drug products

Search Results: *'72526-101'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
+ Rykindo	72526-101-11		KIT		NDA212849	Shandong Luye Pharmaceutical Co., Ltd.	72526-101	Risperidone		HUMAN PRESCRIPTION DRUG	06/20/2023	N/A

Showing 1 to 1 of 1 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Verified M.H 6/3/23

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through June 26, 2023

You have searched Finished drug products

Search Results: *'72526-102'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
+ Rykindo	72526-102-11		KIT		NDA212849	Shandong Luye Pharmaceutical Co., Ltd.	72526-102	Risperidone		HUMAN PRESCRIPTION DRUG	06/20/2023	N/A

Showing 1 to 1 of 1 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through June 26, 2023

You have searched Finished drug products

Search Results: *'72526-103'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
+ Rykindo	72526-103-11		KIT		NDA212849	Shandong Luye Pharmaceutical Co., Ltd.	72526-103	Risperidone		HUMAN PRESCRIPTION DRUG	06/20/2023	N/A

Showing 1 to 1 of 1 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through June 26, 2023

You have searched Finished drug products

Search Results: *'72526-104'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
+ Rykindo	72526-104-11		KIT		NDA212849	Shandong Luye Pharmaceutical Co., Ltd.	72526-104	Risperidone		HUMAN PRESCRIPTION DRUG	06/20/2023	N/A

Showing 1 to 1 of 1 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

RE: Luye Pharma USA, Ltd.

Ownership information, Officer List Information and Registered Agent Listed Below:

Ownership Information:

Luye Pharma USA, Ltd. Is owned 100% by Luye Pharma Group, Ltd. located at No. 9 Baoyuan Road, Laishan District/ Yentai Shandong Province, China 264003.

Executive Officers

Set forth below are the current executive officers of Luye Pharma USA, Ltd.

Name	% Ownership	Title/Position	Date of Birth	Address
Yehong Zhang	N/A	International CEO	[redacted]	[redacted]ongmeadow Street Newton, PA 18940

Registered Agent:

Name: Legalinc Corporate Services Inc.
Address: 701 S. Carson Street, Suite 200,Carson City, Nevada 89701

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "LUYE PHARMA (USA) LTD." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF AUGUST, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "LUYE PHARMA (USA) LTD." WAS INCORPORATED ON THE THIRD DAY OF AUGUST, A.D. 2015.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5795985 8300

SR# 20233227474

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203946523

Date: 08-11-23

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0749201

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

502 CARNEGIE CENTER, STE 100 PRINCETON, NJ 08540-

Reg. No.
5005760

LUYE PHARMA USA, LTD.
502 CARNEGIE CENTER, STE 100
PRINCETON, NJ 08540-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2024

Establishment Copy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 100172067

COPY

Application/License No. _____

Luye Pharma USA, Ltd (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 502 Carnegie Center Dr., Suite 100 Princeton, NJ 08540 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 8, 2023 (Effective Date).

COPY

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 8th day of August, 2023.

APPLICANT/PRINCIPAL

Luye Pharma USA, Ltd

Authorized Representative

Paul Buckley

SURETY COMPANY

Merchants Bonding Company (Mutual)

Surety Company's Representative

, Attorney-in-fact

Scott D. Chapman

SIGNED and SEALED in the presence of:

Witness

Antoinette Sacchetti

Witness

Antoinette Sacchetti
NOTARY PUBLIC
State of New Jersey
ID # 50143795
My Commission Expires 11/23/2025

SIGNED and SEALED in the presence of:

Witness Sam Caringi

Witness Kimberly Stanley

Countersigned by:

N/A

Nevada Resident Agent

LP 4229 NV (5/21)

MERCHANTS
BONDING COMPANY

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (in California only) (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Scott D Chapman

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc , on October 16, 2015

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and aut hority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 8th day of August , 2023 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss

On this 8th day of August , 2023 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

Kim Lee
Commission Number 702737
My Commission Expires
April 14, 2024

Kim Lee
Notary Public

(Expiration of notary's commission
does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 8th day of August , 2023 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

William Warner Jr.
Secretary

POA 0018 (10/22)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Luye Pharma USA, Ltd

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 502 Carnegie Center, Suite 100

City: Princeton State: NJ Zip: 08540

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 609-799-7600 Website: www.luye.cn

Licensing Company Email: compliance.luyepharma@gmail.com

Section 2: Personal Information

First: Antoinette Middle: Last: Sacchetti

Alias(es, nicknames, name changes, etc.): Fuccio + Basletta

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 502 Carnegie Center, Suite 100

City: Princeton State: NJ Zip: 08540

Telephone: [redacted] Email: compliance.luyepharma@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Middlesex County College		2012-Not completed	
Address	**City**	**State**	**Zip**
2600 Woodbridge Ave	Edison	NJ	08837
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Franklin Delano Roosevelt High School		9/1981 - 6/1985	
Address	**City**	**State**	**Zip**
5800 20th Ave	Brooklyn	NY	11204
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2009 - Present	[redacted] Avenue H	Monroe Township	NJ	08831
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Luye Pharma USA, Ltd		2015- Present	
Business Address	**City**	**State**	**Zip**
502 Carnegie Center, Suite 100	Princeton	NJ	08540
Phone	**Title**	**Number of Employed Hours**	
609-799-7600	Office Manager	15,500+ hours	
Description of Duties			
Hold primary accountability for providing high-level administrative support including organizing schedule & expense submission/ travel and telephone liaison etc. Arrange various meetings and conferences with key customers, and partners & management team within group, locally, with Regional Offices in China, Singapore and Princeton NJ. Role as adequate/ accurate communication channel between employee and managers. Ensuring managers receive updates on status of tasks and deliverables			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Antoinette Sacchetti, **certify that as the designated representative for**

Luye Pharma USA, Ltd,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AS I am at least 21 years of age;
3. AS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Antoinette Sacchetti

Print Name (First, Last)

Antoinette Sacchetti

Original Signature (electronic, copies or stamps not accepted)

6/27/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Antoinette Sacchetti

Print Name (First, Last)

Antoinette Sacchetti

Original Signature (electronic, copies or stamps not accepted)

6/29/2023

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Middlesex

I, Antoinette Sacchetti, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Antoinette Sacchetti

Original Signature

6/29/2023

Date

Subscribed and Sworn to before me this 29th day of June 2023.

Notary Public Signature

TIFFANY L MACFEE
Notary Public - State of New Jersey
My Commission Expires Feb 21, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Luye Pharma USA, Ltd

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 502 Carnegie Center, Suite 100

City: Princeton State: NJ Zip: 08540

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 609-799-7600 Website: www.luye.cn

Licensing Company Email: compliance.luyepharma@gmail.com

Section 2: Personal Information

First: Yehong Middle: Last: Zhang

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 502 Carnegie Center, Suite 100

City: Princeton State: NJ Zip: 08540

Telephone: 609-799-7600 Email: compliance.luyepharma@gmail.com

Are you a citizen of the United States? ☐ Yes ☑ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wharton		1998-2000	
Address	**City**	**State**	**Zip**
3733 Spruce Street	Philadelphia	PA	19104.6340
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
University of Pennsylvania		1985-1989	
Address	**City**	**State**	**Zip**
Steinberg Hall-Dietrich Hall, 3620 Locust Walk	Philadelphia	PA	19104.6302
Diploma/Degree obtained, if any			
Ph.D			

School Name		From - To (MM/YY – MM/YY)	
Harvard University		1981-1985	
Address	**City**	**State**	**Zip**
Dillon House Soldiers Field	Boston	MA	02163
Diploma/Degree obtained, if any			
B.A			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]ongmeadow Street	Newtown	PA	18940
From - To (MM/YY – MM/YY)	[redacted] Dispatch Drive	Washington Crossing	PA	18977
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Luye Pharma International & Luye Pharma USA, Ltd			5/16- Present	
Business Address		**City**	**State**	**Zip**
502 Carnegie Center, Suite 100		Princeton	NJ	08540
Phone	**Title**			
609-799-7600	CEO			
Description of Duties				
Responsible for the establishment of overseas business development strategy, and annual business strategy, implementation after approved by the organization.responsible for setting up the organization structure of overseas business, including set up new company, office, department and establish oversea team according to the need. Responsible for overseas business development, looking for external business opportunities, including not limited to technology, products or companies, and finally achieve the acquisition or join venture. Participate in Clinical Research, regulation affairs and joint the implementation				

Business Name			From - To (MM/YY – MM/YY)	
Aetna Greater China			2013-2016	
Business Address		**City**	**State**	**Zip**
Suite 702, 757 Meng Zi Road, Gopher Center, Huang Pu District		Shanghai, China	N/A	N/A
Phone	**Title**			
+86-400-881-1269	President			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yehong Zhang

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/21/2023

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Mercer

I, Yehong Zhang, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/21/2023

Date

Subscribed and Sworn to before me this 21 day of June, 2023

Notary Public Signature

Antoinette Secchetti
NOTARY PUBLIC
State of New Jersey
ID # 50143795
My Commission Expires 11/23/2025

(Seal)

Luye Pharma USA, Ltd-Employees

	First Name	Last Name
1	Adetunji	Adeoba
2	Afsaneh	Asgharian
3	Anthony	Focella
4	Antoinette	Sacchetti
5	Carli	Ballotta
6	Carlos	Garcia
7	Christina	Zhang
8	Denise	Fairman
9	Dong (Walter)	Zhao
10	Florida	Cruz- De Guzman
11	Helena	Tong
12	Hongtao	Zhang
13	Jeffrey	Liao
14	Jiebo	Lu
15	Joe	Tai
16	Juying (Elsie)	Shen
17	Kranthi	Kumar (Jamburi)
18	Le	Zhang
19	Paul	Buckley
20	Paul	Rivellese
21	Robert	Shangguan
22	Yehong	Zhang
23	Ying	Dong
24	Yu	Chen
25	Zhigang	Sun

Luye Pharma USA, Ltd – 3PL Information

Name	Address
Integrated Commercialization Services, Inc. – Brooks	345 International Blvd., Suite 400B, Brooks, KY 40109

Current list of 2 Verified-Accredited Wholesale Distributors®

VAWD accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

Name	Address	Accreditation Date
Integrated Commercialization Solutions, LLC	345 International Blvd, Ste 400B Brooks, KY 40109	03/22/19

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Ownership Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: TailStorm Health INC. DBA Medivant Healthcare

Physical Address: 24416 N 19TH Ave. suite #200

City: Phoenix State: AZ Zip: 85085

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 4806055200 Website: https://medivanthealth.com/contact-us/

Name of Designated Representative (DR): Brian Oran

Licensing Company Email: licensing@medivanthealth.com DR Email: licensing@medivanthealth.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled by Wholesaler (✓ all applicable)	Type of Wholesaler (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	■ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Prescription Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others: Clinics		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

B. A

Original Signature (electronic, copies or stamps not accepted)

7/14/2023

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: CuraScript

Address: 2040 W Rio Salado Pkwy Suite 101A, City: Tempe State: AZ Zip: 85281

Name:

Address: **City:** **State:** **Zip:**

Name:

Address: City: State: Zip:

Name:

Address: **City:** **State:** **Zip:**

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any):

Corporation/Organization Name: Tailstorm Health Inc

Mailing Address: 24416 N 19th Ave

City: Phoenix State: AZ Zip: 85085

Telephone: 4806055200 Email: info@medivanthealth.com

Contact Person Name: Mitesh Gandhi

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Tailstorm Health Inc.

Facility Name

Brian Oran

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Apr. 21, 2023

Date

Board Use Only	Date Received: _____	Amount: 1000-CK-0294

TailStorm Health INC. DBA Medivant Healthcare

State of incorporation: DELAWARE			
Address:	**24416 N 19th Ave. Phoenix AZ 85085**	**EIN#: 364801640**	
Main Number:	480.605.5200		
Main Email:	Info@tailstorm.com	www.medivanthealth.com	
Staff Name/ Title: officers	**Address:**	**DOB:**	**Phone #:**
President: Ramesh Vijayaraghavan	[redacted]ickory Court, Cranbury, NJ, 08512	[redacted]	[redacted]
CEO: Mitesh Gandhi	[redacted] San Carlos Place; Chandler, AZ 85249	[redacted]	[redacted]

TailStorm Health INC. DBA Medivant Healthcare

State of incorporation: DELAWARE				
Address:	**24416 N 19th Ave. Phoenix AZ 85085**	**EIN#: 364801640**		
Main Number:	480.605.5200			
Main Email:	Info@tailstorm.com	www.medivanthealth.com		
Staff Name/ Title:	**Address:**	**DOB:**	**Phone #:**	**OWNERSHIP**
CEO: Mitesh Gandhi	[redacted]E San Carlos Place; Chandler, AZ 85249	[redacted]	[redacted]	100%

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TAILSTORM HEALTH, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SEVENTH DAY OF JANUARY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "TAILSTORM HEALTH, INC." WAS INCORPORATED ON THE TWELFTH DAY OF JANUARY, A.D. 2015.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5672894 8300

SR# 20230286804

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202593002

Date: 01-27-23

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 05/03/2022
Receipt Number: 2022127975
Receipt Amount $: 1000.00

Manufacturer - 503B Outsourcer

PERMIT NO
M002033

EXPIRES
10/31/2023

Issued to : Tailstorm Health Inc dBA Medivant Healthcare
Viraj Gandhi
24416 NORTH 19TH AVENUE SUITE 200 PHOENIX, AZ 85226

Tailstorm Health Inc dBA Medivant Healthcare
24416 NORTH 19TH AVENUE SUITE 200
PHOENIX, AZ 85085

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Tailstorm Health Inc dBA Medivant Healthcare
LICENSE NUMBER : M002033
EXPIRES : 10/31/2023

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

• Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
• You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

• Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
• In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
• Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
• Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

Tailstorm Health Inc., Chandler, AZ	Andrew Stasiak 520-465-8496	10/23/2019	12/10/2022	7/21/2021	Yes (https://www.fda.gov/media/155218/download)	Untitled Letter Issued 6/17/2022 (https://www.fda.gov/media/163521/download)	Yes
Tailstorm Health Inc., Phoenix, AZ	Mitexh Gandhi 480-274-8617	10/23/2019	2/8/2023	Not yet inspected	No	N/A	Yes
The Ritedose Corporation, Columbia, SC	Arianne Lindsey 803-626-3737	12/20/2019	10/28/2022	3/22/2022	Yes (https://www.fda.gov/media/159209/download)	FMD-145 Letter Issued 9/23/2022	Yes
US Specialty Formulations LLC, Allentown, PA	Kyle Flanigan 610-849-5023	1/31/2014	11/22/2022	4/26/2022	Yes (https://www.fda.gov/media/160666/download)	Open[7]	Yes
Wedgewood Connect, LLC, formerly registered as Leiter's Compounding, San Jose, CA	Paul Yamamoto 408-687-0943	1/31/2014	12/5/2022	12/3/2021	Yes (https://www.fda.gov/media/157736/download)	FMD-145 Letter Issued 4/29/2022	Yes
Wells Pharma of Houston, LLC, Houston, TX	Theaquiata A. Mitchell 346-888-1010 Ext=4811	3/9/2020	12/15/2022	6/17/2021	Yes (https://www.fda.gov/media/155873/download)	FMD-145 issued 1/10/2022	Yes
Wells Pharmacy, Inc., Dyersburg, TN	Melissa Stefko 800-622-4510	6/7/2016	12/13/2022	1/28/2021	Yes (https://www.fda.gov/media/147184/download)	Untitled Letter Issued 5/19/2022 (https://www.fda.gov/media/163363/download)	Yes

Notes

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and for firms first registering on or after October 1, 2014, the establishment fee was paid in full).

Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. Beginning in fiscal year (FY) 2015 (October 1, 2014 to September 30, 2015), a facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

Unless a previously registered outsourcing facility re-registers and pays the annual establishment fee in full during the registration period (between October 1 and December 31 of each calendar year), the facility will be removed from the list of registered outsourcing facilities on January 1 of the next calendar year.

2. Inspections identified in this table are associated with the facility at the listed address. A company may own or operate more than one registered outsourcing facility. FDA's web page Compounding: Inspections, Recalls, and Other Actions (/drugs/compounding/compounding-inspections-recalls-and-other-actions) may contain information about compounding facilities under the same ownership as the listed registered outsourcing facility.

Inspections may take place over several days, weeks, or longer. The date of the inspection is the date a Form FDA-483 listing the investigators' observations was issued. If no FDA Form-483 was issued, the date is the last day of the inspection.

3. A Form FDA-483 is issued when investigators observe any significant objectionable conditions. It does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.

4. This table does not include State Board of Pharmacy actions, if any. To determine whether a registered outsourcing facility has been the subject of a state enforcement action, check with the State Board of Pharmacy for the state in which the facility is located. Some states post disciplinary or other actions on their web sites.

5. "Closed" means the inspection has been closed without further action. "Open" means that FDA has not made a determination as to whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include: warning letter; seizure; or injunction.

6. The information in this column was provided by the registered outsourcing facility at the time of registration and has not been verified by FDA. "N/A", indicates the registered outsourcing facility has not provided this information. In the future, FDA intends to provide information about whether the outsourcing facility also intends to compound nonsterile drugs from bulk drug substances. That information is not currently available to the Agency.

7. This facility was the subject of at least one previous inspection relating to compounding that resulted in a Form 483, warning letter, or other action. For information about such inspections and resulting actions, see Compounding: Inspections, Recalls, and other Actions (/drugs/compounding/compounding-inspections-recalls-and-other-actions).

8. Remote Regulatory Assessment (RRA) definition: An RRA is an examination of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. RRAs assist in protecting human and animal health, informing regulatory decisions, and verifying certain information submitted to the Agency.

Registered Outsourcing Facilities FDA Registration.

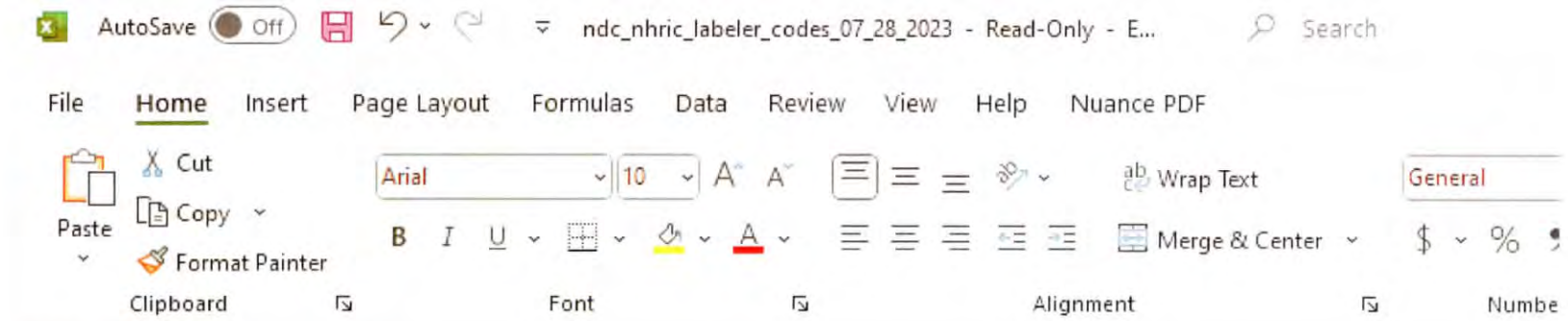
Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 2/22/2023

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility[1]	Date of Most Recent Registration as an Outsourcing Facility[1]	End Date of Last FDA Inspection Related to Compounding[2]	Was a Form FDA-483 Issued?[3]	Other Action, If Any, Based on Last Inspection[4,5]	Intends to Compounds Sterile Drugs From Bulk Drug Substances[6]
AnazaoHealth Corporation, Las Vegas, NV	Jaclyn Wong 800-995-4363 Ext=3120	9/23/2014	11/29/2022	7/29/2022	Yes (https://www.fda.gov/media/163365/download)	Open[7]	Yes
ANNOVEX PHARMA, INC, Lorton, VA	Kenneth Erickson 540-642-5104	10/14/2021	10/30/2022	Not yet inspected	N/A	N/A	Yes
Apollo Care, Columbia, MO	Jarred Dudding 573-441-8900	9/14/2017	1/3/2023	9/8/2021	Yes (https://www.fda.gov/media/158299/download)	Open[7]	Yes
Athenex Pharma Solutions, LLC, Clarence, NY	Lori Giles Aleshin 716-815-6478	4/10/2017	11/10/2022	8/28/2019	Yes (https://www.fda.gov/media/132333/download)	FMD-145 Letter Issued 8/10/2021	Yes
Atlas Pharmaceuticals, Phoenix, AZ	Nickolaus Banda 480-208-1855	11/8/2017	12/21/2022	5/21/2021	Yes (/about-fda/fda-commissioner/atlas-pharmaceuticals-llc-phoenix-az-483-issued-05212021)	FMD-145 Letter Issued 5/3/2022	Yes
BayCare Integrated Service Center, LLC dba BayCare Central Pharmacy, Temple Terrace, FL	Kenneth Jozefczyk 813-901-6339	6/4/2019	11/10/2022	12/10/2019	Yes (https://www.fda.gov/media/152762/download)	FMD-145 Letter Issued 4/4/2022	No
Belcher Pharmaceuticals, LLC, Largo, FL	Shyam Busireddy 727-471-0850	05/18/2021	11/9/2022	Not yet inspected	N/A	N/A	No
Bennett Pharmaceuticals of America LLC, Hudson, WI	James Mulvahill 952-381-9027	4/19/2022	1/16/2023	Not yet inspected	No	N/A	Yes
BPI Labs LLC, Largo, FL	Chandra Kasireddy 727-471-0850	3/4/2019	11/10/2022	4/30/2021	Yes (https://www.fda.gov/media/158757/download)	FMD-145 Letter Issued 9/10/2021	Yes
Brookfield Medical/Surgical Supply, Inc., Brookfield, CT	James Cangelosi 203-775-0862	1/12/2015	12/20/2022	4/4/2022	Yes (https://www.fda.gov/media/161532/download)	Open	Yes
BSO LLC, Lakewood, CO	Anne Szilagyi 877-267-3410	11/24/2015	11/2/2022	3/11/2021	Yes (https://www.fda.gov/media/149780/download)	FMD-145 Letter Issued 9/10/2021	Yes
Central Admixture Pharmacy Services, Inc., Allentown, PA	Thomas Kelsey 216-233-0766	2/28/2014	10/27/2022	8/22/2018	Yes (https://www.fda.gov/media/120740/download)	Remote Regulatory Assessment Assignment Issued 1/26/2021[8]	Yes



	A	B
1	**NDC/NHRIC Labeler**	**Firm Name**
1176	51882	Siddhayu Ayurvedic Research Foundation Pvt. Ltd.
1177	10412	Flint Welding Supply Company
1178	34876	RZN Nutraceuticals, Inc.
1179	62712	Atco International
1180	75956	Kamsut Incorporated
1181	14445	Indoco Remedies Limited
1182	83043	Primera Compounding, LLC
1183	72629	Beacon Pharma, Inc.
1184	74886	KO Distilling (Karlson & O'Mara Distilleries LLC)
1185	77629	Pocket Nurse Enterprises, Inc.
1186	54706	Garrett County Memorial Hospital
1187	73898	Noshinku
1188	57913	ERNO LASZLO, INC.
1189	78170	Blue Chip Group, Inc
1190	82636	Curia Bio California Inc
1191	53010	Daeduck Lab Co., Ltd
1192	62673	Neoteric Cosmetics, Inc.
1193	81483	TAILSTORM HEALTH INC
1194	69498	iSmile Dental Products, Inc.
1195	62835	Midlink LLC

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0801765

Application/License No. _____

Tailstorm Health, Inc. dba Medivant Healthcare (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 24416 N 19th Ave, Phoenix, AZ 85085 (Address of Applicant/Principal), as PRINCIPAL, and Harco National Insurance Company (Surety Company), a corporation organized under the laws of the state of Illinois (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 2850 West Gold Road, Rolling Meadows, IL 60008 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 6/29/2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally lieble on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 29th day of June, 20 23.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Mark Sherwood, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

POWER OF ATTORNEY

Bond # 0801765

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 702 Oberlin Road, Raleigh, North Carolina 27605

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

LELAND PFINGSTAG, MARK SHERWOOD

Napa, CA

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2018

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2018, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, June 29, 2023

A02671

Irene Martins, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Y

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Tailstorm Health Inc

Pharmacy/Wholesaler License # (if applicable) FDA, 3022483154

Physical Address 24416 North 19th Ave

City Phoenix State AZ Zip 85085

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Brian Middle Wayne Last Oran

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] W Gloria Lane

City Phoenix State AZ Zip 85085

Telephone [redacted] Email boran@mediVanthealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	NA	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midwestern University		09/06 – 03/10	
Address	City	State	Zip
555 31st st	Downers Grove	IL	60515
Diploma/Degree obtained, if any			
Pharm D			

School Name		From - To (MM/YY – MM/YY)	
University of Missouri		08/02 - 05/06	
Address	City	State	Zip
230 Jesse Hall	Columbia	MO	65211
Diploma/Degree obtained, if any			
B.S. in Biology			

School Name		From - To (MM/YY – MM/YY)	
Branson High School		08/96 -05/00	
Address	City	State	Zip
935 Buchanan Road	Branson	MO	65616
Diploma/Degree obtained, if any			
H.S. Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/17 - Current	[redacted] W. Gloria Lane	Phoenix	AZ	85085
From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/11 - 12/17	[redacted] N 27th Dr.	Phoenix	AZ	85086
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Tailstorm Health Inc.			03/22 – current
Business Address	**City**	**State**	**Zip**
24416 N. 19th Ave	Phoenix	AZ	85085
Phone	**Title**	**Number of Employed Hours**	
480-605-5200	Pharmacist-in-Charge	2200	
Description of Duties			
Compliance to all federal, state & regulatory laws. Oversee all compounding operations & approve release of all commercial batches			

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			07/07 - 02/22
Business Address	**City**	**State**	**Zip**
106 Wilmot Road	Deerfield	IL	60015
Phone	**Title**	**Number of Employed Hours**	
800-925-4733	Pharmacist / Pharmacy Manager	31000	
Description of Duties			
Oversaw all pharmacy operations, pharmacy technicians, and managed pharmacy to meet all state & regulatory requirements.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
12/2016	05/17/17	AZ	Scottsdale	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
TR2016-159806-001		The State of Arizona / Salt River Police Dept		
Reason/Charge				
Reckless Driving				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
The State of Arizona				
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

See attached

B Q

Original Signature (electronic, copies or stamps not accepted)

Apr. 21st, 2023

Date

I, Brian Oran, **certify that as the designated representative for**

Tailstorm Health Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ PO I am at least 21 years of age;
3. ✓ B I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ PO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ PO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ PO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ PO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Brian Oran

Print Name (First, Last)

B Q

Original Signature (electronic, copies or stamps not accepted)

Apr 21st 2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brian Oran

Print Name (First, Last)

BO

Original Signature (electronic, copies or stamps not accepted)

Apr. 21st, 2023

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Brian Oran, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

BO

Original Signature

Apr 21st, 2023

Date

Subscribed and Sworn to before me this 21ST day of April, 2023

Esthela M Cardenas

Notary Public Signature

ESTHELA M CARDENAS
Notary Public - Arizona
Maricopa County
Commission # 639972
My Comm. Expires Dec 19, 2026

(Seal)

Re: State Board Application

Brian Oran, PharmD
Medivant Healthcare
Associate Director of Quality
December 2nd, 2022

To Whom it may concern at the State Board of Pharmacy,

This document is written to provide my personal account of the 2016 citation enclosed with this application as is required. If this document does not please the Board for fulfilling the pertinent information needed in making a final decision on our application, please feel free to contact me directly with any inquiries.

On the evening of December 16th, 2016, an officer for the Salt River Police Department stopped me for going 42mph in a 35mph zone. During the process the officer inquired about my activities of the night and then proceeded to implement a series of tests that were passed per the officer's comments. At which point, the officer asked to perform a breathalyzer test. I, regretfully, refused to adhere to the test and I was unaware that doing so is an automatic admission of guilt. My ignorance does not excuse placing myself in that regrettable scenario.

After the incident, I immediately notified the Arizona State Board of Pharmacy of the events that occurred. Gratefully, they took no action against me or my pharmacist license. Their only request was for me to submit the final judgement of my case.

I have attached the electronic record of my case to this application. The final judgement was a charge of a misdemeanor for reckless driving. The entire ordeal was an embarrassment for myself and my family. I regret having placed myself in that situation and take full responsibility for my actions. I was fortunate to have no action taken against me by the Arizona Board of Pharmacy and I hope this does not interfere with the approval process of the enclosed application.

Respectfully,
BO
Brian Oran, PharmD
[redacted]

IN THE MCDOWELL MOUNTAIN JUSTICE COURT

OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

THE STATE OF ARIZONA, Plaintiff, vs. BRIAN WAYNE ORAN, Defendant	**CASE #TR2016-159806-001** PLEA AGREEMENT Page 1 of 2

Date of Birth: 9/10/1981

☒ 1. The State of Arizona and the Defendant hereby agree to the following disposition of the case:

Plea: The Defendant agrees to plead guilty to:

Count A: (as amended) Reckless Driving, a class 2 misdemeanor in violation of A.R.S.§§28-693, 13-707 and 13-802, committed on December 17, 2016.

This is a [non] dangerous, [non] repetitive offense under the criminal code.

Terms: On the following understandings, terms and conditions:

The crime carries a maximum sentence of FOUR MONTHS in jail. Probation is available. Restitution of economic loss to the victim and waiver of extradition for probation revocation procedures are required. The maximum fine that can be imposed is $750.00 plus a 83% surcharge plus a $20.00 surcharge and $13.00 SB 1398 assessment.

Special conditions regarding the sentence imposed by statute (if any) are: MVD may assess 8 points against the defendant's driving privileges; MVD may suspend your driver's license.

☒ 2. The parties stipulate to the following additional terms, subject to court approval at the time of sentencing as set forth in paragraph 7.)

The defendant may be placed on probation for up to 5 years. The defendant shall pay a fine of $492.50. The defendant shall pay a $500 assessment to the Prison Construction and Operation Fund and a $500 assessment to the Public Safety Equipment Fund. The defendant shall serve not less than 10 consecutive days in jail. If the defendant completes a court ordered drug or alcohol screening, counseling, education and treatment program, all but two days may be suspended. The defendant is not eligible for work furlough until 24 consecutive hours in jail is completed. The defendant must pay incarceration costs. The defendant shall complete 50 hours of community service.

☒ 3. The following charges are dismissed or, if not yet filed, shall not be brought against the Defendant: **Counts B and C.**

THE STATE OF ARIZONA,

Plaintiff,

vs.

BRIAN WAYNE ORAN,

Defendant.

CASE # TR2016-159806-001

☑ 4. This agreement serves to amend the complaint or information, to charge the offense to which the Defendant pleads, without the filing of any additional pleading. However, if the plea is rejected by the court or withdrawn by either party, or if the conviction is subsequently reversed, the original charges and any charges that are dismissed by reason of this plea agreement are automatically reinstated.

☑ 5. Unless this plea is rejected by the court or withdrawn by either party, the Defendant hereby waives and gives up any and all motions, defenses, objections, or requests which he has made or raised, or could assert hereafter, to the court's entry of judgment against him and imposition of a sentence upon him consistent with this agreement. By entering this agreement, the Defendant further waives and gives up the right to appeal.

☑ 6. The parties hereto fully and completely understand and agree that it is the court's duty to impose sentence upon the Defendant, and that any sentence either stipulated to or recommended herein in paragraph two is not binding on the court. If after accepting this plea the court concludes that any of the plea agreement's provisions regarding the sentence or the term and conditions of probation are inappropriate, it can reject the plea. If the court decides to reject the plea agreement provisions regarding sentencing, it must give both the state and the Defendant an opportunity to withdraw from the plea agreement. In case this plea agreement is withdrawn, all original charges will automatically be reinstated. The Defendant in such case waives and gives up his right to a probable cause determination on the original charges.

☑ 7. If the court decides to reject the plea agreement provisions regarding sentencing and neither the state nor the Defendant elects to withdraw the plea agreement, then any sentence either stipulated to or recommended herein in paragraph 2 is not binding upon the court, and the court is bound only by the sentencing limits set forth in paragraph 1 and the applicable statutes.

☑ 8. I understand that if I am not a citizen of the United States my decision to go to trial or enter into a plea agreement may have immigration consequences. Specifically, I understand that pleading guilty or no contest to a crime may affect my immigration status. Admitting guilt may result in deportation even if the charge is later dismissed. My plea or admission of guilt could result in my deportation or removal, could prevent me from ever being able to get legal status in the United States, or could prevent me from becoming a United States citizen. I understand that I am not required to disclose my legal status in the United States to the court.

☑ 9. This plea agreement in no way affects any forfeiture proceedings pursuant to A.R.S. § 13-4301 et seq., § 13-2314, or § 32-1993, if applicable, nor does the plea agreement in any way compromise or abrogate any civil actions, including actions pursuant to A.R.S. § 13-2301 et seq. or § 13-4301 et seq., or the provisions of A.R.S. § 13-2314 or A.R.S. § 13-4310.

I have read and understand the provision of pages one and two of this agreement. I have discussed the case and my constitutional rights with my lawyer. My lawyer has explained the nature of the charge(s) and the elements of the crime(s) to which I am pleading. I understand that by pleading GUILTY I will be waiving and giving up my right to a determination of probable cause, to a trial by jury to determine guilt and to determine any fact used to impose a sentence within the range stated above in paragraph one, to confront, cross-examine, compel the attendance of witnesses, to present evidence in my behalf, my right to remain silent, my privilege against self-incrimination, presumption of innocence and right to appeal. I agree to enter my plea as indicated above on the terms and conditions set forth herein. I fully understand that if, as part of this plea agreement, I am granted probation by the court, the terms and conditions thereof are subject to modification at any time during the period of probation. I understand that if I violate any of the written conditions of my probation, my probation may be terminated and I can be sentenced to any term or terms stated above in paragraph one, without limitation.

I have personally and voluntarily placed my initials in each of the above boxes and signed the signature line below to indicate I read and approved all of the previous paragraphs in this agreement, both individually and as a total binding agreement.

Date 5/17/17 Defendant BO

I have discussed this case with my client in detail and advised him of his constitutional rights and all possible defenses. I believe that the plea and disposition set forth herein are appropriate under the facts of this case. I concur in the entry of the plea as indicated above and on the terms and conditions set forth herein.

Date 5/17/17 Defense Counsel 025392

I have reviewed this matter and concur that the plea and disposition set forth herein are appropriate and are in the interests of justice.

Date 5/19/2017 Prosecutor 030608

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Y

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Tailstorm Health INC dba Medivant Healthcare

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) M00233

Physical Address 24416 N 19th Ave

City Phoenix State AZ Zip 85085

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Mitesh Middle _____ Last Gandhi

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] E San Carlos Place

City Chandler State AZ Zip 85249

Telephone [redacted] Email licensing@mediwanthealth.com

Are you a citizen of the United States? ☐ Yes ☑ No

Section 3: Military Service (NRS 622.120)

1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirements (NRS 425.520)

1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
P. E. S. College of Pharmacy			
Address	**City**	**State**	**Zip**
Hanumanagar	Banglore	Karnataka	
Diploma/Degree obtained, if any			
Diploma in Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
NIMS			
Address	**City**	**State**	**Zip**
Online	India		
Diploma/Degree obtained, if any			
Diploma in ~~Operations~~ Retail			
School Name		**From - To (MM/YY – MM/YY)**	
NIMS			
Address	**City**	**State**	**Zip**
Online	India		
Diploma/Degree obtained, if any			
Master in Operations			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5'21 -	[redacted] E Son Cailos Place	Chandler	AZ	85249
04/20 5/21	[redacted] E Son Carlos Place	Chandler	AZ	85249
2/12 4/20	[redacted], Highland Baldg no 4, Lokhandwala Township	Mumbai	Maharashtra	400101
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)
Tailstorm Hecata Inc		06/20 -
Business Address	**City**	**State** / **Zip**
158, SE Grove Rd	Chords	/12 / 85226
Phone	**Title**	
Description of Duties		
SR Director of Operation & Finance		

Business Name		From - To (MM/YY – MM/YY)
Man Mumbrella PVT Ltd		2012 - 04/20
Business Address	**City**	**State** / **Zip**
Shop no 6 Abhinav Society	Mumbai	Maharashtra / 400017
Phone	**Title**	
Description of Duties		
Managing Director		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
		/
Phone	**Title**	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
		/
Phone	**Title**	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
		/
Phone	**Title**	
Description of Duties		

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Applicant's initials _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
12/2016	05/17/17	AZ	Scottsdale	Maricopa
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
TR2016-154806-001	The State of Arizona / Salt River Police Dept.			
Reason/Charge				
Reckless Driving				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
The State of Arizona				
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

B. A

Original Signature (electronic, copies or stamps not accepted)

7/14/2023

Date

Applicant's initials BA

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mitesh Gandhi
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/12/2023
Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Mitesh Gandhi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

07/12/2023
Date

Subscribed and Sworn to before me this 12 day of July.

Maria Fernanda Narvaez
Notary Public Signature

MARIA FERNANDA NARVAEZ
Notary Public - Arizona
Maricopa County
Commission # 639968
My Comm. Expires Dec 19, 2026

(Seal)

Re: State Board Application

Brian Oran, PharmD
Medivant Healthcare
Associate Director of Quality
December 2nd, 2022

To Whom it may concern at the State Board of Pharmacy,

This document is written to provide my personal account of the 2016 citation enclosed with this application as is required. If this document does not please the Board for fulfilling the pertinent information needed in making a final decision on our application, please feel free to contact me directly with any inquiries.

On the evening of December 16th, 2016, an officer for the Salt River Police Department stopped me for going 42mph in a 35mph zone. During the process the officer inquired about my activities of the night and then proceeded to implement a series of tests that were passed per the officer's comments. At which point, the officer asked to perform a breathalyzer test. I, regretfully, refused to adhere to the test and I was unaware that doing so is an automatic admission of guilt. My ignorance does not excuse placing myself in that regrettable scenario.

After the incident, I immediately notified the Arizona State Board of Pharmacy of the events that occurred. Gratefully, they took no action against me or my pharmacist license. Their only request was for me to submit the final judgement of my case.

I have attached the electronic record of my case to this application. The final judgement was a charge of a misdemeanor for reckless driving. The entire ordeal was an embarrassment for myself and my family. I regret having placed myself in that situation and take full responsibility for my actions. I was fortunate to have no action taken against me by the Arizona Board of Pharmacy and I hope this does not interfere with the approval process of the enclosed application.

Respectfully,



Brian Oran, PharmD

[redacted]

IN THE MCDOWELL MOUNTAIN JUSTICE COURT

OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

THE STATE OF ARIZONA, Plaintiff, vs. BRIAN WAYNE ORAN, Defendant	**CASE #TR2016-159806-001** PLEA AGREEMENT Page 1 of 2

Date of Birth: 9/10/1981

☒ 1. The State of Arizona and the Defendant hereby agree to the following disposition of the case:

Plea: The Defendant agrees to plead guilty to:

Count A: (as amended) Reckless Driving, a class 2 misdemeanor in violation of A.R.S.§§28-693, 13-707 and 13-802, committed on December 17, 2016.

This is a [non] dangerous, [non] repetitive offense under the criminal code.

Terms: On the following understandings, terms and conditions:

The crime carries a maximum sentence of FOUR MONTHS in jail. Probation is available. Restitution of economic loss to the victim and waiver of extradition for probation revocation procedures are required. The maximum fine that can be imposed is $750.00 plus a 83% surcharge plus a $20.00 surcharge and $13.00 SB 1398 assessment.

Special conditions regarding the sentence imposed by statute (if any) are: MVD may assess 8 points against the defendant's driving privileges; MVD may suspend your driver's license.

☒ 2. The parties stipulate to the following additional terms, subject to court approval at the time of sentencing as set forth in paragraph 7.)

The defendant may be placed on probation for up to 5 years. The defendant shall pay a fine of $492.50. The defendant shall pay a $500 assessment to the Prison Construction and Operation Fund and a $500 assessment to the Public Safety Equipment Fund. The defendant shall serve not less than 10 consecutive days in jail. If the defendant completes a court ordered drug or alcohol screening, counseling, education and treatment program, all but two days may be suspended. The defendant is not eligible for work furlough until 24 consecutive hours in jail is completed. The defendant must pay incarceration costs. The defendant shall complete 50 hours of community service.

☒ 3. The following charges are dismissed or, if not yet filed, shall not be brought against the Defendant: **Counts B and C.**

THE STATE OF ARIZONA,

Plaintiff,

vs.

BRIAN WAYNE ORAN,

Defendant.

CASE # TR2016-159806-001

☑ 4. This agreement serves to amend the complaint or information, to charge the offense to which the Defendant pleads, without the filing of any additional pleading. However, if the plea is rejected by the court or withdrawn by either party, or if the conviction is subsequently reversed, the original charges and any charges that are dismissed by reason of this plea agreement are automatically reinstated.

☑ 5. Unless this plea is rejected by the court or withdrawn by either party, the Defendant hereby waives and gives up any and all motions, defenses, objections, or requests which he has made or raised, or could assert hereafter, to the court's entry of judgment against him and imposition of a sentence upon him consistent with this agreement. By entering this agreement, the Defendant further waives and gives up the right to appeal.

☑ 6. The parties hereto fully and completely understand and agree that it is the court's duty to impose sentence upon the Defendant, and that any sentence either stipulated to or recommended herein in paragraph two is not binding on the court. If after accepting this plea the court concludes that any of the plea agreement's provisions regarding the sentence or the term and conditions of probation are inappropriate, it can reject the plea. If the court decides to reject the plea agreement provisions regarding sentencing, it must give both the state and the Defendant an opportunity to withdraw from the plea agreement. In case this plea agreement is withdrawn, all original charges will automatically be reinstated. The Defendant in such case waives and gives up his right to a probable cause determination on the original charges.

☑ 7. If the court decides to reject the plea agreement provisions regarding sentencing and neither the state nor the Defendant elects to withdraw the plea agreement, then any sentence either stipulated to or recommended herein in paragraph 2 is not binding upon the court, and the court is bound only by the sentencing limits set forth in paragraph 1 and the applicable statutes.

☑ 8. I understand that if I am not a citizen of the United States my decision to go to trial or enter into a plea agreement may have immigration consequences. Specifically, I understand that pleading guilty or no contest to a crime may affect my immigration status. Admitting guilt may result in deportation even if the charge is later dismissed. My plea or admission of guilt could result in my deportation or removal, could prevent me from ever being able to get legal status in the United States, or could prevent me from becoming a United States citizen. I understand that I am not required to disclose my legal status in the United States to the court.

☑ 9. This plea agreement in no way affects any forfeiture proceedings pursuant to A.R.S. § 13-4301 et seq., § 13-2314, or § 32-1993, if applicable, nor does the plea agreement in any way compromise or abrogate any civil actions, including actions pursuant to A.R.S. § 13-2301 et seq. or § 13-4301 et seq., or the provisions of A.R.S. § 13-2314 or A.R.S. § 13-4310.

I have read and understand the provision of pages one and two of this agreement. I have discussed the case and my constitutional rights with my lawyer. My lawyer has explained the nature of the charge(s) and the elements of the crime(s) to which I am pleading. I understand that by pleading GUILTY I will be waiving and giving up my right to a determination of probable cause, to a trial by jury to determine guilt and to determine any fact used to impose a sentence within the range stated above in paragraph one, to confront, cross-examine, compel the attendance of witnesses, to present evidence in my behalf, my right to remain silent, my privilege against self-incrimination, presumption of innocence and right to appeal. I agree to enter my plea as indicated above on the terms and conditions set forth herein. I fully understand that if, as part of this plea agreement, I am granted probation by the court, the terms and conditions thereof are subject to modification at any time during the period of probation. I understand that if I violate any of the written conditions of my probation, my probation may be terminated and I can be sentenced to any term or terms stated above in paragraph one, without limitation.

I have personally and voluntarily placed my initials in each of the above boxes and signed the signature line below to indicate I read and approved all of the previous paragraphs in this agreement, both individually and as a total binding agreement.

Date 5/17/17 Defendant _____

I have discussed this case with my client in detail and advised him of his constitutional rights and all possible defenses. I believe that the plea and disposition set forth herein are appropriate under the facts of this case. I concur in the entry of the plea as indicated above and on the terms and conditions set forth herein.

Date 5/17/17 Defense Counsel _____ 25392

I have reviewed this matter and concur that the plea and disposition set forth herein are appropriate and are in the interests of justice.

Date 5/19/2017 Prosecutor _____ 030608

24416 N 19th Ave Phoenix
AZ 85085

MEDIVANT HEALTHCARE

TailStorm Health Inc. DBA Medivant Healthcare
Employee
Gandhi, Mitesh M.
VIJAYARAGHAVAN, Ramesh
Cardenas, Jose L.
Cardenas, Esthela M.
Karanam, Pratyusha Naren
Valenzuela, Randy A.
Luke, Hila M.
Khemka, Rohan
Dave, Rashesh A.
Valencia, Edgar A.
Shah, Devansh A.
Kludy, Steven C.
Garcia Ceja, Martin
Barraza, Odesa A.
Heiser, Ryan A.
devere, john a.
Espinoza, Isabel P.
Cortez, Cristina
Cortez, Monica
GANESAN, SRIRAM
Rojas, Jorge J.
Gonzalez, Edgar O.
Rodriguez, Bryan A.
Lopez, Ernesto
Lizarraga, Jorge e.
Vargas, Adriel G.
curry, fabian s.
Arguelles, Teresa
Cuesta, Blanca

24416 N 19th Ave Phoenix
AZ 85085

MEDIVANT
HEALTHCARE

Valdez, Lorena
Hernandez, Adrian R.
Valdez, Daniel
Bermudez, Paola
Sharma, Sushil
POLISETTY, DILIP KUMAR
Hagos, Liya
LLC, JCFN AZ Consulting
LLC, Fimark
LLC, MA Workfoce
Beougher, Paula
May, Christianne N.
Oran, Brian W.
Bruyere, Barbara A.
Gundare, Sadanand A.
Narvaez, Maria
Skalyo, Jeffrey J.
NAIK, YOGESH R.
Starnes, Julia M.
Liu, Kevin
Walen, Madison s.
chavez, Gregory G.
Gonzalez, Christian R.
Boanca, Jessica S.
Balmelli, Kathryn A.
Birnbaum, Ethan B.
Harrington, Brittani S.
Baluken, Kenan S.
Patodia, Anuj
Rope JR, Steven
Hawke, Cianna M.

Arizona State Board of Pharmacy

MANUFACTURER (DRUG) SECURITY/EQUIPMENT INSPECTION on 09/28/2022 for Tailstorm Health Inc dBA Medivant Healthcare

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit# :	**AZ Permit Exp.Date :**	**Business Name :**
M002033	10/31/2023	Tailstorm Health Inc dBA Medivant Healthcare
Address :		
24416 North 19th Avenue		
Zip :	**City :**	**State :**
85085	Phoenix	AZ
Phone :	**Email :**	**Inspection Date :**
(480) 605-5207	p.beougher@medivanthealth.com	09/28/2022
PIC :	**Pic License Exp Date :**	**Designated Representative :**
Brian Oran	10/31/2022	Brian Oran
DEA # :	**FDA Registration# :**	**Inspection Reviewed With :**
NA	3022483154	PIC and Paula Beougher
Reviewers License# :	**Inspection type :**	
S018476	Opening	

Inspection Conducted By :

Sharon Richardson , Chirag Patel

ACTIVITIES

1	Controlled Substances	○ YES ◉ NO
2	Prescription Drugs	◉ YES ○ NO
3	Nonprescription Drugs	○ YES ◉ NO
4	Rx Devices	○ YES ◉ NO
5	Precursor/Regulated Chemicals	○ YES ◉ NO
6	Repackaging	◉ YES ○ NO

FACILITY

		S	C/P	U	N/A
1	Security ARS 32-1904(B)(3); R4-23-604(B)(7); 21 CFR 211.28(c); 21 CFR 1301.73 Alarm system with notification to leadership; Badge access to the building and further restricted bade access to manufacturing area based on authoriz athion	◉	○	○	○

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

3	Size and space	◉ S	○ C/P	○ U	○ N/A	R4-23-604; 21 CFR 211.42(a)(b)
5	Separate or defined areas: Receipt/identification Areas in warehouse need to be identified for quarantine, rejected, and released for use-- will follow up on routine inspection	◉ S	○ C/P	○ U	○ N/A	21 CFR 211.42(c)(1)
4	Separate or defined areas: Rejected materials	◉ S	○ C/P	○ U	○ N/A	21 CFR 211.42(c)(2)
5	Separate or defined areas: Released materials	◉ S	○ C/P	○ U	○ N/A	21 CFR 211.42(c)(3)
6	Separate or defined areas: In-process materials No in process materials in current operation	○ S	○ C/P	○ U	◉ N/A	21 CFR 211.42(c)(4)
7	Separate or defined areas: Manufacturing and processing operations	◉ S	○ C/P	○ U	○ N/A	21 CFR 211.42(c)(5)
8	Separate or defined areas: Packaging and labeling	◉ S	○ C/P	○ U	○ N/A	21 CFR 211.42(c)(6)
9	Separate or defined areas: Quarantine of drug products before release	◉ S	○ C/P	○ U	○ N/A	21 CFR 211.42(c)(7)
10	Separate or defined areas: Storage of drug products after release	◉ S	○ C/P	○ U	○ N/A	21 CFR 211.42(c)(8)
11	Separate or defined areas: Laboratory operations lab testing outsourced to third party	○ S	○ C/P	○ U	◉ N/A	21 CFR 211.42(c)(9)
12	Separate or defined areas: Aseptic processing	◉ S	○ C/P	○ U	○ N/A	21 CFR 211.42(c)(10)

13	Penicillin processing	○ S ○ C/P ○ U ◉ N/A	21 CFR 211.42(d); 211.46(d)
14	Lighting	◉ S ○ C/P ○ U ○ N/A	21 CFR 211.44
15	Ventilation/environmental control systems "Lighthouse" system gives real time constant data and alerts when out of range	◉ S ○ C/P ○ U ○ N/A	21 CFR 211.46
16	Plumbing potable water under constant positive pressure	◉ S ○ C/P ○ U ○ N/A	21 CFR 211.48
17	Sewage and refuse	◉ S ○ C/P ○ U ○ N/A	21 CFR 211.50; 211.56
18	Washing/bathroom facilities	◉ S ○ C/P ○ U ○ N/A	21 CFR 211.52
19	Physical plant	◉ S ○ C/P ○ U ○ N/A	ARS 32-1966(3); 21 CFR 211.56; 211.58

EQUIPMENT AND UTENSILS

1	Appropriate design	◉ S ○ C/P ○ U ○ N/A	21 CFR 211.63
2	Construction	◉ S ○ C/P ○ U ○ N/A	21 CFR 211.65
3	Refrigerators/freezers	◉ S ○ C/P ○ U ○ N/A	21 CFR 211.142(b); 21 CFR 211.46
4	Automated equipment/computer PFS filling: Marchesini Group/ FSP05; mfr visit yearly for maintenance and calibration; daily calibration not required by employees	◉ S ○ C/P ○ U ○ N/A	21 CFR 211.68(b)

	Filters	S	C/P	U	N/A
					21 CFR 211.72
	Filters not used in current operation				

STORAGE

1	Components, drug product containers, closures	S	C/P	U	N/A
					21 CFR 211.80(b)(c)
2	Packaging and labeling	S	C/P	U	N/A
					21 CFR 211.122(d)
	Labels not stored- printed on demand by quality				
3	Drug products	S	C/P	U	N/A
					21 CFR 211.142(b)
4	Representative samples	S	C/P	U	N/A
					21 CFR 211.84(b); 211.160; 21 CFR 211.165
5	Reserve samples	S	C/P	U	N/A
					21 CFR 211.170(a)(b)

QUALITY CONTROLS

1	Adequate laboratory facilities	S	C/P	U	N/A
					21 CFR 211.22
	Analysis of samples outsourced; lab room used for air and surface sampling				
2	Written procedures and recordkeeping	S	C/P	U	N/A
					R4-23-604(K); 21 CFR 211. 21; CFR 1304.22

DISTRIBUTION

1	Distribution records	S	C/P	U	N/A
					R4-23-601(D); R4-23-1003(A); 21 CFR 211.196
	Will review on routine inspection once distribution has started: review requirements				

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

2	Stock distribution	◉ S	○ C/P	○ U	○ N/A
		R4-23-604(H); 21 CFR 211.150(a)			
	Sales to medical offices only; procedures in place for verifying and maintaining appropriate license/permits of customers				

MANUFACTURING RECORDS

1	Master production records	◉ S	○ C/P	○ U	○ N/A
		R4-23-604(K); 21 CFR 211.186(a)(b)			
	Combined into batch record				
2	Batch records	◉ S	○ C/P	○ U	○ N/A
		21 CFR 211.134; 21CFR 211.188(a)(b); 21 CFR 211.192			

CONTROLLED SUBSTANCES

1	Security	○ S	○ C/P	○ U	◉ N/A
		21 CFR 1301.71(a); 1301.72			
2	In-process substance security	○ S	○ C/P	○ U	◉ N/A
		21 CFR 1301.73			
3	Limited-access area	○ S	○ C/P	○ U	◉ N/A
		21 CFR 1301.73; 211.28(c)			

NOTES

May begin production once room certifications are received- send copies to compliance officer

Reminders:
Identify areas in warehouse for quarantine, awaiting release, and released components
Ensure distribution records contain the license # of the medical practitioner sold to; retain 3 years

Current operation is repackaging of Avastin in sterile syringes for intravitreal injection for office use only; obtaining commercial product from Curascript (curren t wholesaler permit verified)

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: MidAmerica Pharmaceuticals LLC

Physical Address: 1010 Lake Street Suite 200

City: Oak Park State: IL Zip: 60301

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: (312) 286-9475 Website: N/A

Name of Designated Representative (DR): Linda P. Brennan

Licensing Company Email: compliance.midamerica@gmail.com DR Email: linda@midamericapharmaceuticals.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☑ Pharmacies	☐ Dangerous Drugs	☑ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☑ Others:	☐ Warehouse
☐ Veterinarians	Prescription Drugs	☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

4/24/23
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Lyne Laboratories
Address: 10 Burke Dr. City: Brockton State: MA Zip: 02301

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): N/A
Corporation Name: MidAmerica Pharmaceuticals LLC
Mailing Address: 1010 Lake Street Suite 200
City: Oak Park State: IL Zip: 60301
Telephone: (312) 286-9475 Email: compliance.midamerica@gmail.com
Contact Person Name: Linda Brennan

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

MidAmerica Pharmaceuticals LLC

Facility Name

Linda Brennan

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

4/24/23

Date

Board Use Only	Date Received: 9/5/23	Amount: 1000 - CK - 1560 ✓

MidAmerica PHARMACEUTICALS

1010 Lake Street, Suite 200
Oak Park, Illinois 60301

List of Owners

Owner Name	% Ownership	Address
Linda Brennan	60.00%	1130 Franklin Ave., River Forest, IL, 60305 US
Clara Rubinstein	4.57%	1434 Ashland Ave., River Forest, IL 60305 US
Kevin Conway	2.90%	1426 Clinton Pl., River Forest, IL 60305 US
Jill Javors	1.90%	P.O. Box 4348, Avon, CO 81620 US
Steven Kingwell	1.90%	1760 Winding Oaks Way, Naples, FL 34109 US
Madison Investment Group, Inc.	1.90%	595 Sheridan Rd., Glencoe, IL 60022 US
Martin Ruhaak	1.90%	742 Bonnie Brae Pl., River Forest, IL 60305 US
John Kelly	1.90%	1107 Sunset Rd., Winnetka, IL 60093 US
Charles Doherty	1.50%	6 Carmenere Ct., Henderson, NV 89011 US
James Lynch	1.50%	1129 Park Ave., River Forest, IL 60305 US
George Riedl	1.50%	317 Forest Lane, Libertyville, IL 60048 US
Peter Pellegrino	1.50%	120 W. Maple Ave., Roselle IL 60172 US
Craig Stacey	1.50%	2931 Highwood Drive, Chanhassen, MN 55317 US
Stephen Tardella	0.90%	1313 Jackson Ave., River Forest, IL 60305 US
Andrew Corsini	0.90%	1415 Lathrop Ave., River Forest, IL 60305 US
Michael Haas	0.90%	1632 Woodbine Ave., Oak Park, IL 60302 US
Jeffrey Cox	0.90%	558 Clinton Pl., River Forest, IL 60305 US
Edward Garvey, Jr.	0.90%	931 N. Elmwood, Oak Park, IL 60302 US
John Roy	0.90%	330 E. 79th St. Apt. 10A, New York, NY 10075 US
George Stansfield	0.90%	182 High St., Plainfield, NH 03781 US
Roland Wolfram	0.90%	100 Sun Valley Rd. Unit 1969, Sun Valley, ID 83353 US
Sara Gourley Euler	0.90%	3 Old Rocky Ridge Rd., Chapel Hill, NC 27514 US
Richard Cederoth	0.90%	546 N. Euclid Ave., Oak Park, IL 60302 US
John Beringer	0.90%	14889 Trappers Trail, Russell, OH 44072 US
Lisa Phelan	0.90%	2613 Jeanne St., Falls Church, VA 22046 US
Michael Yungerman	0.90%	1023 Franklin Ave., River Forest, IL 60305 US
David Ellis	0.90%	1048 Ashland Ave., River Forest, IL 60305 US
Todd Huseby	0.90%	1123 Lathrop Ave., River Forest, IL 60305 US
James Brennan	0.50%	8817 Katharina Ct., Raleigh, NC 27613 US
Martha Brennan	0.33%	1130 Franklin Ave., River Forest, IL 60305 US
Laura Brennan	0.33%	180 NE 29th St. Apt 801, Miami, FL 33137 US
George Brennan	0.33%	264 W. 19th St. Apt. 41, New York, NY 10011 US
David Brennan	0.25%	5000 N. Marine Dr. 11E, Chicago, IL 60640 US
Thomas Boyle	0.25%	646 John Wesley Dobbs Ave. NE, Atlanta, GA 30312 US
Matthew Chalek	0.01%	5828 S. Fulton Way, Greenwood Village, CO 80111 US
Robert McCabe	0.01%	237 Belvedere Dr., Cranston, RI 02920 US
Richard Perelman	0.01%	200 Hoffman Ave., Cranston, RI 02920 US
Dominique Kendrick	0.01%	251 W. Fairview Way, Palatine, IL 60067 US
	100.00%	

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Wednesday, April 13, 2022 9:45 AM
To: Linda Brennan <linda@midamericapharmaceuticals.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 13-APR-2022
Labeler DUNS: 118150617
Labeler Name: MidAmerica Pharmaceuticals
Labeler Code Assigned: 82682

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

√verified
9/1/23

MidAmerica
PHARMACEUTICALS

1010 Lake Street, Suite 200
Oak Park, Illinois 60301

List of Officers/Owners

Linda Brennan
CEO
[redacted] Lake Street, Suite [redacted]
Oak Park, IL 60301
DOB [redacted]
SSN [redacted]
60% ownership

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "MIDAMERICA PHARMACEUTICALS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE NOT HAVING BEEN CANCELLED OR REVOKED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF FORMATION, FILED THE THIRTIETH DAY OF AUGUST, A.D. 2018, AT 2:06 O`CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATE IS THE ONLY PAPER OF RECORD, THE LIMITED LIABILITY COMPANY IN QUESTION NOT HAVING FILED AN AMENDMENT NOR HAVING MADE ANY CHANGE WHATSOEVER IN THE ORIGINAL CERTIFICATE AS FILED.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7037532 8315

SR# 20231014318

Authentication: 202931245

Date: 03-16-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.005323

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2024

LICENSED WHOLESALE DRUG DISTRIBUTOR

MANUFACTURER

MIDAMERICA PHARMACEUTICALS LLC
LINDA BRENNAN
1010 LAKE ST STE 253
OAK PARK, IL 60301-1147

MARIO TRETO, JR.
SECRETARY

CECILIA ABUNDIS
DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

17858345

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4631073

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. **999254146**

Application/License No. _____

LINDA BRENNAN DBA MidAmerica Pharmaceuticals LLC

Applicant/Principal

doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1010 Lake St SUITE 253, Oak Park, Oak Park Township, IL 60301

Address of Applicant/Principal

as PRINCIPAL, and The Ohio Casualty Insurance Company, a

Surety Company

corporation organized under the laws of the state of New Hampshire

State of Incorporation

and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is

175 Berkeley Street, Boston, Massachusetts 02116

Address of Surety

as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 27, 2023.

Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 27th day of April, 2023.

APPLICANT/PRINCIPAL

Linda Brennan
Authorized Representative

SURETY COMPANY

Matt Davis
Surety Company's Representative

THE OHIO CASUALTY INSURANCE COMPANY INCORPORATED 1919 NEW HAMPSHIRE

Matt Davis, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Martha Brennan
Witness

Peter Brennan
Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual. SURETY

The Ohio Casualty Insurance Company

POWER OF ATTORNEY

Principal: LINDA BRENNAN DBA MidAmerica Pharmaceuticals LLC
Agency Name: Liberty Mutual Business Center - Unattached (BLSC) Bond Number: 999254146
Obligee: Nevada State Board of Pharmacy
Bond Amount: ($25,000.00) Twenty-five Thousand Dollars And Zero Cents

KNOW ALL PERSONS BY THESE PRESENTS: that The Ohio Casualty Insurance Company, a corporation duly organized under the laws of the State of New Hampshire (herein collectively called the "Company"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint **Matt Davis** in the city and state of **Liberty Lake, WA**, each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Company in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Company and the corporate seal of the Company has been affixed thereto this 26th day of September, 2016.

THE OHIO CASUALTY INSURANCE COMPANY INCORPORATED 1919 NEW HAMPSHIRE

The Ohio Casualty Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA
COUNTY OF MONTGOMERY ss

On this 26th day of September, 2016, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of The Ohio Casualty Insurance Company and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

TERESA PASTELLA COMMONWEALTH OF PENNSYLVANIA NOTARY PUBLIC

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-law and Authorizations of The Ohio Casualty Insurance Company, which is now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature or electronic signatures of any assistant secretary of the Company or facsimile or mechanically reproduced or electronic seal of the Company, wherever appearing upon a certified copy of any power of attorney or bond issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of The Ohio Casualty Insurance Company do hereby certify that this power of attorney executed by said Company is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Company this 27th day of April, 2023.

THE OHIO CASUALTY INSURANCE COMPANY INCORPORATED 1919 NEW HAMPSHIRE

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

MidAmerica
PHARMACEUTICALS
1010 Lake Street, Suite 200
Oak Park, Illinois 60301

Designated Representative Description of Duties

- Oversee the development and execution of a Quality Management System and comply with all federal, state, and local regulations
- Oversee development of Quality Manual
- Development and execution of SOPs, including:
    - Inventory Management
    - Product Distribution
    - Product Traceability Management
    - Document and Records Management
    - Disaster Recovery
    - Product Recalls
    - Drug Loss Controls
    - Complaint Management
    - Customer Communications
    - Quality Auditing
    - Promotional Labeling and Advertising
    - Change Controls
    - Incident Management/CAPA
    - Training Program
    - Developing and Revising Written Procedures
- Ensure timely execution of Quality Agreements and Quality Audits with suppliers and vendors

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler MidAmerica Pharmaceuticals LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 1010 Lake Street, Suite 200

City Oak Park State IL Zip 60301

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone (312) 286-9475 Website N/A

Licensing Company Email compliance.midamerica@gmail.com

Section 2: Personal Information

First Linda Middle Perelman Last Brennan

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Lake Street, Suite [redacted]

City Oak Park State IL Zip 60301

Telephone (312) 286-9475 Email compliance.midamerica@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wharton School, University of Pennsylvania		09/84 - 05/86	
Address	**City**	**State**	**Zip**
3733 Spruce Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
MBA			
School Name		**From - To (MM/YY – MM/YY)**	
The American University		09/79 - 12/82	
Address	**City**	**State**	**Zip**
4400 Massachusetts Avenue, NW	Washington	DC	20016
Diploma/Degree obtained, if any			
BS			
School Name		**From - To (MM/YY – MM/YY)**	
Cranston High School East		09/76 - 06/79	
Address	**City**	**State**	**Zip**
899 Park Avenue	Cranston	RI	02910
Diploma/Degree obtained, if any			
HS Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/07 - present	[redacted]Franklin Avenue	River Forest	IL	60305
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
MidAmerica Pharmaceuticals LLC			08/18 - present
Business Address	**City**	**State**	**Zip**
1010 Lake Street, Suite 200	Oak Park	IL	60301
Phone	**Title**	**Number of Employed Hours**	
(312) 286-9475	CEO	12,000	
Description of Duties			
See attached.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2007	2008 settled	IL	Chicago	Cook
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
do not recall		Cook County Circuit Court		
Reason/Charge				
contractors' dispute				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Defendant			Arbitration	
Name of Business/Industry/Entity				
Heartland Construction (general contractor) and Broad Spectrum (painting subcontractor)				

Provide explanation below:

dispute between us and general contractor and painting subcontractor for services performed during our home renovation

Original Signature (electronic, copies or stamps not accepted)

4/24/23
Date

I, Linda Brennan, **certify that as the designated representative for**

MidAmerica Pharmaceuticals LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

LINDA BRENNAN

Print Name (First, Last)

Linda Brennan

Original Signature (electronic, copies or stamps not accepted)

4/24/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LINDA BRENNAN

Print Name (First, Last)

Linda Brennan

Original Signature (electronic, copies or stamps not accepted)

4/6/23

Date

Please have this section completed in the presence of a Notary Public.

State of ILLINOIS, ss. County of COOK

I, LINDA BRENNAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Linda Brennan

Original Signature

4/6/23

Date

Subscribed and Sworn to before me this 6th day of April 2023

Rhonda C Finley

Notary Public Signature

"OFFICIAL SEAL"
RHONDA C FINLEY
Notary Public, State Of Illinois
My Commission Expires 08/31/2026
Commission No. 881601

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: MidAmerica Pharmaceuticals LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): NA

Physical Address: 1010 Lake Street, Suite 200

City: Oak Park State: IL Zip: 60301

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: (312) 286-9475 Website: NA

Licensing Company Email: compliance.midamerica@gmail.com

Section 2: Personal Information

First: Linda Middle: Perelman Last: Brennan

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address: 1010 Lake Street, Suite 200

City: Oak Park State: IL Zip: 60301

Telephone: (312) 286-9475 Email: compliance.midamerica@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wharton School, University of Pennsylvania		09/84 - 05/86	
Address	**City**	**State**	**Zip**
3733 Spruce Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
The American University		09/79 - 12/82	
Address	**City**	**State**	**Zip**
4400 Massachusetts Avenue, NW	Washington	DC	20016
Diploma/Degree obtained, if any			
BS			

School Name		From - To (MM/YY – MM/YY)	
Cranston High School East		09/76 - 06/79	
Address	**City**	**State**	**Zip**
899 Park Avenue	Cranston	RI	02910
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/07 - present	[redacted] Franklin Avenue	River Forest	IL	60305
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
MidAmerica Pharmaceuticals LLC			08/18 - present
Business Address	**City**	**State**	**Zip**
1010 Lake Street Suite 200	Oak Park	IL	60301
Phone	**Title**		
(312) 286-9475	CEO		

Description of Duties

determine the corporate vision and strategy; raise capital to fund the business; ensure the successful distribution and sales of pharmaceutical products

Business Name			From - To (MM/YY – MM/YY)
The Brennan Group LLC			08/03 - present
Business Address	**City**	**State**	**Zip**
1130 Franklin Avenue	River Forest	IL	60305
Phone	**Title**		
(312) 286-9475	CEO		

Description of Duties

consult to consumer products manufacturers and marketing services companies

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2007	2008 settled	IL	Chicago .	Cook
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
do not recall		Cook County Circuit Court		
Reason/Charge				
contractors' dispute				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Defendant			Arbitration	
Name of Business/Industry/Entity				
Heartland Construction (general contractor) and Broad Spectrum (painting subcontractor)				

Provide explanation below:

dispute between us and general contractor and painting subcontractor for services performed during our home renovation

Original Signature (electronic, copies or stamps not accepted)

4/24/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Linda Brennan

Print Name (First, Last)

Linda Brennan

Original Signature (electronic, copies or stamps not accepted)

4/6/23

Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Cook

I, LINDA BRENNAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Linda Brennan

Original Signature

4/6/23

Date

Subscribed and Sworn to before me this 6th day of April 2023

Rhonda C Finley

Notary Public Signature

"OFFICIAL SEAL"
RHONDA C FINLEY
Notary Public, State Of Illinois
My Commission Expires 08/31/2026
Commission No. 881601

(Seal)

MidAmerica
PHARMACEUTICALS

1010 Lake Street, Suite 200
Oak Park, Illinois 60301

List of Employees, Contractors, Consultants

Linda Brennan – CEO
Peter Pellegrino – CFO/COO
Craig Stacey – CMO
Susan Thoss – Supply Chain
Lisa Apolis – Regulatory
George Riedl – Go To Market
Darina Byrne – Quality Systems
Angela Byrne – Pharmacovigilance
John McGill – IT
Dr. Eve del Rio – Medical
Don Reitberg – Pharmacology
Wes Meador – Media
David Houck – Chemistry/Manufacturing/Controls

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Facility Name: Mobius Therapeutics, LLC

Physical Address: 1000 Executive Parkway Drive, Suite 224

City: St. Louis State: MO Zip: 63141

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 314-615-6930 Website: www.mitosol.com

Name of Designated Representative (DR): Edward J. Timm

Licensing Company Email: chris.patullo@mobiustx.com DR Email: ed.timm@mobiustx.com

■ Pharmacies ■ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	■ Dangerous Drugs ☐ Controlled Substances ☐ [3]Medical devices, equipment, supplies, gases ☐ Others:	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ■ Others: Virtual Manufacturer

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

April 22, 2023
Date

Name: Intas Pharmaceuticals Limited (FDA FEI 3003157498) drug vial manufacturer
Address: Plot No. 457,458, Sarkhej Bavla Highway City: Ahmedabad State: India Zip: 382210
Name: B. Braun Medical Inc
Address: 901 Marcon Blvd. City: Allentown State: PA Zip: 18109
Name: Amphastar Pharmaceuticals, Inc
Address: 11570 6th Street, City: Rancho Cucamonga State: CA Zip: 91730
Name:
Address: City: State: Zip:

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

State of Incorporation/Organization: Delaware
Parent Company (if any):
Corporation/Organization Name: Mobius Therapeutics, LLC
Mailing Address: 1000 Executive Parkway Drive
City: St. Louis State: MO Zip: 63141
Telephone: 314-615-6930 Email: ed.timm@mobiustx.com
Contact Person Name: Edward J. Timm

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Mobius Therapeutics, LLC

Facility Name

Edward J. Timm

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

04/19/2023

Date

Board Use Only	Date Received: 7/31/23	Amount: 1000-CK-12001

Mobius Therapeutics, LLC
1000 Executive Parkway Drive
Suite 224
Saint Louis, MO 63141 USA
p: +1 314-615-6930
f: +1 314-615-6931
tf: 1-877-EYE-MITO
www.MitosoL.com

CORPORATE OFFICER INFORMATION FOR MOBIUS THERAPEUTICS, LLC

Formed in the State of Delaware on 17 May 2007.

1). Edward J. Timm, President & CEO
Mobius Therapeutics, LLC
1000 Executive Parkway Drive
Suite 224
Saint Louis, MO 63141
Phone – 314-615-6930

2). Mark Wright, CFO
Mobius Therapeutics, LLC
1000 Executive Parkway Drive
Suite 224
Saint Louis, MO 63141
Phone – 314-615-6930

Mobius Therapeutics, LLC - Cap Table

April 30, 2023

Member	Common	Class B Preferred	Equity Incentive Plan	Total Units	%
Merle Symes	50.00			50.00	1.80%
Mobius Therapeutics, Inc.	1.00			1.00	0.04%
Philip Howard Bentley Moss a/k/a Howard Moss	152.89	347.61		500.50	17.97%
Carl C. Awh	8.00			8.00	0.29%
Actionnaires, LLC	12.00			12.00	0.43%
Anthony, Allan & Quinn, Inc.	48.00			48.00	1.72%
Jeffrey Scott Cooper	40.00			40.00	1.44%
John L. Meyer	8.00			8.00	0.29%
KKP, LLC	19.11			19.11	0.69%
Mantic Investments, LLC	8.00			8.00	0.29%
Mark Wright			91.40	91.40	3.28%
Thomas A. Tomaro Living Trust, dated April 3, 1998	24.00			24.00	0.86%
Dawn Durham Trust 2005	6.00			6.00	0.22%
Jay Krippes	6.00			6.00	0.22%
Thomas C. Brough	6.00			6.00	0.22%
David and Anina Pfeiffer	8.00			8.00	0.29%
Susan G. DeShong	6.00			6.00	0.22%
Stephen & Benedicte Duryea, TTES REV TRUST U/A DTD 12/15/1995	6.00			6.00	0.22%
Steve Hanley	6.00			6.00	0.22%
Sean Donlin	6.00			6.00	0.22%
Christopher Frederick Effer	6.00			6.00	0.22%
John L. Meyer Living Trust Dated December 14, 2006	12.00			12.00	0.43%
Timothy Hanley and Monica Hanley, as joint tenants with right of survivorship	6.00			6.00	0.22%
Stephen B. Scolnik and Melinda S. Krippes, as joint tenants with right of survivorship	6.00			6.00	0.22%
Richard J Rizzo Revocable Living Trust Dated Nov 2009	12.00			12.00	0.43%
B & W Hand, LLC	12.00			12.00	0.43%
Frank Ruffo	5.00			5.00	0.18%
Janet Francescangeli	1.00			1.00	0.04%
W. Raymond Barrett Revocable Trust Dated September 24, 1996 and Timothy R. Barrett Revocable Trust Dated May 21, 2003, as Tenants in Common	6.00			6.00	0.22%
Adooring Designs, LLC	6.00			6.00	0.22%
Kevin J. Klingler and Lucille J. Klingler	6.00			6.00	0.22%
Radix International LLC	8.00			8.00	0.29%
Thomas L. Tangaro	6.00			6.00	0.22%
James M. Barry Revocable Trust, UAD 7/21/00	8.00			8.00	0.29%
Douglas J. Paschall	6.00			6.00	0.22%
Terry A. Meek and Cathie L. Meek	6.00			6.00	0.22%
Edward J. Timm and Carla A. Timm, as Trustees of the Edward J. Timm Revocable Trust dated December 31, 2011	415.00			415.00	14.90%
Carla A. Timm and Edward J. Timm, as Trustees of the Carla A. Timm Revocable Trust dated December 31, 2011	533.20	1.08	2.00	536.28	19.26%
BioGenerator	24.27	25.91		50.18	1.80%
James A. Quaile and Henry W. Mulholland, as Trustees of the Rosemary Quaile 2012 Credit Shelter Trust	27.11			27.11	0.97%
Janet Lupnacca			18.00	18.00	0.65%
Daniel Campbell			10.00	10.00	0.36%
Lawrence V. Toomey III			4.00	4.00	0.14%
Kathryn M. Norton, as Trustee of the Kathryn M. Norton Revocable Trust Agreement dated July 1, 2004			1.34	1.34	0.05%
Cultivation Capital Life Sciences Fund, LLC		64.77	13.93	78.70	2.83%
TLMS Holdings LLC		6.48		6.48	0.23%
GPC Holdings, LLC		3.24		3.24	0.12%
Sage Capital Holdings, Inc.		3.24		3.24	0.12%
James P. McCarter Rev. Tr DTD 03-04-2010		6.48		6.48	0.23%
John W. McCarter, Jr., as Trustee of the McCarter Exempt Trust		6.48		6.48	0.23%
Frederic Lee Rohlfing, u/d/t dated August 13, 2002 F/B/O Trust Beneficiaries		6.48		6.48	0.23%
James A. Veldkamp		6.48		6.48	0.23%
Edward J. Timm		27.86	20.00	47.86	1.72%
Sean and Gina Donlin, JTWROS		6.07		6.07	0.22%

Mobius Therapeutics, LLC Shareholders and % Ownership

Thomas L. Tangaro		6.07		6.07	0.22%
Daniel Wiggins		26.29		26.29	0.94%
James A. Quaile and Henry W. Mulholland, as Trustees of the Rosemary Quaile 2012 Credit Shelter Trust		39.78		39.78	1.43%
H. Dean VandeKamp Revocable Trust U/A/D 12/21/99			13.93	13.93	0.50%
Robert Ritch, M.D.			4.00	4.00	0.14%
William Oman			2.00	2.00	0.07%
Danielle Ashbach			2.00	2.00	0.07%
Marlene R. Moster, M.D.			2.00	2.00	0.07%
Thomas Janulis			0.67	0.67	0.02%
Linda Kalata			6.00	6.00	0.22%
Owen Bishop			23.00	23.00	0.83%
Edward J. Timm, as Trustee of the Carla A. Timm 2011 Grantor Retained Annuity Trust dated December 31, 2011	81.80			81.80	2.94%
Charles J. Kretschmer, as Trustee of the Charles J. Kretschmer Revocable Trust Agreement dated July 15, 2014	40.00		2.97	42.97	1.54%
Accord Healthcare, Inc.	152.00			152.00	5.46%
James Brocato			1.36	1.36	0.05%
Gregory J. Divis			13.37	13.37	0.48%
Childress Trust dated September 15, 2016	6.00	6.07		12.07	0.43%
Christina Patullo			15.00	15.00	0.54%
Pensco Trust Company LLC Custodian FBO John A. Young IRA	9.56			9.56	0.34%
Kline Hill Partners Fund LP	38.22	33.15		71.37	2.56%
James A. Anderson and Beth A. Anderson, Trustees, or their successors in interest, of the Anderson Family Trust dated December 29, 2020, and any amendments thereto	12.00	8.09	29.00	49.09	1.76%
Alan Beckman, as trustee under the Alan and Jennifer Beckman Revocable Living Trust Agreement dated 2 March 2023			5.00	5.00	0.18%
Total	**1,872.16**	**631.63**	**280.97**	**2,784.76**	**100.00%**

STATE OF MISSOURI

John R. Ashcroft
Secretary of State

CORPORATION DIVISION
CERTIFICATE OF GOOD STANDING

I, JOHN R. ASHCROFT, Secretary of State of the STATE OF MISSOURI, do hereby certify that the records in my office and in my care and custody reveal that

Mobius Therapeutics, LLC

using in Missouri the name

Mobius Therapeutics, LLC
FL0818088

a DELAWARE entity was created under the laws of this State on the 21st day of May, 2007, and is Active, having fully complied with all requirements of this office.

IN TESTIMONY WHEREOF, I hereunto set my hand and cause to be affixed the GREAT SEAL of the State of Missouri. Done at the City of Jefferson, this 22nd day of February, 2023.

Secretary of State

Certification Number: CERT-02222023-0069

State of Missouri

Division of Professional Registration
Licensed Drug Distributor
Wholesale Drug Distributor

VALID THROUGH OCTOBER 31, 2023
ORIGINAL CERTIFICATE/LICENSE NO. 2010041865
MOBIUS THERAPEUTICS LLC
MOBIUS THERAPEUTICS LLC
EDWARD TIMM, MIC
1000 EXECUTIVE PKWY STE 224
SAINT LOUIS MO 63141
USA

MOBIUS THERAPEUTICS LLC
MOBIUS THERAPEUTICS LLC
EDWARD TIMM, MIC
1000 EXECUTIVE PKWY STE 224
SAINT LOUIS MO 63141
USA

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy
Licensed Drug Distributor

Wholesale Drug Distributor

VALID THROUGH OCTOBER 31, 2023
ORIGINAL CERTIFICATE/LICENSE NO. 2010041865
Edward Timm
MOBIUS THERAPEUTICS LLC
MOBIUS THERAPEUTICS LLC
EDWARD TIMM, MIC
1000 EXECUTIVE PKWY STE 224
SAINT LOUIS MO 63141
USA

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through May 12, 2023

You have searched Finished drug products

Search Results: *'Mitosol'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
– Mitosol	49771-002-03		KIT		NDA022572	Mobius Therapeutics LLC	49771-002	mitomycin		HUMAN PRESCRIPTION DRUG	02/08/2012	N/A

Sample Package No

Listing Record Certified Through: 12/31/2023

Showing 1 to 1 of 1 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Verified Mtt 5/3/23

Mobius Therapeutics, LLC - 3PL

NABP ACCREDITED
DRUG DISTRIBUTOR

Foundation Care, LLC

located at

4090 Wedgeway Ct, Earth City, MO 63045

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

7/23/2020 - 7/22/2023
Period of Accreditation

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 100093477

Application/License No. _____

Mobius Therapeutics, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1000 Executive Parkway, Suite 224 St. Louis, MO 63141 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Suraty) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 19, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 19th day of May, 2023.

APPLICANT/PRINCIPAL

Mobius Therapeutics, L

Authorized Representative

SURETY COMPANY

Merchants Bonding Company (Mutual)

Surety Company's Representative

Kathy M Schwartz, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

LP 4229 NV (5/21)

MERCHANTS BONDING COMPANY™

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (in California only) (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Kathy M Schwartz

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 19th day of May , 2023 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.
On this 19th day of May , 2023 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL
Kim Lee
Commission Number 702737
My Commission Expires
April 14, 2024

Kim Lee
Notary Public

(Expiration of notary's commission
does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 19th day of May , 2023 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

William Warner Jr.
Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Y

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Mobius Therapeutics, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1000 Executive Parkway Drive, Suite 224

City St. Louis State MO Zip 63141

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 314-615-6930 Website www.mitosol.com

Licensing Company Email chris.patullo@mobiustx.com

Section 2: Personal Information

First Edward Middle Jerome Last Timm

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Sylvester Avenue

City Webster Groves State MO Zip _____

Telephone [redacted] Email ed.timm@mobiustx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

School Name			From - To (MM/YY – MM/YY)	
Marquette Catholic High School			09/74 - 06/78	
Address		City	State	Zip
306 W 10th Street		Michigan City	IN	46360
Diploma/Degree obtained, if any				
College Prep				

School Name			From - To (MM/YY – MM/YY)	
University of Dayton			08/79 - 04/82	
Address		City	State	Zip
300 College Park		Dayton	OH	45469
Diploma/Degree obtained, if any				
BA				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/17 - present	[redacted] Sylvester Avenue	Webster Groves	MO	63119
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name		From - To (MM/YY – MM/YY)	
Mobius Therapeutics, LLC		04/06 - present	
Business Address	**City**	**State**	**Zip**
1000 Executive Parkway Drive	St. Louis	MO	63141
Phone	**Title**	**Number of Employed Hours**	
314-615-6930	President & CEO	35,360	
Description of Duties			
Oversees design, sales, marketing, promotion, delivery and quality of products			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01/1991	02/1992	NM	Albuquerque	Bernalillo
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		NM Civil Courts		
Reason/Charge				
Violation of non-compete agreement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Baxter Healthcare Corporation			Lawsuit	
Name of Business/Industry/Entity				
Healtchare				

Provide explanation below:

Timm resigned employment from Baxter Healthcare to pursue a venture capital backed medical device company. Timm relocated from Albuquerque NM to Dallas TX, specifically seeking avoidance of infringement of the non-compete agreement. Prior to court appearance, Baxter settled, paying treble damages for withheld pay and all attorney fees.

Original Signature (electronic, copies or stamps not accepted)

04/19/2023
Date

I, Edward Jerome Timm, **certify that as the designated representative for**

Mobius Therapeutics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ejt I am at least 21 years of age;
3. ejt I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ejt I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ejt I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ejt I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ejt I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Edward Timm

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/19/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Edward Timm

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/24/2023

04/19/2023

Date

Please have this section completed in the presence of a Notary Public.

State of District of Columbia, ss. County of _____

I, Edward J. Timm, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04/24/2023

Date

Subscribed and Sworn to before me this 24th day of April 2023

Notary Public Signature

HADDESA BELAY GESSESSE
District of Columbia Notary Public
My Commission Expires August 31, 2024

(Seal)

NATIONAL PRACTITIONER DATA BANK
NPDB
P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

DCN: 5500000129951627
Process Date: 12/08/2017
Page: 1 of 3
MOBIUS THERAPEUTICS, LLC
For authorized use by:
MOBIUS THERAPEUTICS, LLC

MOBIUS THERAPEUTICS, LLC

ALABAMA STATE BOARD OF PHARMACY

STATE LICENSURE ACTION

Date of Action: 11/28/2017

Initial Action

- PUBLICLY AVAILABLE FINE/MONETARY PENALTY

Basis for Initial Action

- OPERATING WITHOUT A LICENSE OR PERMITS OR ON A LAPSED LICENSE

A. REPORTING ENTITY

Entity Name:	ALABAMA STATE BOARD OF PHARMACY
Address:	111 VILLAGE ST
City, State, Zip:	BIRMINGHAM, AL 35242-6477
Country:	
Name or Office:	RHONDA COKER
Title or Department:	LICENSING SUPERVISOR
Telephone:	(205) 981-4764
Entity Internal Report Reference:	
Type of Report:	INITIAL

B. SUBJECT IDENTIFICATION INFORMATION (ORGANIZATION)

Organization Name:	MOBIUS THERAPEUTICS, LLC
Other Organization Name(s) Used:	
Business Address:	1000 EXECUTIVE PARKWAY DR STE 224
City, State, ZIP:	SAINT LOUIS, MO 63141
Organization Type:	OTHER TYPE NOT CLASSIFIED - SPECIFY (999)
Other, as Specified:	VIRTUAL MANUFACTURER
Names and Titles of Principal Officers and Owners (POO):	
Federal Employer Identification Numbers (FEIN):	770686376
Social Security Numbers (SSN):	
Individual Taxpayer Identification Numbers (ITIN):	
State License Number, State of Licensure:	194096, AL
Is the Subject a health care entity that provides health care services and engages in a formal peer review process for the purpose of furthering quality health care?:	YES
Drug Enforcement Administration (DEA) Numbers:	
Clinical Laboratory Act (CLIA) Numbers:	
Food and Drug Administration (FDA) Numbers:	
National Provider Identifiers (NPI):	
Medicare Provider/Supplier Numbers:	
Name(s) of Health Care Entity (Entities) With Which Subject Is Affiliated or Associated (Inclusion Does Not Imply Complicity in the Reported Action.):	
Business Address of Affiliate:	
City, State, ZIP:	
Nature of Relationship(s):	

NATIONAL PRACTITIONER DATA BANK
NPDB
P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

DCN: 5500000129951627
Process Date: 12/08/2017
Page: 2 of 3
MOBIUS THERAPEUTICS, LLC
For authorized use by:
MOBIUS THERAPEUTICS, LLC

C. INFORMATION REPORTED

Type of Adverse Action:	STATE LICENSURE
Basis for Action:	OPERATING WITHOUT A LICENSE OR PERMITS OR ON A LAPSED LICENSE (AE)
Name of Agency or Program That Took the Adverse Action Specified in This Report:	ALABAMA STATE BOARD OF PHARMACY
Adverse Action Classification Code(s):	PUBLICLY AVAILABLE FINE/MONETARY PENALTY (3233)
Date Action Was Taken:	11/28/2017
Date Action Became Effective:	11/28/2017
Total Amount of Monetary Penalty, Assessment and/or Restitution:	$ 1,500.00
Is Subject Automatically Reinstated After Adverse Action Period Is Completed?:	
Description of Subject's Act(s) or Omission(s) or Other Reasons for Action(s) Taken and Description of Action(s) Taken by Reporting Entity:	Facility fined $1500.00 due to distributing 63 drug products into the State of Alabama without a permit.

☐ Subject identified in Section B has appealed the reported adverse action.

D. SUBJECT STATEMENT

If the subject identified in Section B of this report has submitted a statement, it appears in this section.

E. REPORT STATUS

Unless a box below is checked, the subject of this report identified in Section B has not contested this report.

☐ This report has been disputed by the subject identified in Section B.

☐ At the request of the subject identified in Section B, this report is being reviewed by the Secretary of the U.S. Department of Health and Human Services to determine its accuracy and/or whether it complies with reporting requirements. No decision has been reached.

☐ At the request of the subject identified in Section B, this report was reviewed by the Secretary of the U.S. Department of Health and Human Services and a decision was reached. The subject has requested that the Secretary reconsider the original decision.

☐ At the request of the subject identified in Section B, this report was reviewed by the Secretary of the U.S. Department of Health and Human Services. The Secretary's decision is shown below:

Date of Original Submission:	12/08/2017
Date of Most Recent Change:	12/08/2017

This report is maintained under the provisions of: Section 1921

The information contained in this report is maintained by the National Practitioner Data Bank for restricted use under the provisions of Section 1921 of the Social Security Act, and 45 CFR Part 60. All information is confidential and may be used only for the purpose for which it was disclosed. Disclosure or use of confidential information for other purposes is a violation of federal law. For additional information or clarification, contact the reporting entity identified in Section A.

NATIONAL PRACTITIONER DATA BANK
NPDB
P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

END OF REPORT

CONFIDENTIAL DOCUMENT - FOR AUTHORIZED USE ONLY

Mobius Therapeutics, LLC
1000 Executive Parkway
Suite 224
St. Louis, MO 63141 USA
tf +1-877-EYEMITO
p +1-314-615-6930
f +1-314-615-6931
www.Mitosol.com

December 5, 2017

Wendy Passmore
Legal / Executive Assistant
Alabama State Board of Pharmacy
111 Village Street
Birmingham, AL 35242-6477

Re: **Case Number 17-L-0029**
Final Order - Payment of Administrative Fine
Mobius Therapeutics, LLC Permit No. 194096

Enclosed please find check number 9622 in the amount of $1,500.00 for payment of the above mentioned administrative fine.

In addition to this cover letter, the following documents are included:

- Final Order Letter from Alabama Board of Pharmacy dated November 28, 2017 (1 page)
- Consent Order from Alabama Board of Pharmacy signed November 28, 2017 (6 pages)

Mobius Therapeutics, LLC presumes Case No. 17-L-0029 will be closed as all obligations to the Board have been met.

If the Board has any queries or comments concerning this payment, please contact me by phone at (314) 615-6934, by fax at (314) 615-6931, or by email at Chris.Patullo@Mobiustx.com.

Sincerely,

Christina Patullo
VP, Regulatory, Quality & Compliance
Mobius Therapeutics, LLC

ALABAMA
BOARD OF PHARMACY

SUSAN ALVERSON R.Ph.
Executive Secretary

Location:
111 Village Street
Birmingham, AL 35242

(205) 981-2280
(205) 981-2330 Fax
www.albop.com

MEMBERS 2017

BUDDY BUNCH, R.Ph.
President

DAVID DARBY, R.Ph.
Vice President

DONNA YEATMAN, R.Ph.
Treasurer

RALPH SORRELL, R.Ph.

Brenda Denson, PharmD.

November 28, 2017



Mobius Therapeutics, LLC
1000 Executive Parkway Drive Suite 224
St Louis, MO 63141

RE: Final order

Dear Mobius Therapeutics, LLC

Enclosed you will find a FINAL ORDER resulting from your hearing before the Board. While the entire order is important, I particularly direct your attention to the portion of the Order setting forth discipline and specifically the mandatory obligation of your payment of a fine and costs. As you will see, those amounts are due within a specified period of time from the date of the Final Order and not the date of this letter.

If the referenced fine and costs are not received by the Board within the prescribed period of time, or special arrangements have not been made with the Secretary of the Board, the Board will file a lawsuit to enforce the Final Order which can result in the entry of a judgment against you and subsequent collection procedures.

Sincerely,

Wendy Passmore

Legal / Executive Assistant
Alabama State Board of Pharmacy
Phone 205-981-4764
Fax 205-803-6481
Email - wpassmore@albop.com

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MOBIUS THERAPEUTICS, LLC	)	**BOARD OF PHARMACY**
	)	
Virtual Manufacturer Permit No. 194096	)	**CASE NO: 17-L-0029**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Mobius Therapeutics, LLC (hereinafter referred to as "Mobius") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties through counsel have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. Counsel for the Board and counsel for Mobius stipulate that Mobius denies for all legal purposes other than this proceeding the allegations set forth in the Statement but stipulates that for the purposes of this proceeding the Board would introduce sufficient evidence to meet its required burden of proof. Accordingly, the Board finds Mobius has violated the provisions of the Alabama Pharmacy Practice Act based upon the conduct set forth in all Counts of the Statement.

2. Mobius shall pay to the Board an administrative fine in the amount of One Thousand Five Hundred dollars ($1,500.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of

payment to the Board shall not be dischargeable in bankruptcy and Mobius shall not attempt to discharge the same in any bankruptcy proceeding.

3. That Mobius expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Mobius further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Mobius hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That Mobius agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Mobius acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Mobius acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing

this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the 22nd day of November, 2017.

Mobius Therapeutics, LLC

By: _____
Its: President & CEO

_____
C. Steven Ball, Attorney for Mobius Therapeutics, LLC

DONE this the 11/28/2017 day of _____, 2017.

ALABAMA STATE BOARD OF PHARMACY

By: Buddy Bunch
Buddy Bunch, R.Ph., President

By: _____
James S. Ward
Its Attorney

WARD & COOPER, LLC.
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

- EXHIBIT "A" -

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
MOBIUS THERAPEUTICS, LLC	)	BOARD OF PHARMACY
	)	
Virtual Manufacturer Permit No. 194096	)	CASE NO: 17-L-0029
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Mobius Therapeutics, LLC
1000 Executive Parkway Drive
St. Louis, Missouri 63141

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on November 14th, 2017 at 8:30 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Mobius Therapeutics, LLC (Mobius) as a Manufacturer/Wholesaler/Distributor and/or Non-Resident Pharmacy should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that Mobius has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors

include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state in that during 2017 you distributed sixty-three (63) drug products into the State of Alabama without a current and valid permit to do so.

The Board alleges that each distribution is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be

directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 1st day of September, 2017.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MOBIUS THERAPEUTICS, LLC	)	**BOARD OF PHARMACY**
	)	
Virtual Manufacturer	)	
Permit No. 194096	)	**CASE NO: 17-L-0029**
	)	

AFFIDIVIT OF CHRISTINA M. PATULLO

STATE OF MISSOURI)

COUNTY OF St. Louis)

Before me, the undersigned notary, personally appeared Christina M. Patullo and after being duly sworn, deposes and states as follows:

1. My name is Christina M. Patullo. I am over 19 years old and have personal knowledge of the facts set forth below.

2. I am the Vice President of Regulatory, Quality & Compliance for Mobius Therapeutics, LLC ("Mobius") and I am competent to testify to the matters herein.

3. I began work for Mobius on January 3, 2017. The regulatory position had been vacant since September 2016. I learned some time afterwards that the Alabama State Board of Pharmacy Renewal Application had not been submitted.

4. Mobius is a virtual manufacturer. It is the holder of NDA 022572 for Mitosol® (mitomycin for solution) 0.2 mg/vial Kit for Ophthalmic Use. All manufacturing, packaging and distribution of the drug product is contracted out. Mobius does not take physical possession of the drug product.

5. On February 1, 2017, I mailed the Alabama State Board of Pharmacy Renewal Application with corrected current address, as our physical address had changed.

6. On February 13, 2017, I received email communications (3) from Kim Pickett regarding additional information required to continue processing our renewal application.[1] She requested that we complete a renewal statement and controlled substance waiver, submit a $50 late fee, provide the date of birth, Social Security number, and email for Edward Timm & Mark Wright, name, date of birth, Social Security number, address, phone number, and email for a facility designated representative and Mobius drug establishment registration with FDA and asked how the drug is distributed.

7. On February 13, 2017, I provided the information as requested and sent the following original documents to her on February 17, 2017, to continue processing our renewal application.

1. Completed Renewal Statement;
2. Completed Controlled Substance Waiver;
3. Corporate Officer Information Document listing:
    a. Date of birth, social security number and e-mail for Edward Timm and Mark Wright;
    b. Facility Designated Representative information; (Please note that Edward Timm is also the Facility Designated Representative.)
4. Description of Operations for Mobius Therapeutics, LLC detailing:
    a. Contract manufacturer name and proof FDA establishment registration;
    b. Product distribution details;
    c. Third-party logistics provider (Foundation Care, LLC):
        i. Alabama State Board of Pharmacy Wholesale Distributor License
        ii. Missouri Board of Pharmacy Wholesale Drug Distributor License

[1] The emails referenced in this Affidavit are attached hereto, collectively, as Exhibit "A".

iii.National Association of Boards of Pharmacy VAWD Certificate; and

5. Check for $50.00 late fee.

8. On February 28, 2017, I received email correspondence from Kim Pickett acknowledging receipt of the information and request for information for the contract manufacturer and I provided the additional requested information for our contract packager and sterilizer via email.

9. On March 1, 2017, (10:56 am) I received an email from Kim Pickett requesting Mitosol vial manufacturer information and copy of agreement with our drug vial manufacturer. I provided the information.

10. On March 2, 2017, (9:27 am) I emailed Kim Pickett the Intas agreement.

11. On March 17, 2017, (10:05 am) I emailed Kim Pickett asking about the status of our renewal application. I did not receive a response from her.

12. On April 3, 2017, I conducted an online lookup for Mobius License # 194096; ALBOP site stated license was active with expiry of 12/31/2017 so I believed the license was current and the issue had been remedied.

13. I never received a hard copy of the license, but as some states do not mail licenses and the website indicated the license was active and expired in December 2017, I did not make further inquiry.

14. On August 26, 2017, (6:30 AM) I received an email from ALBOP@cyberbesttech.com regarding a fine payment due.

15. On August 28, 2017, (3:39 pm) I sent an email to ALBOP@cybetbesttech.com, L Martin and Kim Pickett requesting information regarding the business fine.

16. On August 29, 2017, (2:30 pm) I had a telephone call with Wendy Passmore regarding the reason for the fine and how to proceed. She indicated a Notice of Hearing had

been sent via USPS certified mail to the previous address and because we did not respond and did not attend the hearing that a fine was assessed. She told me that the BOP did not make the necessary address change in their system, therefore, they would be rescinding the order and issuing a new statement of charges.

17. On September 1, 2017, (6:00 am) I received an email from ALBOP@cyberbesttech.com stating the fine was now past due, so I replied to ALBOP, W. Passmore and L Martin regarding action needed. Later in the day, I received an email from Wendy Passmore with new Statement of Charges and Notice of Hearing attached (SOC). I immediately emailed Wendy Passmore asking if there was a way to resolve the issue prior to the November 14th scheduled hearing date.

18. On September 5, 2017, we received a US mail receipt of Order Rescinding Final Order and received an email from Jim Ward stating, "My name is Jim Ward and I represent the Alabama Board of Pharmacy. If you would like me to discuss with the Board and see if can resolve with a consent order please let me know regarding possible discussion with Board to resolve via consent order"

19. On September 6, 2017, (4:04 pm) I emailed Jim Ward requesting call with him prior to his discussion with the Board and let him know that I received the order rescinding the Board's final order dated July 31, 2017, and asked if I was correct in assuming that our license status will resume to active.

20. On September 7, 2017, (11:55 am) I received an email from Mr. Ward agreeing to a call but indicating that I please understand he has no authority until he speaks with the Board next week. He asked if there is anything in mitigation that I would like him to share with the Board, please do so by September 11, 2017. He stated he preferred it in writing so there is no mistake in what he communicates.

21. On September 7, 2017, (12:03 pm) I emailed to Mr. Ward – "I have attached a document listing the communications with the Board regarding our renewal application for your reference. I understand that our renewal was late, and we did submit the late fee. I look forward to speaking with you this afternoon."

Brief summary of the call:

- We filed our renewal application in February 2017 (prior permit expired December 31, 2016). I had ongoing communication with Kim Picket, Licensing Specialist providing requested additional information and late fee for approval of our renewal application between February 13th and March 2nd.
- My email to Kim on March 17th regarding the status of our application was not answered.
- I verified our license was active on the ALBOP online lookup on April 3rd and assumed everything was processed.
- I received notice of the fine on August 26th and had correspondence with Wendy Passmore to understand the nature of the fine.
- I received the Board's order rescinding the prior final order on September 5th. I understand you will be discussing our matter with the Board regarding our license status.

22. On September 13, 2017, (3:02 pm) in an email to Mr. Ward, I told him I had received the information from the Board of Pharmacy via certified mail and we are interested in a settled proposal from the Board. I asked that he please send the proposed settlement when available. He replied via email and stated, "Okay, will discuss with Board at next month meeting and let you know. Deeds put on list for next month, please."

23. On October 12, 2017, (1:57 pm) in an email to Mr. Ward, I asked if he could provide the details regarding the outcome of the October 10th Board meeting regarding a settlement for

our case number 17-L-0029. Mr. Ward's October 12, 2017 (2:01 pm) email stated, "It was not discussed. It was inadvertently left off my list of cases to discuss. I'm sorry"

24. On October 12, 2017, (2:06 pm) I emailed Mr. Ward asking if he could please call me and that I just needed to understand if there are any actions we can take to get this resolved. No response was ever received, so I engaged counsel in Alabama to assist with resolution of this matter.

Further the Affiant saith not.

Christina M. Patullo
Vice President of Regulatory, Quality & Compliance
Mobius Therapeutics, LLC

STATE OF MISSOURI)

COUNTY OF St. Louis)

Before me, the undersigned, a notary public in and for said county and state, personally appeared Christina M. Patullo, who is known to me and who being by me first duly sworn, states that she has read the above and that the facts set forth therein are true and correct.

Sworn to and subscribed before me this the 10th day of November, 2017.

CARLA ANN TIMM
Notary Public – Notary Seal
State of Missouri, St. Louis County
Commission # 16084837
My Commission Expires March 14, 2020

Carla Ann Timm
Notary Public

My Commission Expires: March 14, 2020

ALABAMA STATE BOARD OF PHARMACY

111 Village Street, Birmingham, AL 35242
www.albop.com Phone: 205-981-2280

License Verification

Name: MOBIUS THERAPEUTICS, LLC
1000 EXECUTIVE PARKWAY DR
SUITE 224
ST. LOUIS, MO 63141

Permit/Registration/License Number: 194096

License Type: Private Label Distributor (Virtual)

License Status: Active – There are not pending disciplinary proceedings

Date Issued: 01/11/2011

Expiration Date: 12/31/2023

Disciplinary Action: Yes - Fine has been paid

Date Prepared: 07/18/2023

Donna C Yeatman

Donna Yeatman, R.Ph.
Executive Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Name of Pharmacy/MDEG/Wholesaler Mobius Therapeutics, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 1000 Executive Parkway Drive, Suite 224

City St. Louis State MO Zip 63141

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 314-615-6930 Website www.mitosol.com

Licensing Company Email chris.patullo@mobiustx.com

First Edward Middle Jerome Last Timm

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] Sylvester Avenue

City Webster Groves State MO Zip 63141

Telephone [redacted] Email ed.timm@mobiustx.com

Are you a citizen of the United States? ■ Yes ☐ No

1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

School Name			From - To (MM/YY – MM/YY)	
Marquette Catholic High School			09/74 - 09/78	
Address		City	State	Zip
306 W. 10th Street		Michigan City	IN	46360
Diploma/Degree obtained, if any				
College Prep				
School Name			From - To (MM/YY – MM/YY)	
University of Dayton			08/79 - 04/82	
Address		City	State	Zip
300 College Park		Dayton	OH	45469
Diploma/Degree obtained, if any				
BA				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/07 - present	[redacted] Sylvester Avenue	Webster Groves	MO	63119
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name			From - To (MM/YY – MM/YY)	
Mobius Therapeutics, LLC			04/06 - present	
Business Address		**City**	**State**	**Zip**
1000 Executive Parkway Drive Suite #224		Saint Louis	MO	63141
Phone	**Title**			
314-614-6932	Founder and CEO			
Description of Duties				
Oversees design, sales, marketing, promotion, delivery and quality of products				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01/91	02/91	NM	Albuquerque	Bernalillo
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		NM Civil Courts		
Reason/Charge				
Violation of non-compete agreement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Baxter Healthcare Corporation			Lawsuit	
Name of Business/Industry/Entity				
Heaalthcare				

Provide explanation below:

Timm resigned employment from Baxter Healthcare to pursue a venture capital backed medical device company. Timm relocated from Albuquerque NM to Dallas TX, specifically seeking avoidance of infringement of the non-compete agreement. Prior to court appearance, Baxter settled, paying treble damages for withheld pay and all attorney fees.

Original Signature (electronic, copies or stamps not accepted)

04/19/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Edward Timm

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/19/2023 04/24/2023

Date

Please have this section completed in the presence of a Notary Public.

State of District of Columbia ss. County of —

I, Edward J. Timm, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04/24/2023

Date

Subscribed and Sworn to before me this 24th day of April 2023

Notary Public Signature

HADDESA BELAY GESSESSE
District of Columbia Notary Public
My Commission Expires August 31, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Mobius Therapeutics, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 1000 Executive Parkway Drive, Suite 224

City Saint Louis State MO Zip 63141

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 314-615-6930 Website www.mitosol.com

Licensing Company Email chris.patullo@mobiustx.com

Section 2: Personal Information

First Phillip Middle Howard Bentley Last Moss

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Glenisle Way

City Fort Meyers State FL Zip 33912

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
UNIVERSITY OF LIVERPOOL ENGLAND			9/1966 - 6/1969
Address	**City**	**State**	**Zip**
UNIVERSITY OF LIVERPOOL	LIVERPOOL L69 3BX	ENGLAND	
Diploma/Degree obtained, if any			
B.A. ECONOMICS			

School Name			From - To (MM/YY – MM/YY)
KINGS GRAMMAR SCHOOL			9/56 - 6/66
Address	**City**	**State**	**Zip**
ALDERLEY ROAD PRESTBURY	MACCLESFIELD SK10 4SP	ENGLAND	
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/1997 - NOW	[redacted] GLENISLE WAY	FORT MYERS	FL.	33912
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
RETIRED 2001			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Philip H. B. Moss

Print Name (First, Last)

PHBMoss

Original Signature (electronic, copies or stamps not accepted)

7/20/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Lee

I, Philip Howard Bentley Moss, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

PHBMoss

Original Signature

7/20/2023

Date

Subscribed and Sworn to before me this 20th day of July.

Notary Public Signature

JAMES H. RAULERSON
Commission # HH 075623
Expires December 29, 2024
Bonded Thru Troy Fain Insurance 800-385-7019

(Seal)

Mobius Therapeutics, LLC
1000 Executive Parkway Drive
Suite 224
Saint Louis, MO 63141 USA
p +1 314-615-6930
f +1 314-615-6931
tf 1-877-EYE-MITO
www.Mitosol.com

August 3, 2023

Mobius Employee List

Name	Title
Ed Timm	President/CEO
Mark Wright	CFO
Chris Patullo	VP - Regulatory, Quality, & Compliance
Sara Garner	Director - Quality Systems
Linda Kalata, RN, BSN, CNOR	Director -Clinical Applications
Louis Schwartz, MD	Director - Medical/Medical Affairs
Carla Timm	Director - Customer Service/Sales Support
Jan Lupnacca	East Area Sales Manager (Direct Sales Rep)
Rick Bancroft	Independent Ophthalmic Surgical Rep
Shawn Bidot	Independent Ophthalmic Surgical Rep
Mike Corsini	Independent Ophthalmic Surgical Rep
Stan Durham	Independent Ophthalmic Surgical Rep
Carol Diamantine	Independent Ophthalmic Surgical Rep
Stan Ferguson	Independent Ophthalmic Surgical Rep
Tom Gregory	Independent Ophthalmic Surgical Rep
Nicholas Kostechko	Independent Ophthalmic Surgical Rep
Randy Loren	Independent Ophthalmic Surgical Rep
David Patterson	Independent Ophthalmic Surgical Rep
Mark Purdy	Independent Ophthalmic Surgical Rep
Andy Rivero	Independent Ophthalmic Surgical Rep
Paul Salmon	Independent Ophthalmic Surgical Rep
Jason Smith	Independent Ophthalmic Surgical Rep
Jerry St. Pierre	Independent Ophthalmic Surgical Rep

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www.Mitosol.com

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

Re: **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of Mobius Therapeutics**

Dear Sir/Madam,

Mobius Therapeutics, LLC has no debt and as such, the company has no indebtedness to any employee, independent contractor, consultant, guardian, personal representative, or lender.

All Mitosol manufacturing and packaging is performed by contractors.

The finished drug product is manufactured by Intas Pharmaceuticals Limited.

Firm Name	Facility Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Intas Pharmaceuticals Limited	3003157498	725927649	ANALYSIS; MANUFACTURE; PACK;	Plot No. 457, 458, Sarkhej Bavla Highway,Village Matoda,Taluka Sanand, Ahmedabad, Gujarat 382210, India (IND)	12/31/2023

The Mitosol finished drug product kit is packaged and sterilized by B. Braun Medical.

Firm Name	Facility Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
B. Braun Medical Inc.	2523676	783179463	REPACK;	901 Marcon Blvd., Allentown, Pennsylvania (PA) 18109	12/31/2023

All warehousing and distribution is performed by our 3PL, Foundation Care, LLC, 4090 Wedgeway Court, Earth City, MO, 63045. Copy of Foundation Care's VAWD Accreditation is provided.

Mobius Therapeutics, LLC
1000 Executive Parkway Drive
Suite 224
Saint Louis, MO 63141 USA
p: +1 314-615-6930
f: +1 314-615-6931
tf: 1-877-EYE-MITO
www.Mitosol.com

Facility Name	Facility Type	License Number	License State	License Expire	Reporting Year	Address
Foundation Care, LLC	WDD	2011007755	US-MO	10/31/2023	2023	4090 Wedgeway Court Earth City, MO, 63045
	3PL	2019004838	US-MO	10/31/2023	2023	
	WDD w/ 3PL	WHO1943	US-NV	10/31/2024	2023	

Mobius Therapeutics, LLC requests that all information in this application be treated as confidential. If the Board has any queries or comments concerning this application, please contact Chris Patullo by phone at (314) 566-2617 or by email at Chris.Patullo@MobiusTherapeutics.com.

Sincerely,

Mark Wright
CFO
Mobius Therapeutics, LLC

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located? ☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)

- ☒ New Wholesaler
- ☐ Ownership Change*
- ☐ Name Change*
- ☐ Location Change* (in-state only)

* If making a change, provide current license number:

WH _____

Wholesaler Business Type (check applicable box)

- ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
- ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
- ☒ Partnership (complete sections 1, 2, 3, 6, 8, 9)
- ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Omnivium Pharmaceuticals, LLC.

Physical Address: 2131 Felver Ct. Suite A

City: Rahway State: NJ Zip: 07065

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 917-693-8820 Website: www.omniviumpharma.com

Name of Designated Representative (DR): Jayanti Patel

Licensing Company Email: jpatel@omniviumpharma.com jpatel@omniviumpharma.com

Entities the Wholesaler will Serve (✓ all applicable)

- ☒ Pharmacies
- ☐ Practitioners
- ☒ Hospitals
- ☐ Wholesalers
- ☐ Veterinarians
- ☐ Others:

Products to be Handled or Wholesaled (✓ all applicable)

- ☐ Dangerous Drugs
- ☒ Controlled Substances
- ☐ [a]Medical devices, equipment, supplies, gases
- ☐ Others:

Type of Wholesaling (✓ all applicable)

- ☐ Manufacturer
- ☐ Repacker
- ☐ Reverse Distributor
- ☐ Warehouse
- ☐ Retail pharmacy wholesale distributor
- ☒ Others: Virtual Manufacturer

Section 2: History of Company

		Yes	No
1.	Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2.	Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3.	Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4.	Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5.	Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following ***where applicable***:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

08/19/2023
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: Omnivium Pharmaceuticals, LLC.

Mailing Address: 2131 Felver Ct. Suite A

City: Rahway State: NJ Zip: 07065

Telephone: 917-693-8820 Email: jpatel@omniviumpharma.com

Contact Person Name: Jayanti Patel

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right:	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the **last 12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Omnivium Pharmaceuticals, LLC.
Facility Name

Jayanti Patel
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

08/19/2023
Date

Board Use Only	Date Received: _____ Amount: _____

National Drug Code Directory

Current through August 18, 2023

You have searched Finished drug products

Search Results: *'Omnivium'*

Back to Search Page () | **Search Again ()**

CSV Excel

Display 50 **records per pege**

Search for text in the table:

	Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Descript
+	Sodium Bicarbonate	81665-200-05	84 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA216364	OMNIVIUM PHARMACEUTICALS LLC.	81665-200	SODIUM BICARBONATE	SODIUM BICARBONATE	HUMAN PRESCRIPTION DRUG	06/16/2023	N/A	ANDA	20 VIAL in CARTON (81665-20 05) / 50 n 1 VIAL (81665-20 01)
+	Sodium Bicarbonate	81665-200-25	84 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA216364	OMNIVIUM PHARMACEUTICALS LLC.	81665-200	SODIUM BICARBONATE	SODIUM BICARBONATE	HUMAN PRESCRIPTION DRUG	06/16/2023	N/A	ANDA	25 VIAL in CARTON (81665-20 25) / 50 n 1 VIAL (81665-20 01)

Showing 1 to 2 of 2 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

ATTESTATION

Omnivium Pharmaceuticals LLC is a virtual pharmaceutical entity and does not manufacture any pharmaceutical drug products. Omnivium Pharmaceuticals LLC does not take possession of any pharmaceutical drugs products at any point. Omnivium Pharmaceuticals LLC utilizes a third-party entity to facilitate warehousing, distribution, and logistics associated with pharmaceutical distribution.

Considering above Omnivium Pharmaceutical does not require VAWD certification. Please see attached VAWD certification from our Third party logistics company (3PL).

Omnivium Pharmaceuticals

Type of Ownership: Limited Liability Company (LLC)

State of Formation: Delaware

Address of Corporation: 2131 Felver Ct. Suite A
Rahway, NJ 07065

Principal Officers and Members of Omnivium Pharmaceuticals LLC.

Name: **Jayanti Patel** Phone: [redacted]
Address: [redacted]**Williams Crest. Park Ridge, NJ, 07656** Email: **jpatel@omniviumpharma.com**
DOB: [redacted]
Title: **Member**
Ownership: **30%**

Name: **Utpal Patel** Phone: [redacted]
Address: [redacted]**Rector Pl. Apt. 409 NY, NY 10280** Email: **upatel@omniviumpharma.com**
DOB: [redacted]
Title: **CEO**
Ownership: **27%**

Name: **Ajay Desai** Phone: 2[redacted]
Address: [redacted]**MacArthur Ave. Closter NJ 07624** Email: [redacted]
DOB: [redacted]
Title: **Member**
Ownership: **24%**

Name: **Shivani Desai** Phone: [redacted]
Address: [redacted]**Williams Crest. Park Ridge, NJ, 07656** Email: s[redacted]
DOB: [redacted]
Title: **Member**
Ownership: **12%**

Name: **Kaniyalal Patel** Phone: [redacted]
Address: [redacted]**Pincy Meeting House Rd. Potomac, MD, 20854** Email: [redacted]
DOB: [redacted]
Title: **Member**
Ownership: **7%**

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "OMNIVIUM PHARMACEUTICALS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF AUGUST, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3023970 8300

SR# 20233181285

Authentication: 203917349

Date: 08-08-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0748724

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

2131 FELVER CT, STE A RAHWAY, NJ 07065-

Reg. No.
5005925

OMNIVIUM PHARMACEUTICALS LLC
2131 FELVER CT, STE A
RAHWAY, NJ 07065-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2024

Establishment Copy

1046

Omnivium
Pharmaceuticals

DEA License

Omnivium Pharmaceuticals LLC is a virtual pharmaceutical entity and does not manufacture any pharmaceutical drug products including controlled substances. Omnivium Pharmaceuticals LLC does not take possession of any pharmaceutical drugs products at any point. Omnivium Pharmaceuticals LLC utilizes a third-party entity to facilitate warehousing, distribution, and logistics associated with pharmaceutical distribution.

Considering above Omnivium Pharmaceutical does not require a DEA license.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RR0577241	04-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-03-2023

RXCROSSROADS 3PL LLC
4200 BINION WAY STE 200
MASON, OH 450369469

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RR0577241	04-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
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RXCROSSROADS 3PL LLC
4200 BINION WAY STE 200
MASON, OH 450369469

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 02BSBJC0145

Application/License No. _____

Omnivium Pharmaceutical LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2131 Felver Ct., Suite A, Rahway, NJ 07065 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 200 Colonial Center Parkway, 5th floor Lake Mary, FL 32746 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 1, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

02BSBJC0145

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 7th day of August, 2023.

APPLICANT/PRINCIPAL

Omnivium Pharmaceutical LLC

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Shari Ruff, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler OMNIVIUM PHARMACEUTICALS, LLC.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2131 FELVER CT. SUITE A

City RAHWAY State NJ Zip 07065

Mailing Address (if different from physical address) _____

City RAHWAY State NJ Zip 07065

Telephone 917-693-8820 Website WWW.OMNIVIUMPHARMA.COM

Licensing Company Email JPATEL@OMNIVIUMPHARMA.COM

Section 2: Personal Information

First JAYANTI Middle _____ Last PATEL

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] FELVER CT. SUIT[redacted]

City RAHWAY State NJ Zip 07065

Telephone [redacted] Email JPATEL@OMNIVIUMPHARMA.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
L.M COLLEGE OF PAHRMACY			
Address	**City**	**State**	**Zip**
MG SCIENCE COLLEGE RD. OPP UNIVERSITY	AHMEDABAD		INDIA
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/91 -PRESENT	[redacted]VILLIAMS CREST	PARK RIDGE	NJ	07656
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
SUNRISE PHARMACEUTICAL INC.			06/2007-PRESENT	
Business Address		City	State	Zip
665 E LINCOLN AVE		RAHWAY	NJ	07065
Phone	Title		Number of Employed Hours	
732-382-6085	PRESIDENT			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, JAYANTI PATEL, **certify that as the designated representative for**

OMNIVIUM PHARMACEUTICALS, LLC.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JP I am at least 21 years of age;
3. JP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JAYANTI PATEL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08·09·2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JAYANTI PATEL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08-09-2023

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Union

I, Jayanti Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08.09.2023

Date

Subscribed and Sworn to before me this 9th day of August 2023

OMAR TORRES
Commission # 50185892
Notary Public, State of New Jersey
My Commission Expires
February 16, 2027

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Omnivium Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 2131 Felver Ct. Suite A.

City: Rahway State: NJ Zip: 07065

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 917-693-8820 Website: www.omniviumpharma.com

Licensing Company Email: jpatel@omniviumpharma.com

Section 2: Personal Information

First: Jayanti Middle: _____ Last: Patel

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: Williams Crest

City: Park Ridge State: NJ Zip: 07656

Telephone: [redacted] Email: jpatel@omniviumpharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
L.M College of Pharmacy			
Address	**City**	**State**	**Zip**
Mg Science College Rd. Opp. University	Ahmedabad		India
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/91-Present	[redacted]Williams Crest	Park Ridge	NJ	07656
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Sunrise Pharmaceutical Inc			06/2007- Present
Business Address	**City**	**State**	**Zip**
665 E Lincoln Ave	Rahway	NJ	07065
Phone	**Title**		
732-382-6085	President		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

07-31-2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jayanti Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07.31.2023

Date

Please have this section completed in the presence of a Notary Public.

State of NEW York, ss. County of Bronx

I, Jayanti Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-1-23

Date

Subscribed and Sworn to before me this 1st day of August 2023.

Notary Public Signature

DINESH K. DESAI
NOTARY PUBLIC STATE OF NEW YORK
QUALIFIED IN BRONX COUNTY
NO. 01DE5067081
MY COMMISSION EXPIRES OCT. 7, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Omnivium Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2131 Felver Ct. Suite A.

City: Rahway State: NJ Zip: 07065

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 917-693-8820 Website: www.omniviumpharma.com

Licensing Company Email: jpatel@omniviumpharma.com

Section 2: Personal Information

First: Utpal Middle: Last: Patel

Alias(es, nick[redacted]hanges, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Rector Pl.

City: New York State: NY Zip: 10280

Telephone: [redacted] Email: upatel@omniviumpharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Boston University		1994-1998	
Address	City	State	Zip
	Boston	MA	02215
Diploma/Degree obtained, if any			
MBA, MA			

School Name		From - To (MM/YY – MM/YY)	
Tufts University		1998-2001	
Address	City	State	Zip
419 Boston Ave	Medford	MA	02155
Diploma/Degree obtained, if any			
MS			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/23-Present	[redacted]Rector Pl. Apt.[redacted]	New York	NY	10280
06/92-06/23	[redacted]Villiams Crest	Park Ridge	NJ	07656

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

08.01.2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Utpal Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08-01-2023

Date

Please have this section completed in the presence of a Notary Public.

State of NEW YORK, ss. County of BRONX

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-1-2023

Date

Subscribed and Sworn to before me this 1st day of August 2023.

Notary Public Signature

DINESH K. DESAI
NOTARY PUBLIC STATE OF NEW YORK
QUALIFIED IN BRONX COUNTY
NO. 01DE5067081 (Seal)
MY COMMISSION EXPIRES OCT. 7, 2026

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Omnivium Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 2131 Felver Ct. Suite A

City: Rahway State: NJ Zip: 07065

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 917-693-8820 Website: www.omniviumpharma.com

Licensing Company Email: jpatel@omniviumpharma.com

Section 2: Personal Information

First: Ajay Middle: _____ Last: Desai

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] MacArthur Ave

City: Closter State: NJ Zip: 07624

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Michigan		09/99 - 06/05	
Address	**City**	**State**	**Zip**
500 S. State Street	Ann Arbor	MI	48109
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Park Ridge High School		09/95 - 06/99	
Address	**City**	**State**	**Zip**
2 W Park Ave	Park Ridge	NJ	07656
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18 - current	[redacted]MacArthur Ave	Closter	NJ	07624
11/10 - 12/18	[redacted]Vaccaro Drive	Cresskill	NJ	07626
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Oval Pharmacy			07/05 - current	
Business Address		**City**	**State**	**Zip**
255 E Gun Hill Road		Bronx	NY	10467
Phone	**Title**			
718-654-2200	Pharmacist			
Description of Duties				
Retail Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

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Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ 7-31-2023

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ajay Desai

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-31-2023

Date

Please have this section completed in the presence of a Notary Public.

State of NEW York, ss. County of Bronx

I, Ajay Desai, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-1-2023

Date

Subscribed and Sworn to before me this 1st day of August 2023.

Notary Public Signature

DINESH K. DESAI
NOTARY PUBLIC STATE OF NEW YORK
QUALIFIED IN BRONX COUNTY
NO. 01DE5067081
MY COMMISSION EXPIRES OCT. 7. 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Omnivium Pharmaceuticals, LLC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2131 Felver Ct. Suite A

City: Rahway State: NJ Zip: 07065

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 917-693-8820 Website: www.omniviumpharma.com

Licensing Company Email: jpatel@omniviumpharma.com

Section 2: Personal Information

First: Shivani Middle: Last: Desai

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address: [redacted]Villiams Crest

City: Park Ridge State: NJ Zip: 07656

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Long Island University		09/11 - 5/17	
Address	**City**	**State**	**Zip**
1 University Plaza	Brooklyn	NY	11201
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Park Ridge High School		09/07 - 6/11	
Address	**City**	**State**	**Zip**
2 W Park Ave	Park Ridge	NJ	07656
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/93 - current	[redacted]Williams Crest	Park Ridge	NJ	07656
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Health Wise Pharmacy			6/18 - current
Business Address	**City**	**State**	**Zip**
1494 York Ave	New York	NY	10075
Phone	**Title**		
212- 472-5600	Pharmacist		
Description of Duties			
Retail Pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7-31-2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shivani Desai

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-31-23

Date

Please have this section completed in the presence of a Notary Public.

State of NEW York, ss. County of Bronx

I, Shivani Desai, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-1-23

Date

Subscribed and Sworn to before me this 1st day of August 2023.

Notary Public Signature

DINESH K. DESAI
NOTARY PUBLIC STATE OF NEW YORK
QUALIFIED IN BRONX COUNTY
NO. 01DE5067081
MY COMMISSION EXPIRES OCT. 7. 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Omnivium Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2131 Felver Ct. Suite A

City: Rahway State: NJ Zip: 07065

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 917-693-8820 Website: www.omniviumpharma.com

Licensing Company Email: jpatel@omniviumpharma.com

Section 2: Personal Information

First: Kaniyalal Middle: Last: Patel

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Piney Meeting House Rd

City: Potomac State: MD Zip: 20854

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
B J Medical College		1969-1975	
Address	**City**	**State**	**Zip**
Civil Hopiatal	Ahmedabad	India	
Diploma/Degree obtained, if any			
MB, BS			
School Name		**From - To (MM/YY – MM/YY)**	
M G Science College			
Address	**City**	**State**	**Zip**
Navarangpra	Ahmedabad	India	
Diploma/Degree obtained, if any			
F Y Science Pre Medical			
School Name		**From - To (MM/YY – MM/YY)**	
C F High School			
Address	**City**	**State**	**Zip**
Ambavadi	Ahmedabad	India	
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1989-Present	[redacted]Piney Meeting House Rd.	Potomac	MD	20854
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Kanu Patel MDPA			1982-Cont
Business Address	**City**	**State**	**Zip**
7235 Hanover Parkway	Greenbelt	MD	20770
Phone	**Title**		
301-441-3122	MD		
Description of Duties			
Private Practice ENT & Sleep Specialist Surgery			

Business Name			From - To (MM/YY – MM/YY)
Sunrise Pharmaceutical Inc.			
Business Address	**City**	**State**	**Zip**
665 E Lincoln Ave	Rahway	NJ	07065
Phone	**Title**		
732-382-6085	Medical Officer & Stock Holder		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

n/a

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kanaiyalal J Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/8/23

Date

Please have this section completed in the presence of a Notary Public.

State of NEW JERSEY, ss. County of UNION

I, KANAIYALAL J PATEL, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/8/23

Date

Subscribed and Sworn to before me this 8th day of August 2023.

Notary Public Signature

VIRAJ D DESAI
NOTARY PUBLIC
STATE OF NEW JERSEY
ID # 50195944
MY COMMISSION EXPIRES MAY 24, 2027

(Seal)

Applicant's initials KP

Omnivium
Pharmaceuticals

2131 Felver Court Suite A ♦ Rahway, NJ 07065 ♦ 888-807-9195(p) ♦ 732-382-6880 (f) ♦
www.omniviumpharma.com

Employees of Omnivium Pharmaceutical:

Jayanti Patel – Chairman
Utpal Patel – CEO
Himanshu Brahmbhatt – VP Sales/BD
Jignesh Gohil – Regulatory Affair/Quality
Raunaq Saran – Finance
Tushar Gupta – Engineering/Serialization
Wendi Guevera – Executive Assistant

Thank you,
Omnivium Pharma

Omnivium Pharmaceuticals, LLC. ©

NABP ACCREDITED
DRUG DISTRIBUTOR

RxCrossroads 3PL LLC

located at

4200 Binion Way, Ste 200, Mason, OH 45036

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

8/31/2021 - 8/30/2024
Period of Accreditation

1095

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: Current MDEG license WH #: MP01141	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Philips Healthcare Informatics, Inc.

Physical Address: 4430 Rosewood Drive, Suite 200

City: Pleasanton State: CA Zip: 94588

Mailing Address (if different from physical address): Phillips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 650-293-2300 Website: www.usa.philips.com/healthcare

Name of Designated Representative (DR): Kannan Chellappan

Licensing Company Email: beth.c.rogers@philips.com DR Email: Kannan.chellappan@philips.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☑ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - No pharmaceuticals products are handled or sold. See Attachment A.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Philips Holding USA, Inc.

Corporation/Organization Name: Philips Healthcare Informatics, Inc.

Mailing Address: Phillips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 978-659-4884 Email: beth.c.rogers@philips.com

Contact Person Name: Beth C. Rogers

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

N/A

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment D		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly-owned by parent company, Philips Holding USA, Inc.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment D	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I	✓	✓	✓	✓

N/A

ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019_Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Philips Healthcare Informatics, Inc.

Facility Name

Kannan Chellappan

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

July 27Th 2023

Date

Board Use Only	Date Received: 8/2/23	Amount: 1000-CK-910

Attachment A

Nature of Business

Philips Healthcare Informatics, Inc. (Informatics) is a manufacturer of prescription medical devices. Informatics' Pleasanton, CA location produces software-only products. The Pleasanton location sells this Software as a Service on a per use basis. As such, the Software products produced at the location are installed remotely.

The Pleasanton Location has a 24 hour CARE support center to monitor the products and take customer calls.

The Software product is a clinical device also referred to as Picture Archiving and Communication System (PACS).

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
Philips Healthcare Informatics, Inc.
Business Trade Names:
(1) Philips (2) Philips Healthcare (3) Philips Medical Systems (4) Philips Radiology Informatics

4430 Rosewood Drive, Suite 200
Pleasanton, CA 94588
Registration Number: 2954704
FEI Number*: 3002971142
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2023

Owner/Operator:

Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
Owner/Operator Number: 1217116[7]

Official Correspondent:
Martin Pedroza
Philips
100 Park Avenue
Suite 300
Orange Village, OH 44122
Phone: 440-2197243

Verified 6/15/23

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Links on this page:

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator

7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator

Attachment D

Corporation Information

Philips Healthcare Informatics, Inc.

Philips Healthcare Informatics, Inc. is wholly-owned by its parent company, Philips Holding USA, Inc.

Corporate Officers:

Ling Liu
President

Joseph E. Innamorati
Vice President and Secretary

Paul Cavanaugh
Vice President and Treasurer

Irma I. Gomez
Assistant Secretary

Directors:

Ling Liu
Joseph E. Innamorati

Facility Manager:

Kannan Chellappan
Director R&D

Enclosed please find a list of all site employees.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PHILIPS HEALTHCARE INFORMATICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF MARCH, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PHILIPS HEALTHCARE INFORMATICS, INC." WAS INCORPORATED ON THE SIXTH DAY OF NOVEMBER, A.D. 1998.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





2953146 8300

SR# 20230976718

Authentication: 202907035

Date: 03-14-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Philips Healthcare Informatics, Inc.
4430 Rosewood Drive, Suite 200
Pleasanton, CA 94588

LICENSE NUMBER: 98066
EXPIRATION DATE: 12/6/2024

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/03/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Marsh USA, Inc.
1166 Avenue of the Americas
New York, NY 10036

CN101736188-GAUW-NI-22-23

CONTACT NAME:
PHONE (A/C, No, Ext):
FAX (A/C, No):
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : National Union Fire Insurance Co Of Pittsburgh	19445
INSURER B : Safety National Casualty Corp	15105
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Philips North America LLC
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

COVERAGES **CERTIFICATE NUMBER:** NYC-011181363-12 **REVISION NUMBER:** 10

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	COMMERCIAL GENERAL LIABILITY			536-18-48	12/31/2022	12/31/2023	EACH OCCURRENCE	$	2,000,000
	[ ] CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	500,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	5,000,000
	[X] POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$	5,000,000
	[ ] OTHER							$	
B	AUTOMOBILE LIABILITY			CA6675481	12/31/2022	12/31/2023	COMBINED SINGLE LIMIT (Ea accident)	$	2,000,000
	[X] ANY AUTO						BODILY INJURY (Per person)	$	
	[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	[ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
A	[X] UMBRELLA LIAB [X] OCCUR			10-736-193	12/31/2022	12/31/2023	EACH OCCURRENCE	$	5,000,000
	[ ] EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$	5,000,000
	DED RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			LDS4047559 (AOS)	12/31/2022	12/31/2023	[X] PER STATUTE [ ] OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N [N]	N / A		PS4047560 (WI)	12/31/2022	12/31/2023	E.L. EACH ACCIDENT	$	2,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	2,000,000
							E.L. DISEASE - POLICY LIMIT	$	2,000,000
A	CYBER LIABILITY			03-932-59-76 'Subject to a policy deductible'	12/31/2022	12/31/2023	Occurrence Limit		10,000,000
							Aggregate Limit		10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Additional Certificate Holder: Virginia Community College System Commonwealth of Virginia Virginia Community College System 147 Daleville Centre Drive Daleville, VA 24083

Evidence of coverage.

CERTIFICATE HOLDER

Philips North America LLC
See above for the Complete Cert. Holder Name
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

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The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: CN101736188
LOC #: New York

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAIC CODE	NAMED INSURED
Marsh USA, Inc.		Philips North America LLC 222 Jacobs Street, 3rd Floor Cambridge, MA 02141
POLICY NUMBER		
CARRIER		EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Includes:
370 West Trimble Road LLC
AllParts Medical, LLC
BioTelemetry, Inc.
BioTel Research, LLC
BioTelemetry Care Management, LLC
Telcare Medical Supply, LLC
Telcare, LLC
Braemar Manufacturing, LLC
Cardiac Monitoring Holding Company, LLC
LifeWatch Corp.
LifeWatch Services, Inc.
Cardiologs Technologies Inc.
CardioNet, LLC
BioTel INR, LLC
Geneva Healthcare, LLC
VirtualScopics, LLC
Blue Willow Systems LLC
Discus Holdings, LLC
Discus Dental, LLC
Discus International, LLC
Discus Dental Canada, LLC
Electrical Geodesics LLC
Cerebral Data Systems, Inc. (CDS)
Intact Vascular, Inc.
Philips CS Corporation (formerly "Vita Topco, Inc." and "Philips Capsule Corporation")
Capsule Technologies, Inc.
CapsuleTech, Inc.
Philips Healthcare Informatics, Inc.
Philips Image Guided Therapy Corporation
Cardioprolific Inc
Crux Biomedical, LLC
Spectranetics LLC
Volcano Atheromed, Inc.
Philips Medical Systems (Cleveland), Inc.
Philips Medical Systems MR, Inc.
Philips DS North America LLC
Philips North America, LLC
Philips North America, LLC D/B/A Philips Healthcare
Philips Oral Healthcare, LLC
Philips RS North America Holding Corporation
Philips RS North America LLC
Respironics California, LLC
Respironics Colorado, Inc.
Respironics Logistics Services, LLC
Respironics Novametrix, LLC
Philips Semiconductors Inc.
Remote Diagnostics Technologies LLC

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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Marsh USA, Inc.	Philips North America LLC 222 Jacobs Street, 3rd Floor Cambridge, MA 02141
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Respiratory Technologies, Inc.
Tomtec Corporation
TR Management Company, LLC
U.S. Philips Corporation
Vesper Medical, Inc.
VISICU, Inc.
VitalHealth Software Corp.
Wellcentive LLC (formerly "Wellcentive, Inc.")
Wellcentive QR, LLC
American Color & Chemical, L.L.C.
ATL Ultrasound, Inc.
Philips Ultrasound LLC (formerly "Philips Ultrasound, Inc.")
ATL International LLC
Philips Electronics North America Foundation
Philips Electronics Realty, LLC
Philips Medical Systems Export, Inc.
Philips MPEG Inc.
Philips Project Management, LLC

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Western Surety Company

POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

Know All Men By These Presents, That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint Kristin S. Bender

, Individually

of Morristown, New Jersey, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

- In Unlimited Amounts -

Surety Bond Number: 30185503
Principal: See attached list of principals
Obligee: State of Nevada and Nevada State Board of Pharmacy

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the By-Law printed on the reverse hereof, duly adopted, as indicated, by the shareholders of the corporation.

In Witness Whereof, WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 2nd day of February, 2021.

WESTERN SURETY COMPANY

Paul T. Bruflat, Vice President

State of South Dakota } ss
County of Minnehaha }

On this 2nd day of February, 2021, before me personally came Paul T. Bruflat, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is the Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent, Notary Public

CERTIFICATE

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law of the corporation printed on the reverse hereof is still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 21 day of April, 2023.

WESTERN SURETY COMPANY

L. Nelson, Assistant Secretary

Form F4280-2-2021

Authorizing By-Law

ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

WESTERN SURETY COMPANY
Sioux Falls, South Dakota
Statement of Net Admitted Assets and Liabilities
December 31, 2021

ASSETS

Bonds	$	1,940,298,870
Stocks		19,721,943
Cash, cash equivalents, and short-term investments		32,146,891
Receivables for securities		140,000
Investment income due and accrued		17,433,547
Premiums and considerations		54,366,110
Amounts recoverable from reinsurers		3,204,634
Current federal and foreign income tax recoverable and interest thereon		-
Net deferred tax asset		14,565,007
Receivable from parent, subsidiaries, and affiliates		14,891,869
Other assets		1,037
Total Assets	$	2,096,769,908

LIABILITIES AND SURPLUS

Losses	$	214,859,103
Loss adjustment expense		48,667,258
Commissions payable, contingent commissions and other similar charges		10,885,216
Other expenses (excluding taxes, license and fees		-
Taxes, License and fees (excluding federal and foreign income taxes)		2,781,662
Federal and foreign income taxes payable		300,285
Unearned premiums		263,317,295
Advance premiums		6,618,279
Ceded reinsurance premiums payable (net of ceding commissions)		5,081,348
Amounts withheld or retained by company for account of other		10,237,011
Provision for reinsurance		6,261,560
Payable to parent, subsidiaries and affiliates		7,170
Payable on security transactions		35,226
Other liabilities		155,189
Total Liabilities	$	569,206,602

Surplus Account:			
Common stock	$ 4,000,000		
Gross paid in and contributed surplus	286,896,195		
Unassigned funds	1,236,667,111		
Surplus as regards policyholders		$	1,527,563,306
Total Liabilities and Capital		$	2,096,769,908

I, Julie Lee, Assistant Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2021, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Assistant Vice President, External Reporting

Subscribed and sworn to me this 14th day of March, 2022.

My commission expires:

"OFFICIAL SEAL"
CHRISTOPHER LOPATOWSKI
Notary Public, State of Illinois
My Commission Expires 01/14/2024

By Christopher Lopatowski
Notary Public

APPLICANT/PRINCIPALS:

AllParts Medical, LLC, 400 Brick Church Park Drive, Nashville, TN 37207
Discus Dental, LLC, 1700 A South Baker Ave., Ontario, CA 91761
Philips Healthcare Informatics, Inc., 4430 Rosewood Drive, Suite 200, Pleasanton, CA 94588
Philips Healthcare, a division of Philips North America LLC, 22100 Bothell Everett Hwy, Bothell, WA 98021
Philips Healthcare, a division of Philips North America LLC, 222 Jacobs Street, Cambridge, MA 02141 Philips Ultrasound LLC, 22100 Bothell Everett Highway, Bothell, WA 98021
Philips Image Guided Therapy Corporation, 3721 Valley Center Drive, Suite 500, San Diego, CA 92130
Philips Image Guided Therapy Corporation, 2451 Mercantile Drive, Rancho Cordova, CA 95742
Respironics Logistics Services, LLC, 174 Tech Center Drive, Suite 200, Mt. Pleasant, PA 15666
Spectranetics LLC, 9965 Federal Drive, Colorado Springs, CO 80921
Visicu, Inc., 217 E. Redwood Street, Suite 1900, Baltimore, MD 21202

Authorized Representative - [redacted] Paul Cavanaugh
Witness
Witness

Philips RS North America LLC, 1010 Murry Ridge Lane, Murrysville, PA 15668
Philips RS North America LLC, 174 Tech Center Drive, Suite 100, Mt. Pleasant, PA 15666

Authorized Representative - Stuart Cashman
Witness
Witness

Philips RS North America LLC LIMITED LIABILITY COMPANY SEAL 1984 DELAWARE

DISCUS DENTAL LLC LIMITED LIABILITY COMPANY SEAL 2007 CALIFORNIA

PHILIPS NORTH AMERICA LLC LIMITED LIABILITY COMPANY SEAL 1987 DELAWARE

PHILIPS ULTRASOUND LLC LIMITED LIABILITY COMPANY SEAL 1973 WASHINGTON

SPECTRANETICS LLC LIMITED LIABILITY COMPANY SEAL 1988 DELAWARE

IMAGE GUIDE SEAL 000

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30185503

Application/License No. _____

*See attached list of principal names (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is *See attached list of principal addresses (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 151 N Franklin Street Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 21, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of April, 20 23.

APPLICANT/PRINCIPAL

**See attached principal signature page

Authorized Representative

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Kristin S. Bender, Attorney-in-fact
print name
Nevada Non-Resident Producer License No. 829075

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Jessica Iannotta

Witness April D. Perez

Countersigned by:

N/A
Nevada Resident Agent

Attachment H

Medical Devices, Equipment and Gases (MDEG) Administrator Application

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Philips Healthcare Informatics, Inc. MDEG License # (if applicable) MP01141

Physical Address 4430 Rosewood Drive, Suite 200

City Pleasanton State CA Zip 94588

Mailing Address (if different from physical address) Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City Andover State MA Zip 01810

Telephone 650-293-2300 Website www.usa.philips.com/healthcare

Licensing Company Email beth.c.rogers@philips.com

Section 2: Personal Information

First Kannan Middle _____ Last Chellappan

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City Andover State MA Zip 01810

Telephone [redacted] Email Kannan.chellappan@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
BITS Pilani		08/96 - 03/98	
Address	**~~City~~**	**~~State~~**	**~~Zip~~**
Vidya Vihar, Pilani 333031, Rajasthan, India			
Diploma/Degree obtained, if any			
MS (Software Systems)			
School Name		From - To (MM/YY – MM/YY)	
University of Madras		08/91 - 04/95	
Address	**~~City~~**	**~~State~~**	**~~Zip~~**
Navalar Nagar, Chepauk, Triplicane, Chennai, Tamil Nadu 600005, India			
Diploma/Degree obtained, if any			
BE (Computer Science)			
School Name		From - To (MM/YY – MM/YY)	
A V Meiyappan Matriculation Higher Secondary School		06/89 – 03/91	
Address	**~~City~~**	**~~State~~**	**~~Zip~~**
155 AVM Colony, Virugambakkam, Chennai, Tamil Nadu 600092, India			
Diploma/Degree obtained, if any			
High School			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/17 - Present	[redacted]Kilrush Ave.	Dublin	CA	94568
From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/13 - 03/17	[redacted]oster City Blvd., Unit P3	Foster City	CA	94404
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Philips Healthcare Informatics, Inc.		04/17 - Present	
Business Address	**City**	**State**	**Zip**
4430 Rosewood Drive, Suite 200	Pleasanton	CA	94588
Phone	**Title**	**Number of Employed Hours**	
650-293-2300	Director R&D	40 hours per week	
Description of Duties			
Lead the team for Design and Development of Philips PACS Product. Meet quality norms, customer satisfaction KPIs and other KPIs defined by the organization. Responsible for team and career management of all R&D personnel.			

N/A

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

N/A

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

N/A **Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Kannan Chellappan, **certify that as the MDEG Administrator for**

Philips Healthcare Informatics, Inc.,

that I (initial that you have read and meet the following requirements):

1. ____ Have a high school diploma or its equivalent;
2. ____ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ____ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ____ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kannan Chellappan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 27th 2023
Date

Board Use Only	Date Received: 8/2/23

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Philips Healthcare Informatics, Inc.

Pharmacy/Wholesaler License # (if applicable) Pending; current MDEG License #: MP01141

Physical Address 4430 Rosewood Drive, Suite 200

City Pleasanton State CA Zip 94588

Mailing Address (if different from physical address) Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City Andover State MA Zip 01810

Telephone 650-293-2300 Website www.usa.philips.com/healthcare

Licensing Company Email beth.c.rogers@philips.com

Section 2: Personal Information

First Kannan Middle _____ Last Chellappan

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City Andover State MA Zip 01810

Telephone [redacted] Email Kannan.chellappan@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
BITS Pilani		08/96 - 05/98	
Address	**~~City~~**	**~~State~~**	**~~Zip~~**
Vidya Vihar, Pilani 333031, Rajasthan, India			
Diploma/Degree obtained, if any			
MS (Software Systems)			

School Name		From - To (MM/YY – MM/YY)	
University of Madras		08/91 - 04/95	
Address	**~~City~~**	**~~State~~**	**~~Zip~~**
Navalar Nagar, Chepauk, Triplicane, Chennai, Tamil Nadu 600005, India			
Diploma/Degree obtained, if any			
BE (Computer Science)			

School Name		From - To (MM/YY – MM/YY)	
AV MEIYAPPAN MATRICULATION HIGHER SECONDARY SCHOOL		06/89 - 03/91	
Address	City	State	Zip
155, AVM Colony, VIRUGAMBAKKAM, Chennai	Chennai, India	TN	600092
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/17 - Present	[redacted] Kilrush Ave.	Dublin	CA	94568
03/13 - 03/17	[redacted] Foster City Blvd., Unit [redacted]	Foster City	CA	94404
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Philips Healthcare Informatics, Inc.				From - To (MM/YY – MM/YY): 04/17 - Present
Business Address: 4430 Rosewood Drive, Suite 200	City: Pleasanton		State: CA	Zip: 94588
Phone: 650-293-2300	Title: Director R&D		Number of Employed Hours: 40 hours per week	
Description of Duties: Lead the team for Design and Development of Philips PACS Product. Meet quality norms, customer satisfaction KPIs and other KPIs defined by the organization. Responsible for team and career management of all R&D personnel.				

N/A

Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

April 07 2023
Date

I, Kannan Chellappan, **certify that as the designated representative for**

Philips Healthcare Informatics, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kannan Chellappan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

April 07 2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kannan Chellappan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

April 07 2023
Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Contra Costa

I, Kannan Chellappan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

April 07 2023
Date

Subscribed and Sworn to before me this 7th day of April, 2023.

Notary Public Signature

DEJAUNA HAWKINS
COMM. # 2316863
NOTARY PUBLIC • CALIFORNIA
CONTRA COSTA COUNTY
Comm. Exp. DEC. 24, 2023

(Seal)

Employee List

- Abdul Aiyaz
- Alina Shapira
- Anup Mahajan
- Banu Kiran Sunkara
- Chris Kay
- Clifford Iokepa
- Diwakar Kasibhotla
- Gunawan Laksmono
- Herschel Turner
- James Hammer
- John Vintayen
- Kannan Chellappan
- Kathleen Mcclure
- Kathleen Ruvolo
- Kate Feit
- Lokesh Gopal
- Louella Vo
- Michael Ona
- Rex Garcia
- Sachin Sarode
- Simon Lau
- Souri Rajan Venkatesan
- Steven Chemarum
- Umesh Toranagatti
- Venkata Sukumar Gudugunta
- Venkatraman Narayanaswamy
- Vikrant Kalhan
- Vinay Gupta

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: PMI Branded Pharmaceuticals, Inc.

Physical Address: 515 Eastern Avenue

City: Allegan State: MI Zip: 49010

Mailing Address (if different from physical address): 515 Eastern Ave, Attn: Regulatory Affairs

City: Allegan State: MI Zip: 49010

Telephone: 269-673-8451 Website: www.perrigo.com

Name of Designated Representative (DR): Kathleen A. Olgers

Licensing Company Email: deacontact@perrigo.com DR Email: kathleen.olgers@perrigo.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies ☐ Practitioners ☐ Hospitals ■ Wholesalers ☐ Veterinarians ■ Others: Pharmacy Chain Warehs	■ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical devices, equipment, supplies, gases ■ Others: List 1 & 2 Chemicals, Cosmetics Solid Dose, Liquids (oral), Topical, Vitamins	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: L. Perrigo Company
Address: 900 Industrial Drive City: Allegan State: MI Zip: 49010

Name: Perrigo New York, Inc.
Address: 1700 Bathgate Avenue City: Bronx State: NY Zip: 10457

Name: Laboratoires HRA Harma SAS
Address: 200 Avenue De Paris 92320 City: Chatillon, Ile De France State: Zip:

Name: Patheon Softgels Inc.
Address: 4125 Premier Dr City: High Point State: NC Zip: 27265

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Michigan
Parent Company (if any): Perrigo Company
Corporation/Organization Name: PMI Branded Pharmaceuticals, Inc.
Mailing Address: 515 Eastern Ave, Attn: Regulatory Affairs
City: Allegan State: Mi Zip: 49010
Telephone: 269-673-8451 Email: deacontact@perrigo.com
Contact Person Name: Kathleen A. Olgers

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

PMI Branded Pharmaceuticals, Inc.

Facility Name

Kyle. L. Hanson

Print Name of Authorized Person Submitting Application

Kyle L. Hanson

Original signature of Authorized Person (copies or stamps not accepted)

06/30/2023

Date

Board Use Only	Date Received: 8/15/23	Amount: 1000 - CK 652387

FDA Registration Information

PMI Branded Pharmaceuticals, Inc.

515 Eastern Avenue, Allegan, MI, 49010:

Perrigo Company is one of the largest over-the-counter self-care companies selling products globally. In the Americas, its primary business is manufacturing store brand products that are sold under the label of Perrigo's customers, such as large pharmacy chains. Perrigo Company also sells generic products under the labeler code of its subsidiary, L. Perrigo Company (labeler code 0113).

In addition, Perrigo Company sells national brand products through its subsidiary PMI Branded Pharmaceuticals, Inc. These products also use the L. Perrigo Company labeler code 0113 and are a subset of the products listed with FDA using that labeler code. Currently, all drug products sold by PMI Branded Pharmaceuticals, Inc. are over-the-counter.

In April 2022, Perrigo Company acquired Héra SAS (HRA). This acquisition included primarily over-the-counter products, but also a prescription emergency contraceptive product, listed below. PMI Branded is applying for licensing as a virtual manufacturer of prescription drugs in preparation for the transition of title and labeling of this product from HRA to PMI Branded.

Product Name	Product Type	NDC
Ella® (ulipristal acetate tablet 30 mg)	Rx Drug	73302-456-01

PMI Branded Pharmaceuticals, Inc.
515 Eastern Ave., Allegan, MI 49010
FEIN: 81-1656738
Incorporated in the State of Michigan on 8/28/2015

Parent Company
Perrigo Company – 515 Eastern Ave, MI 49010
FEIN: 38-2799573
Ownership 100%

James Dillard III **EVP & President CSCA**
Business Address: 515 Eastern Avenue, Allegan, MI 49010
Business Phone: 269-673-8451

Kyle Hanson **EVP & Secretary**
Business Address: 515 Eastern Avenue, Allegan, MI 49010
Business Phone: 269-673-8451

Sonia Hollies **Treasurer**
Business Address: 515 Eastern Avenue, Allegan, MI 49010
Business Phone: 269-673-8451

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

PMI BRANDED PHARMACEUTICALS, INC.

was validly incorporated on August 28 , 2015 as a Michigan DOMESTIC PROFIT CORPORATION, and said corporation is validly in existence under the laws of this state.

This certificate is issued pursuant to the provisions of 1972 PA 284 to attest to the fact that the corporation is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS ★ Corporations, Securities & Commercial Licensing Bureau ★

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 10th day of January , 2023.

Linda Clegg

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 23010170202

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

PMI BRANDED PHARMACEUTICALS, INC.
515 EASTERN AVE
ALLEGAN, MI 49010

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

PMI BRANDED PHARMACEUTICALS, INC.
515 EASTERN AVE
ALLEGAN, MI 49010

LICENSE NO.
5306007407

EXPIRATION DATE
06/14/2025

23165090629

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107661866

Application/License No. _____

PMI BRANDED PHARMACEUTICALS, INC., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
515 Eastern Ave Allegan, MI 49010, as
Address of Applicant/Principal
PRINCIPAL, and TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA, a
Surety Company
corporation organized under the laws of the state of CT
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Tower Square Hartford, CT 06183 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 13, 2023.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 13th day of April, 2023.

APPLICANT/PRINCIPAL
PMI BRANDED PHARMACEUTICALS, INC.

Authorized Representative

SURETY COMPANY
TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

Surety Company's Representative

Derek J. Elston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Ann Formhals

Witness Chris Troha

Countersigned by:

N/A
Nevada Resident Agent

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Derek J Elston** of **CHICAGO**, **Illinois**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April, 2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April, 2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **13th** day of **April**, **2023**.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Name of Pharmacy/Wholesaler: PMI Branded Pharmaceuticals, Inc.

Pharmacy/Wholesaler License # (if applicable): Pending in process

Physical Address: 515 Eastern Avenue

City: Allegan State: MI Zip: 49010

Mailing Address (if different from physical address): 515 Eastern Avenue, Attn: Regulatory Affairs

City: Allegan State: MI Zip: 49010

Telephone: 269-673-8451 Website: www.perrigo.com

Licensing Company Email: DEAContact@perrigo.com

First: Kathleen Middle: Anne Last: Olgers

Alias(es, nicknames, name changes, etc.): Kathy Hogenboom

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted] W 32nd St

City: Holland State: MI Zip: 49423

Telephone: [redacted] Email: deacontact@perrigo.com

Are you a citizen of the United States? ☑ Yes ☐ No

1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

School Name		From - To (MM/YY – MM/YY)
Oak Park and River Forest High School		09/1977 to 06/1981

Address	City	State	Zip
201 N Scoville Ave	Oak Park	IL	60302

Diploma/Degree obtained, if any: High School Diploma

School Name		From - To (MM/YY – MM/YY)
Hope College		8/1981 to 05/1985

Address	City	State	Zip
PO Box 9000	Holland	MI	49422-9000

Diploma/Degree obtained, if any: Bachelor of Science

School Name		From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name		From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name		From - To (MM/YY – MM/YY

Address	City	State	Zip

Diploma/Degree obtained, if any:

From - To (MM/YY – MM/YY)	Address	City	State	Zip
October 1990	[redacted] W 32nd St	Holland	MI	49423
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name		From - To (MM/YY – MM/YY)	
Perrigo Company (PMI Branded Pharmaceuticals, Inc. is a subsidiary)		11/2008 to Present	
Business Address	**City**	**State**	**Zip**
515 Eastern Avenue	Allegan	MI	49010
Phone	**Title**	**Number of Employed Hours**	
269-686-1691	Senior Regulatory Affairs Project Manager, DEA	15 years	
Description of Duties			
See attached resume			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Kathleen A Olgers, **certify that as the designated representative for**

PMI Branded Pharmaceuticals, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✔ I am at least 21 years of age;
3. ✔ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✔ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✔ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✔ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✔ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kathleen Olgers

Print Name (First, Last)

Kathleen A Olgers

Original Signature (electronic, copies or stamps not accepted)

6/28/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kathleen Olgers

Print Name (First, Last)

Kathleen A Olgers — 6/28/2023

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Kent

I, Kathleen Olgers, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Kathleen A Olgers — 6/28/2023

Original Signature — **Date**

Subscribed and Sworn to before me this 28 day of June 2023.

Wanda Kay Kerr

Notary Public Signature

(Seal)

Kathleen Olgers
[redacted] W. 32nd St.
Holland, MI 49423
[redacted]

PROFESSIONAL EXPERIENCE

PERRIGO COMPANY, Allegan, Michigan

2013-Present **Regulatory Affairs Project Manager (Senior RAPM since 2015)**

- Managed VAWD accreditation for two facilities, including several first cycle approvals
- Coordinate state licensing activities for five entities, increasing to 15 entities over time
- Corporate point person for DEA compliance, both internally and externally; subject matter expert for SAP integration of acquired controlled substance manufacturer

2010-2013 **Regulatory Affairs Team Lead, OTC Monograph**

- Supervised four project managers and one support staff team lead
- Managed team's implementation of FDA warning letter response
- Responsible for assuring that label copy changes were completed in a timely way for evolving regulatory changes such as acetaminophen dosing and child resistant closure requirements for imidazoline nasal sprays
- Continued responsibilities with DEA

2008-2010 **Regulatory Affairs Project Manager**

- Supervised three support staff persons
- Managed initial implementation of electronic drug listing
- Liaison with Drug Enforcement Administration

J.B. LABORATORIES, INC., Holland, Michigan

2000-2008 **Regulatory Affairs positions (administrator, manager)**

- Hosted regulator (FDA, TGA, DEA, Mich. Dept. of Agriculture) and customer audits; prepared responses to observations
- Coordinated implementation of new dietary supplement GMPs, corrective and preventive action program, computerized system validation program; responsible for compliance aspects of company-wide ERP software implementation

1991-2000 **Quality Control positions (QC Supervisor, Technical Affairs)**

- Wrote specifications and test methods for products and materials
- Approved master manufacturing records and product label copy
- Participated in FDA and customer GMP compliance audits
- Supervised four chemists supporting production schedule and stability program
- Developed validation program, equipment qualification program in support of construction of new manufacturing facility
- Evaluated new regulations for potential impact on the company and/or products

Previous experience as a Chemist (Perrigo Company and J.B. Laboratories), 1986-1991

PROFESSIONAL MEMBERSHIPS AND ACCREDITATIONS

Regulatory Affairs Professionals Society (Regulatory Affairs Certified since 2000)

Lean Sigma Green Belt

EDUCATION

B.S. – Chemistry, Hope College 1985

Employee List

PMI Branded Pharmaceuticals, Inc.

515 Eastern Avenue, Allegan, MI, 49010

James Dillard III

Kyle L. Hanson

Sonia Hollies

Kathleen A. Olgers

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: Pending; current MDEG license #: WH MP01409	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Respironics Logistics Services, LLC

Physical Address: 174 Tech Center Drive, Suite 200

City: Mt. Pleasant State: PA Zip: 15666

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 724-387-5200 Website: www.philips.com

Name of Designated Representative (DR): Robert P. Mansberry

Licensing Company Email: beth.c.rogers@philips.com DR Email: robert.mansberry@philips.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: DME Dealers and DME Distributors.		☑ Others: Own Label and Wholesale Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9-9-2022
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - No pharmaceuticals products are handled or sold. See Attachment A.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Philips RS North America LLC

Corporation/Organization Name: Respironics Logistics Services, LLC

Mailing Address: Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 978-659-4884 Email: beth.c.rogers@philips.com

Contact Person Name: Beth C. Rogers

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
N/A 1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment D		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly owned by parent company, Philips RS North America LLC.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment D	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I	✓	✓	✓	✓
N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)**				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%207-1-19.pdf		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Respironics Logistics Services, LLC

Facility Name

Robert P. Mansberry

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9-9-2022

Date

Board Use Only	Date Received: 5-11-23	Amount: 1000.00 CK-645

Attachment A

Nature of Business

Respironics Logistics Services, LLC (RILS) is a wholesale distributor of prescription and nonprescription medical devices for the diagnosis, treatment and monitoring of various medical conditions, including, but not limited to, sleep, respiratory, and cardiopulmonary disorders. RILS is a wholly-owned subsidiary of its parent company, Philips RS North America LLC. RILS distributes the parent company's products to customers (wholesalers, hospitals, durable medical equipment (DME) dealers, and distributors). All sales of these products are made by the manufacturer to its DME or homecare provider customers, and not to individual patients, but the items will be shipped directly to the DME or homecare provider's patient. The patient's DME or homecare provider provides medical supervision of the patient.

Currently, RILS ships replacement masks and other accessories (including headgear, tubing, filters, chinstraps, and humidifier chambers) for CPAP devices. No drugs, whether prescription or non-prescription, are distributed.

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
RESPIRONICS, INC.
174 Tech Center Drive
Mount Pleasant, PA 15666
Registration Number: 3002797442
FEI Number*: 3002797442
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2023

Owner/Operator:
Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
Owner/Operator Number: 2518422[7]

Official Correspondent:
Tom Fallon
Philips
6501 Living Place
Pittsburgh, PA 15206
Phone: 978-9415572

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2518422&OwnerOperator
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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2518422&OwnerOperator

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
RESPIRON CS, INC.
174 Tech Center Drive
Mount Pleasant, PA 15666
Reg stration Number: 3002797442
FEI Number*: 3002797442
Status: Act ve
Initial Distributor/Importer: Yes
*Note Firm May Have Add t ona Estab ishment Types.
P ease Rev ew List ngs For Further Informat on
Date Of Registration Status: 2022

Owner/Operator:
Ph lps Medical Systems Internationa BV[6]
Veenp uls 6
Best, NL 5684PC
Owner/Operator Number: 2518422[7]

Officia Correspondent
Tom Fa on
Ph ips
6501 Living Place
P ttsburgh, PA 15206
Phone: 978 9415572

* F rm Estab shment dentifier (FEI) shou d be used for dentificat on of entities within the mports message set

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4. https://www.fda.gov/Med ca Devices
5. https://www.fda.gov/med ca -devices/dev ce-adv ce-comprehensive-regulatory-assistance/med cal-device-databases
6. /scr pts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&estab lshmentName=&Num=&StateName=&CountryName=&Reg strat onNumber=&OwnerOperatorNumber=2518422&OwnerOperator
7. /scr pts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&estab lshmentName=&Num=&StateName=&CountryName=&Reg strat onNumber=&OwnerOperatorNumber=2518422&OwnerOperator

Page Last Updated: 08/08/2022

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FDA

U.S. Food and Drug Admin stration
10903 New Hampshire Avenue
Si ver Spring, MD 20993
Ph. 1 888 INFO FDA (1 888 463 6332)
Contact FDA

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6. /scr pts/cdrh/cfdocs/cfRL/rl.cfm?start search=1&estab ishmentName=&Num=&StateName=&CountryName=&Reg strat onNumber=&OwnerOperatorNumber=2518422&OwnerOperator
7. /scr pts/cdrh/cfdocs/cfRL/rl.cfm?start search=1&estab ishmentName=&Num=&StateName=&CountryName=&Reg strat onNumber=&OwnerOperatorNumber=2518422&OwnerOperator

Attachment D

LLC Information

Respironics Logistics Services, LLC

Respironics Logistics Services, LLC is wholly-owned by its parent company, Philips RS North America LLC.

LLC Officers:

David Ferguson
President and Chief Executive Officer

Paul Cavanaugh
Vice President

Ling Liu
Vice President and Manager

Joseph E. Innamorati
Vice President, Secretary, and Manager

Irma I. Gomez
Assistant Secretary

Facility Manager:

Robert P. Mansberry
Operations Manager

Enclosed please find a list of site employees.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RESPIRONICS LOGISTICS SERVICES, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF MARCH, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RESPIRONICS LOGISTICS SERVICES, LLC" WAS FORMED ON THE TWENTIETH DAY OF AUGUST, A.D. 2007.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



Jeffrey W. Bullock, Secretary of State

4409766 8300

SR# 20230976722

Authentication: 202907038

Date: 03-14-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Certificate of Registration

Certificate No. 6000008932
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Devices

Drug & Device Registration
555 WALNUT ST
FORUM PLACE -7th FLOOR -SUITE 701
HARRISBURG, PA 17101
(717) 787-4779

RESPIRONICS LOGISTICS SERVICES, LLC
174 TECH CENTER DRIVE
SUITE 200
MT. PLEASANT, PA 15666

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: June 20, 2016
Expiration Date: The Last Day of August, 2023

Susan Coble
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

K Klinepeter
Keara Klinepeter
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
01/03/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Marsh USA, Inc. 1166 Avenue of the Americas New York, NY 10036 CN101736188-GAUW-NI-22-23	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED Philips North America LLC 222 Jacobs Street, 3rd Floor Cambridge, MA 02141	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : National Union Fire Insurance Co Of Pittsburgh — 19445 INSURER B : Safety National Casualty Corp. — 15105 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** NYC-011181363-12 **REVISION NUMBER:** 10

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [ ] OCCUR [X] GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [X] PRO-JECT [ ] LOC [ ] OTHER:			536-18-48	12/31/2022	12/31/2023	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ $ $ $ $ $ $	2,000,000 500,000 10,000 2,000,000 5,000,000 5,000,000
B	AUTOMOBILE LIABILITY [X] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY			CA6675481	12/31/2022	12/31/2023	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ $ $ $ $	2,000,000
A	[X] UMBRELLA LIAB [X] OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $			10-736-193	12/31/2022	12/31/2023	EACH OCCURRENCE AGGREGATE $	$ $ $	5,000,000 5,000,000
B B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			LDS4047559 (AOS) PS4047560 (WI)	12/31/2022 12/31/2022	12/31/2023 12/31/2023	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	2,000,000 2,000,000 2,000,000
A	CYBER LIABILITY			03-932-59-76 'Subject to a policy deductible'	12/31/2022	12/31/2023	Occurrence Limit Aggregate Limit		10,000,000 10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Additional Certificate Holder: Virginia Community College System Commonwealth of Virginia Virginia Community College System 147 Daleville Centre Drive Daleville, VA 24083.

Evidence of coverage

CERTIFICATE HOLDER

Philips North America LLC
See above for the Complete Cert. Holder Name
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

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The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: CN101736188
LOC #: New York

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Marsh USA, Inc.	Philips North America LLC 222 Jacobs Street, 3rd Floor Cambridge, MA 02141
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Includes:
370 West Trimble Road LLC
AllParts Medical, LLC
BioTelemetry, Inc.
BioTel Research, LLC
BioTelemetry Care Management, LLC
Telcare Medical Supply, LLC
Telcare, LLC
Braemar Manufacturing, LLC
Cardiac Monitoring Holding Company, LLC
LifeWatch Corp.
LifeWatch Services, Inc.
Cardiologs Technologies Inc.
CardioNet, LLC
BioTel INR, LLC
Geneva Healthcare, LLC
VirtualScopics, LLC
Blue Willow Systems LLC
Discus Holdings, LLC
Discus Dental, LLC
Discus International, LLC
Discus Dental Canada, LLC
Electrical Geodesics LLC
Cerebral Data Systems, Inc. (CDS)
Intact Vascular, Inc.
Philips CS Corporation (formerly "Vita Topco, Inc." and "Philips Capsule Corporation")
Capsule Technologies, Inc.
CapsuleTech, Inc.
Philips Healthcare Informatics, Inc.
Philips Image Guided Therapy Corporation
Cardioprolific Inc.
Crux Biomedical, LLC
Spectranetics LLC
Volcano Atheromed, Inc.
Philips Medical Systems (Cleveland), Inc.
Philips Medical Systems MR, Inc.
Philips DS North America LLC
Philips North America, LLC
Philips North America, LLC D/B/A Philips Healthcare
Philips Oral Healthcare, LLC
Philips RS North America Holding Corporation
Philips RS North America LLC
Respironics California, LLC
Respironics Colorado, Inc.
Respironics Logistics Services, LLC
Respironics Novametrix, LLC
Philips Semiconductors Inc.
Remote Diagnostics Technologies LLC

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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Marsh USA, Inc.	Philips North America LLC 222 Jacobs Street, 3rd Floor Cambridge, MA 02141
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Respiratory Technologies, Inc.
Tomtec Corporation
TR Management Company, LLC
U.S. Philips Corporation
Vesper Medical, Inc.
VISICU, Inc.
VitalHealth Software Corp.
Wellcentive LLC (formerly "Wellcentive, Inc.")
Wellcentive QR, LLC
American Color & Chemical, L.L.C.
ATL Ultrasound, Inc.
Philips Ultrasound LLC (formerly "Philips Ultrasound, Inc.")
ATL International LLC
Philips Electronics North America Foundation
Philips Electronics Realty, LLC
Philips Medical Systems Export, Inc.
Philips MPEG Inc.
Philips Project Management, LLC

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30185503

Application/License No. _____

*See attached list of principal names (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is *See attached list of principal addresses (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 151 N Franklin Street Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 21, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of April, 20 23.

APPLICANT/PRINCIPAL

**See attached principal signature page

Authorized Representative

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Kristin S. Bender, Attorney-in-fact

print name

Nevada Non-Resident Producer License No. 829075

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Jessica Tannotta

Witness April D. Perez

Countersigned by:

N/A

Nevada Resident Agent

APPLICANT/PRINCIPALS:

AllParts Medical, LLC, 400 Brick Church Park Drive, Nashville, TN 37207
Discus Dental, LLC, 1700 A South Baker Ave., Ontario, CA 91761
Philips Healthcare Informatics, Inc., 4430 Rosewood Drive, Suite 200, Pleasanton, CA 94588
Philips Healthcare, a division of Philips North America LLC, 22100 Bothell Everett Hwy, Bothell, WA 98021
Philips Healthcare, a division of Philips North America LLC, 222 Jacobs Street, Cambridge, MA 02141 Philips Ultrasound LLC, 22100 Bothell Everett Highway, Bothell, WA 98021
Philips Image Guided Therapy Corporation, 3721 Valley Center Drive, Suite 500, San Diego, CA 92130
Philips Image Guided Therapy Corporation, 2451 Mercantile Drive, Rancho Cordova, CA 95742
Respironics Logistics Services, LLC, 174 Tech Center Drive, Suite 200, Mt. Pleasant, PA 15666
Spectranetics LLC, 9965 Federal Drive, Colorado Springs, CO 80921
Visicu, Inc., 217 E. Redwood Street, Suite 1900, Baltimore, MD 21202

Paul Cavanaugh
Authorized Representative - [redacted] Paul Cavanaugh

Witness

Witness

Philips RS North America LLC, 1010 Murry Ridge Lane, Murrysville, PA 15668
Philips RS North America LLC, 174 Tech Center Drive, Suite 100, Mt. Pleasant, PA 15666

Authorized Representative - Stuart Cashman

Witness

Witness

Philips RS North America LLC LIMITED LIABILITY COMPANY SEAL 1984 DELAWARE

DISCUS DENTAL LLC LIMITED LIABILITY COMPANY SEAL 2007 CALIFORNIA

PHILIPS NORTH AMERICA LLC LIMITED LIABILITY COMPANY SEAL 1987 DELAWARE

PHILIPS ULTRASOUND LLC LIMITED LIABILITY COMPANY SEAL 1973 WASHINGTON

SPECTRANETICS LLC LIMITED LIABILITY COMPANY SEAL 1988 DELAWARE

IMAGE GUIDED THERAPY CORP SEAL 2000

WESTERN SURETY COMPANY
Sioux Falls, South Dakota
Statement of Net Admitted Assets and Liabilities
December 31, 2021

ASSETS

Bonds	$	1,940,298,870
Stocks		19,721,943
Cash, cash equivalents, and short-term investments		32,146,891
Receivables for securities		140,000
Investment income due and accrued		17,433,547
Premiums and considerations		54,366,110
Amounts recoverable from reinsurers		3,204,634
Current federal and foreign income tax recoverable and interest thereon		-
Net deferred tax asset		14,565,007
Receivable from parent, subsidiaries, and affiliates		14,891,869
Other assets		1,037
Total Assets	$	2,096,769,908

LIABILITIES AND SURPLUS

Losses	$	214,859,103
Loss adjustment expense		48,667,258
Commissions payable, contingent commissions and other similar charges		10,885,216
Other expenses (excluding taxes, license and fees		-
Taxes, License and fees (excluding federal and foreign income taxes)		2,781,662
Federal and foreign income taxes payable		300,285
Unearned premiums		263,317,295
Advance premiums		6,618,279
Ceded reinsurance premiums payable (net of ceding commissions)		5,081,348
Amounts withheld or retained by company for account of other		10,237,011
Provision for reinsurance		6,261,560
Payable to parent, subsidiaries and affiliates		7,170
Payable on security transactions		35,226
Other liabilities		155,189
Total Liabilities	$	569,206,602

Surplus Account:			
Common stock	$ 4,000,000		
Gross paid in and contributed surplus	286,896,195		
Unassigned funds	1,236,667,111		
Surplus as regards policyholders		$	1,527,563,306
Total Liabilities and Capital		$	2,096,769,908

I, Julie Lee, Assistant Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2021, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Assistant Vice President, External Reporting

Subscribed and sworn to me this 14th day of March, 2022.

My commission expires:

"OFFICIAL SEAL"
CHRISTOPHER LOPATOWSKI
Notary Public, State of Illinois
My Commission Expires 01/14/2024

By Christopher Lopatowski
Notary Public

Attachment H

Medical Devices, Equipment and Gases (MDEG) Administrator Form

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Respironics Logistics Services, LLC

Pharmacy/Wholesaler License # (if applicable) Pending; current MDEG license #: MP01409

Physical Address 174 Tech Center Drive, Suite 200

City Mt. Pleasant State PA Zip 15666

Mailing Address (if different from physical address) Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City Andover State MA Zip 01810

Telephone 724-387-5200 Website www.philips.com

Licensing Company Email beth.c.rogers@philips.com

Section 2: Personal Information

First Robert Middle Paul Last Mansberry

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City Andover State MA Zip 01810

Telephone [redacted] Email robert.mansberry@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	**Yes**	**No**
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) Honorably discharged 09/2001	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	**Yes**	**No**
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
McGuffey High School		08/91 - 06/95	
Address	**City**	**State**	**Zip**
86 McGuffey Drive	Claysville	PA	15323
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/22 - Present	[redacted] Barclay Street, Greensburg, PA 15601	Greensburg	PA	15601
05/04 - 03/22	[redacted] Rehoboth Church Road	Perryopolis	PA	15473
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Respironics Logistics Services, LLC			From - To (MM/YY – MM/YY): 03/21 - Present	
Business Address: 174 Tech Center Drive, Suite 200		City: Mt. Pleasant	State: PA	Zip: 15666
Phone: 724-387-5200	Title: Operations Manager		Number of Employed Hours: 55 hours per week	
Description of Duties: Responsible for record keeping, oversight of product distribution, management of employees, responsible for inspection & Q/C of materials of product flow, safety standards, all monthly and audit reporting.				
Business Name: United States Military	Fort Benning		From - To (MM/YY – MM/YY): 08/97 - 12/97	
Business Address: 1775 Legacy Way		City: Columbus	State: GA	Zip: 31903
Phone: (706) 545-2011	Title: Enlisted Solider		Number of Employed Hours: 55 hours per week	
Description of Duties: Position One : E1 (Private) Basic Training				
Business Name: United State Militarily	Fort Myer		From - To (MM/YY – MM/YY): 12/97 - 10/01	
Business Address: 201 Custer Road		City: Fort Myer	State: VA	Zip:
Phone: (703) 545-6700	Title: Enlisted Solider		Number of Employed Hours: 55 hours a week	
Description of Duties: E4 (Specialist) Junior Private				
Business Name: United States Militarily	Fort McNair		From - To (MM/YY – MM/YY): 12/97 - 10/01	
Business Address: P St SW, Washington		City: Washington DC	State: DC	Zip: 20319
Phone: 703-545-6700	Title: Enlisted Solider		Number of Employed Hours: 55 hours per week	
Description of Duties: E4 (Specialist) Junior Private				
Business Name:			From - To (MM/YY – MM/YY):	
Business Address:		City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9-9-2022
Date

I, Robert P. Mansberry, **certify that as the designated representative for**

Respironics Logistics Services, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Robert Mansberry
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-9-2022
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Mansberry
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-9-22
Date

Please have this section completed in the presence of a Notary Public.

State of PENNSYLVANIA, ss. County of WESTMORELAND

I, ROBERT P. MANSBERRY, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9-9-2022
Date

Subscribed and Sworn to before me this 9 day of Sept 2022

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Michelle L. Kwasny, Notary Public
Westmoreland County
My commission expires December 6, 2023
Commission number 1238412
Member, Pennsylvania Association of Notaries
(Seal)

Robert P. Mansberry

[redacted]Rehoboth Church Road
Perryopolis, PA 15473
[redacted]

Current Position:
Respironics Logistics Services, LLC
Operations Manager
3/2021 - Present

Responsible for management of all personnel in Mount Pleasant Distribution Center. Oversee all operations and product flow. Inspection of materials/QC of product flow. Responsible for maintaining highest safety standards, and monthly audit reporting.

Carlisle Construction Materials
Smithfield, PA 15478
Production
Production Supervisor
2018- 3/2021

- Weekly, monthly reporting and audits
- Maintain highest standard of FPY and Utilization
- Assist in hiring, training, discipline, termination of workforce
- Scheduling and directing of workforce
- Inspection of materials for quality/defects
- Familiar with Lean concepts, 5S, SFIS, Gemba, Kaizen
- Outlook, Word, and Excel, SAP
- Champion IdeaGen and Employee Recognition Programs
- Work harmoniously with all levels of company personnel

Eastman Chemical
West Elizabeth, PA 15088
Production
Skilled Labor
2017-2019

- Trained on all aspects of safety for all tasks
- Forklift certified
- Able to perform multiple functions, on multiple units
- Sample batch products to ensure integrity of material
- Daily, weekly, monthly inventory / SAP
- Load, unload, handle hazardous chemicals

Arcelor Mittal Steel
Monessen, PA 15062
Production
Skilled Labor
2016-2017

- Trained on all aspects of safety for labor tasks
- Qualified on multiple labor grade positions
- Qualified and operate all battery equipment
- Work as a team to accomplish daily production quota

Global Pump
Brownsville, PA 15417
Branch Manager,
Operations and Logistics
Skilled labor
2014-2016

- Order, receive, reconcile all products/parts
- Establish parts room using KANBAN system of inventory
- Daily supervision of office and shop personnel
- Establish/maintain new and existing vendors/trucking accounts
- Communicate daily with Regional Account Manager and corporate personnel to establish lines of transportation between branches/jobsites
- Maintain jobsites, inventory, records for PA and MD branches
- Establish and implement safety procedures, office and yard policies
- Load / off load trucks by hand, fork truck, JLG
- Negotiate pricing/contracts
- Experience with Dedicated loads/LTL
- Integration of SAP

U.S. Steel Corporation
Clairton, Pa 15025
Crew Leader
Production
Skilled Labor
2005-2014

- Achieved new department safety record for days without incident
- Supervised crew on daily tasks to ensure consistent operations
- Oversaw and reconciled shipment information
- Communicated with multiple departments and companies to maintain flow of multiple jobs/tasks/materials
- Responsible for payroll and vacation scheduling
- Load railcars with conveyor /boom for shipment
- Experienced with diesel locomotive and 240v electric locos

Education/Affiliations

- VP - American Legion Riders, 2018
- OSHA 10 Certified, 2015
- Safe Land PEC Certified, 2014
- Certificate of Training, Class 5-98, Regimental Orientation Program, Fort Myer, VA, 1998
- Diploma, Class 47-97, Infantry School, 19th Infantry Regiment, Fort Benning, GA, 1997
- Diploma, McGuffey High School, Claysville, PA, 1995

Qualifications

- Reliable, result oriented professional with over 20 years management skills working with teams of 10+ personnel
- Selected for highly elite Army ceremonial unit (top 2% of the Army)
- Proven ability to motivate self and team members in accomplishing all assignments at above standard levels
- 20+ years of experience in customer relations.
- 16+ years of experience in an industrial atmosphere.
- Knowledge of SAP
- Over 9 years Logistics and Operations experience
- Efficiently/effectively perform duties and assignments under pressure
- Quickly and successfully adapt to new ideas and methods
- Confident in making independent decisions
- 7+ years working in rail yard/with railed equipment

References Available upon request

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Respironics Logistics Services, LLC — MDEG License # (if applicable): MP01409

Physical Address: 174 Tech Center Drive, Suite 200

City: Mt. Pleasant — State: PA — Zip: 15666

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover — State: MA — Zip: 01810

Telephone: 724-387-5200 — Website: www.philips.com

Licensing Company Email: beth.c.rogers@philips.com

Section 2: Personal Information

First: Robert — Middle: Paul — Last: Mansberry

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover — State: MA — Zip: 01810

Telephone: [redacted] — Email: robert.mansberry@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) Honorably discharged 09/2001	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
McGuffey High School		08/91 - 06/95	
Address	**City**	**State**	**Zip**
86 McGuffey Drive	Claysville	PA	15323
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/22 - Present	[redacted]Barclay Street	Greensburg	PA	15601
05/04 - 03/22	[redacted]Rehoboth Church Road	Perryopolis	PA	15473
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Respironics Logistics Services, LLC		03/21 - Present	
Business Address	**City**	**State**	**Zip**
174 Tech Center Drive, Suite 200	Mt. Pleasant	PA	15666
Phone	**Title**	**Number of Employed Hours**	
724-387-5200	Operations Manager	45 hours per week	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

N/A

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9-9-2022
Date

I, Robert P. Mansberry, **certify that as the MDEG Administrator for**

Respironics Logistics Services, LLC,

that I (initial that you have read and meet the following requirements):

1. RPM Have a high school diploma or its equivalent;
2. RPM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RPM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RPM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Mansberry
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-1-2022
Date

Board Use Only	Date Received: 5-11-23

Respironics Logistics Services, LLC Employee List

Anthony Orange
Brendan Jalosky
David Zofsak
Garrett Twardesky
Rita Thompson

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Amended page 1 and 2 of pending CHOW & Name Change application for Section 2: History of Company

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☒ Ownership Change* ☒ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02615	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Sagent Pharmaceuticals

Physical Address: 1901 North Roselle Road, Suite 450 RM 4032

City: Schaumburg State: IL Zip: 60195

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.sagentpharma.com

Name of Designated Representative (DR): Jerry C. Webb

Licensing Company Email: SAG@slsny.com DR Email: jwebb@sagentpharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☒ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Distributors		☒ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/08/2023		AR		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2023-050		Arkansas State Board of Pharmacy		
Reason/Charge				
Failure to Notify of Change of Ownership				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Sagent Pharmaceuticals				

Provide explanation below:

Sagent Pharmaceuticals underwent a change of Ownership and did not notify Arkansas State Board of Pharmacy per their regulations within 14 days of the effective date. Sagent Pharmaceuticals agreed to Arkansas Board of Pharmacy consent agreement and paid the fine.

Jerry C. Webb

Original Signature (electronic, copies or stamps not accepted)

1 Aug 2023

Date

STATE LICENSE SERVICING, INC
1751 State Route 17A, Suite 3
Florida, NY 10921
Tel. 845/544-2482
Fax. 845/544-2481
statelicenseservicing.com

July 21, 2023

To: Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: **Notice of Non-Disciplinary Consent Agreement**

Sagent Pharmaceuticals
1901 North Roselle Road
Suite 450 RM 4032
Schaumburg IL 60195

License/Permit No.: WH02615

Dear Licensing Authority:

This letter shall serve as disclosure of a non-disciplinary Consent Agreement for the above-referenced company. Sagent Pharmaceuticals entered into a non-disciplinary Consent Agreement on 6/6/2023 from the Arkansas State Board of Pharmacy under Case # 2023-050 for failure to notify their change in ownership in time.

Sagent Pharmaceuticals has agreed to pay a non-disciplinary administrative cost of two thousand five hundred dollars ($2,500). The cost has been paid and the matter is now satisfactorily closed. Please find a copy of the signed consent agreement attached.

If you need any additional information, please feel free to email me at the address below.

Kind regards,

Jennifer Schneider
VP, Client Services
State License Servicing, Inc.
SPW@SLSNY.COM

JUL 26 2023

AR- Consent Agmt
Discipline
Docs

RECEIVED
MAY 26 2023
ARKANSAS STATE
BOARD OF PHARMACY

BEFORE THE ARKANSAS STATE BOARD OF PHARMACY

IN THE MATTER OF
SAGENT PHARMEUTICALS
WD03445 **CASE # 2023-050**

CONSENT AGREEMENT

WHEREAS, Respondent **SAGENT PHARMEUTICALS,** located in Schaumburg, IL., is licensed as a Wholesale Distributor of Prescription Drugs and holds license WD03445;

WHEREAS, a change of ownership occurred on February 28, 2023. The Board did not receive notification from Respondent **SAGENT PHARMEUTICALS** of said change of ownership until April 27, 2023.

WHEREAS, SAGENT PHARMEUTICALS may be charged with violations of Board Regulation 08-00-0003 and A.C.A. §17-92-407, and § 17-92- 315;

WHEREAS, Respondent makes no admission of guilt but wishes to resolve these charges informally. By entering into this non-disciplinary Consent Agreement, Respondent's statements herein shall not be used as evidence in a formal hearing if this agreement is not accepted by the Board. Respondent and the Board therefore agree that this Agreement shall not constitute disciplinary action but rather an informal resolution of these charges. Respondent expressly waives its right to an administrative hearing and consents to the terms incorporated in this Agreement. Respondent further consents to the *ex parte* presentation of this Agreement to the Board and agrees that, if the Agreement is not accepted by the Board, the presentation and consideration of this Consent Agreement by the Board shall not constitute a basis for disqualification of the Board or any of its members from further participation in this matter, including a formal hearing; and

WHEREAS, Respondent acknowledges that this Consent Agreement is not effective until its acceptance by the Board, that Respondent has had the opportunity to consult with legal counsel of its own choosing concerning the advisability, meaning and effect of this Consent Agreement, that the Board shall retain jurisdiction to enforce the provisions of this Consent Agreement, and that failure to comply with the terms and conditions of this agreement shall be grounds for disciplinary action in the form of a civil penalty and/or suspension or revocation of Respondent's license, registration or permit.

THEREFORE, Respondent consents to the following terms in full resolution of this complaint:

1. Respondent **SAGENT PHARMEUTICALS, (WD03445)** willingly agrees and stipulates that it shall pay a non-disciplinary investigative cost of two thousand five hundred dollars ($2,500.00) to the Board on or before July 15, 2023.

#3450
$2500
5.26.23

EXECUTED this 23 day of May, 2023.

Authorized Representative of SAGENT PHARMEUTICALS
Respondent

SAGENT LEGAL

Attorney for Respondent (Optional)

John Clay Kirtley
Executive Director
Arkansas State Board of Pharmacy

President
Arkansas State Board of Pharmacy 6/6/2023

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Inforlife SA
Address: Casai, CH-7748 City: Campascio State: Italy Zip:
Name: Gland Pharma Ltd.
Address: Plot Nos. 42-52 APIIC, Phase III Pashamylaram City: Patencheru Mandal Hyderbad 502307, Telangana State: India Zip:
Name: Corden Pharma S.p.A.
Address: Viale Dell'Industria, 3 20867 City: Caponago State: Italy Zip:
Name: Avara Liscate Pharmaceutical Services SPA
Address: Via Fosse Ardeatine 2, City: Liscate 20050 State: Milan Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: WY
Parent Company (if any): Que Pharma Inc.
Corporation/Organization Name: Sagent Pharmaceuticals
Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: SAG@slsny.com
Contact Person Name: Christine Cannon

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: Labeler Code: 25021	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Sagent Pharmaceuticals

Facility Name

Jerry C. Webb

Print Name of Authorized Person Submitting Application

JCWebb

Original signature of Authorized Person (copies or stamps not accepted)

5/9/2023

Date

Board Use Only	Date Received: 7/17/23	Amount: 1000-CK-4981

TOTAL P.02

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, Maryland 20857

Apr 27, 2007

SAGENT PHARMACEUTICALS INC
812 LAKELAND DR ATTN: JEFFREY M YORDON
SCHAUMBURG IL 60173

The Food and Drug Administration (FDA) has assigned the following Labeler Code Number to your firm:

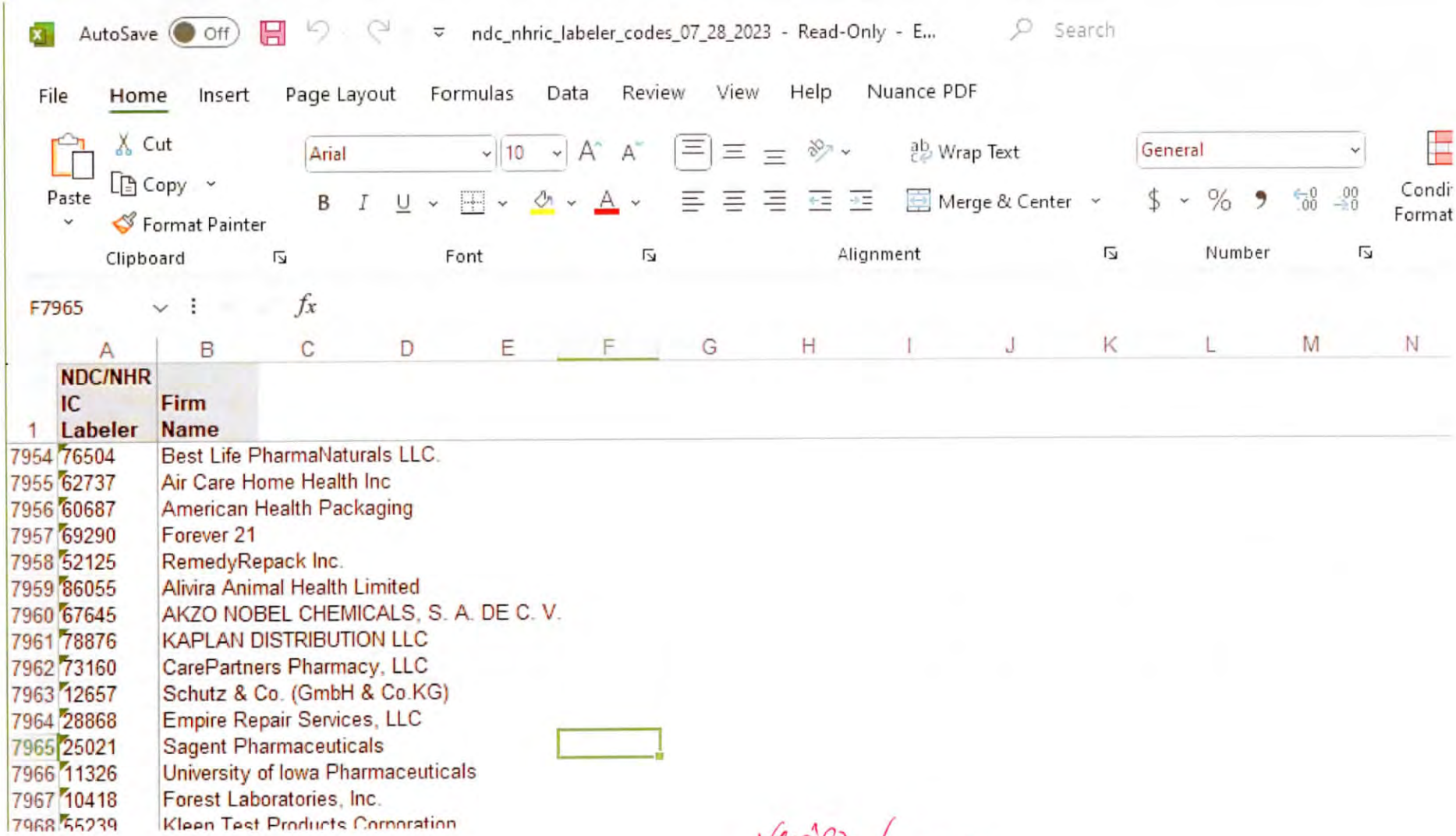
25021

This Labeler Code should be used on all forms related to drug establishment registration and/or drug product listing. Per Title 21, Part 207 of the Code of Federal Regulations (CFR), owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list every drug in commercial distribution within 5 days after the beginning of operation.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products. If you have any questions, please contact the Quality Control Team (301) 210-2840.

Sincerely,

Paul M. Loebach
Public Health Analyst
Office of Compliance
(Drug Registration and Listing)



	A	B
1	NDC/NHRIC Labeler	Firm Name
7954	76504	Best Life PharmaNaturals LLC.
7955	62737	Air Care Home Health Inc
7956	60687	American Health Packaging
7957	69290	Forever 21
7958	52125	RemedyRepack Inc.
7959	86055	Alivira Animal Health Limited
7960	67645	AKZO NOBEL CHEMICALS, S. A. DE C. V.
7961	78876	KAPLAN DISTRIBUTION LLC
7962	73160	CarePartners Pharmacy, LLC
7963	12657	Schutz & Co. (GmbH & Co.KG)
7964	28868	Empire Repair Services, LLC
7965	25021	Sagent Pharmaceuticals
7966	11326	University of Iowa Pharmaceuticals
7967	10418	Forest Laboratories, Inc.
7968	55239	Kleen Test Products Corporation

Verified M.17
7/28/23

Home State (IL) Permit

1205

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.005364

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2024

LICENSED WHOLESALE DRUG DISTRIBUTOR

BROKER

SAGENT PHARMACEUTICALS
JERRY WEBB
1901 N ROSELLE RD STE 450
SCHAUMBURG, IL 60195-3190

MARIO TRETO, JR.
SECRETARY

CECILIA ABUNDIS
DIRECTOR

The official status of this license can be verified at IDFPR.Illinois.gov

18149252

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4424493

Home State (IL) Verification of license

Illinois Department of Financial and Professional Regulation

Lookup Detail View

Contact

Contact Information

Name	City/State/Zip	DBA / AKA
SAGENT PHARMACEUTICALS	Schaumburg, IL 60195	•

License

License Information

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
004005364	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	07/31/2023	07/31/2023	12/31/2024	N

Other Licenses

Other Licenses

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
004005037	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	03/05/2021	03/13/2023	12/31/2024	N

Generated on: 8/10/2023 11:29:46 AM

Sagent Pharmaceuticals

Corporate Address: 1901 North Roselle Road, Suite 450 RM 4032, Schaumburg, IL 60195 USA
FEIN: 20-5522946
www.sagentpharma.com

Drug Labeler Code: 25021
Incorporation State: WY
Incorporation Date: 5/5/2006

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
1901	1901 North Roselle Road Suite 450 RM 4032 Schaumburg, IL 60195 County: Cook	N/A	N/A - Uses 3PL DEA	08-057-9617	No	(847) 908-1600	(847) 908-1601

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License	
Jerry C. Webb	[redacted]King Avenue East Dundee, IL 60118	EVP of Global Operations	No	[redacted]	[redacted]	[redacted]	*All States*

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Que Pharma Inc.	251 Little Falls Dr. Wilmington, DE 19808	N/A	100	N/A	92-2844630	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License	
Jerry C. Webb	[redacted]King Avenue East Dundee, IL 60118	EVP of Global Operations	No	[redacted]	[redacted]	[redacted]	*All States*
Kara B Venegas	[redacted]Bristol Ct. , Lake County Lincolnshire, IL 60069	VP Controller		[redacted]	[redacted]	[redacted]	
Donald Ray Bullock	[redacted]W. Ruhl Road Palatine, IL 60074	Executive Vice President of Sales and National Accounts	No		[redacted]	[redacted]	
Peter Kaemmerer	[redacted] Wabash Avenue Unit [redacted] Chicago, IL 60611	CEO	No	[redacted]	[redacted]	[redacted]	
Jeffrey Greve	[redacted]Woodridge Lane Buffalo Grove, IL 60089	Executive Vice President Global Finance	No	[redacted]	[redacted]	[redacted]	

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Corporation Service Company (CSC)			

Company Particulars

Sagent Pharmaceuticals

3PLS Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Eversana Life Science Services, LLC	4580 Mendenhall Road Memphis, TN 38141					

WY Good Standing

STATE OF WYOMING
Office of the Secretary of State

I, CHUCK GRAY, Secretary of State of the State of Wyoming, do hereby certify that according to the records of this office,

Sagent Pharmaceuticals

is a

Profit Corporation

formed or qualified under the laws of Wyoming did on **May 5, 2006**, comply with all applicable requirements of this office. Its period of duration is Perpetual. This entity has been assigned entity identification number **2006-000514030**.

This entity is in existence and in good standing in this office and has filed all annual reports and paid all annual license taxes to date, or is not yet required to file such annual reports; and has not filed Articles of Dissolution.

I have affixed hereto the Great Seal of the State of Wyoming and duly generated, executed, authenticated, issued, delivered and communicated this official certificate at Cheyenne, Wyoming on this 5th day of May, 2023 at 9:39 AM. This certificate is assigned ID Number 060643319.

Chuck Gray

Secretary of State

Notice: A certificate issued electronically from the Wyoming Secretary of State's web site is immediately valid and effective. The validity of a certificate may be established by viewing the Certificate Confirmation screen of the Secretary of State's website https://wyobiz.wyo.gov and following the instructions displayed under Validate Certificate.

Registrant Verification For

EVERSANA LIFE SCIENCE SERVICES, LLC

DEA Number:	RD0205333
Expiration Date:	08/31/2023
Additional Company Info:	
Registered Address:	4580 S MENDENHALL RD
City:	MEMPHIS
State:	TN
Zip Code:	38141
Business Activity:	DISTRIBUTOR
DEA Schedules:	2 2N 3 3N 4 5
Payment Indicator:	Paid
Registration Status:	ACTIVE
Date of Verification:	03/30/2023

Department of Justice Drug Enforcement Administration Diversion Control Division

This Primary Source Verification was obtained from the Drug Enforcement Administration's Controlled Substance Act Registrant Database.

GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	0736295
For	NV Pharmaceutical Wholesaler Bond
Dated effective	09/09/2020 (MONTH, DAY, YEAR)
Executed by	Sagent Pharmaceuticals, Inc., as Principal, (PRINCIPAL)
And by	Harco National Insurance Company, as Surety, (SURETY)
And in favor of	Nevada State Board of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Principal Name	Sagent Pharmaceuticals, Inc.	Sagent Pharmaceuticals

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective 09/09/2022
(MONTH, DAY, YEAR)

Signed and Sealed 04/03/2023
(MONTH, DAY, YEAR)

Sagent Pharmaceuticals
PRINCIPAL
BY

TITLE

Harco National Insurance Company
SURETY
BY

Tamara Bowser

Tamara Bowser, ATTORNEY-IN-FACT

POWER OF ATTORNEY

HARCO NATIONAL INSURANCE COMPANY

INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

Bond # 0736295

Principal Sagent Pharmaceuticals

Obligee Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS That **HARCO NATIONAL INSURANCE COMPANY** a corporation organized and existing under the laws of the State of Illinois and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey and having their principal offices located respectively in the cities of Rolling Meadows Illinois and Newark New Jersey, do hereby constitute and appoint

Tamara Bowser

their true and lawful attorneys-in-fact to execute, seal and deliver for and on its behalf as surety any and all bonds and undertakings contracts of indemnity and other writings obligatory in the nature thereof which are or may be allowed required or permitted by law statute rule regulation contract or otherwise and the execution of such instrument(s) in pursuance of these presents shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply to all intents and purposes as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices

This Power of Attorney is executed, and may be revoked pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December 2018

RESOLVED that (1) the Chief Executive Officer President, Executive Vice President, Senior Vice President Vice President or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto bonds undertakings recognizances contracts of indemnity and other written obligations in the nature thereof or related thereto and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation: and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking recognizance contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2021

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December 2021 before me came the individual who executed the preceding instrument, to me personally known and being by me duly sworn said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** that the seals affixed to said instrument are the Corporate Seals of said Companies that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

SHIRELLE A. OUTLEY NOTARY PUBLIC NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney with the originals on file in the home office of said companies, and that the same are correct transcripts thereof and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect

IN TESTIMONY WHEREOF, I have hereunto set my hand this 3rd day of April, 2023

Irene Martins Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Sagent Pharmaceuticals

Pharmacy/Wholesaler License # (if applicable): WH02615

Physical Address: 1901 North Roselle Road, Suite 450 RM 4032

City: Schaumburg State: IL Zip: 60195

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.sagentpharma.com

Licensing Company Email: SAG@slsny.com

Section 2: Personal Information

First: Jerry Middle: C. Last: Webb

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] King Avenue

City: East Dundee State: IL Zip: 60118

Telephone: [redacted] Email: jwebb@sagentpharma.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Virginia Commonwealth University		1979 - 1981	
Address	**City**	**State**	**Zip**
907 Floyd Ave	Richmond	VA	23284
Diploma/Degree obtained, if any			
Graduate Studies, Chemistry			

School Name		From - To (MM/YY – MM/YY)	
University of Arkansas		1973 - 1977	
Address	**City**	**State**	**Zip**
1125 West Maple Street	Fayetteville	AR	72701
Diploma/Degree obtained, if any			
Bachelors of Science, Biology			

School Name		From - To (MM/YY – MM/YY)	
Mountain Home High School		1969 - 1973	
Address	**City**	**State**	**Zip**
500 Bomber Blvd	Mountain Home	AR	72653
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2018 - present	[redacted]King Avenue	East Dundee	IL	60118
2006 - 2018	[redacted]Sycamore Springs Pl.	Mountain Home	AR	72653
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Sagent Pharmaceuticals			From - To (MM/YY – MM/YY): 09/2019 - Currently
Business Address: 1901 North Roselle Road, Suite 450 RM 4032	City: Schaumburg	State: IL	Zip: 60195
Phone: (847) 908-1600	Title: EVP of Global Operations		Number of Employed Hours: ~ 7,453 hrs
Description of Duties: Executive responsibilities for Operations, which includes Manufacturing, Quality, Regulatory Affairs, Product Development, and full P&L for 4 facilities: a virtual manufacturer, a 503B outsourcing facility, and 2 sterile injectable (vial) facilities. Sagent is a major generic drug provider for the US market, ($350M in sales) acquiring finished sterile injectables from 24 different contract manufacturing organizations across the globe.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Jerry C. Webb, **certify that as the designated representative for**

Sagent Pharmaceuticals,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JW I am at least 21 years of age;
3. JW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jerry C. Webb

Print Name (First, Last)

JCWebb

Original Signature (electronic, copies or stamps not accepted)

5/9/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jerry C. Webb

Print Name (First, Last)

J Webb

Original Signature (electronic, copies or stamps not accepted)

5/9/2023

Date

Please have this section completed in the presence of a Notary Public.

State of ILLINOIS, ss. County of DuPage

I, Amy Sorapuru, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

J Webb

Original Signature Jerry C Webb

5/9/2023

Date

Subscribed and Sworn to before me this 9 day of May 2023

Amy L Sorapuru

Notary Public Signature

AMY L. SORAPURU
OFFICIAL SEAL
Notary Public, State of Illinois
My Commission Expires
August 26, 2025
Seal

Last Name	First Name	Job Title Description
Addagulla	Swapna	Director, Product Development
Adewumi	Rebecca	Operations Information Analyst, Supply Chain
Agnello	Nicole	Senior Analyst, IT
Alexander	Irene	Senior Manager, Procurement/Logistics
Alfaro	Violeta	Sr. Associate, Regulatory Affairs - Labeling
Anderson	Kylie	Analyst, Contracting
Bagri	Jojhar	Senior Analyst, Commercial Business
Balla	Kelly	Project Manager, Commercial
Barouni	Eleftheria	Specialist, Quality Assurance - Batch Release
Batey	Stephanie	Regional Business Manager
Beisler	Amanda	Regional Business Manager
Belen	Rey	Specialist, Quality Assurance -Change Control
Bielinska	Magdalena	Specialist, Quality Assurance - Batch Release
Bjork	Jay	Urology Business Manager
Blasik	Matthew	National Sales Manager - Urology
Brahmbhatt	Rushi	Sr. Associate, Regulatory Affairs -Publishing
Buird	Brian	Regional Business Manager
Bullock	Donald	EVP , Sales and National Accounts
Caldwell	Iwona	Director, Accounting
Cook	Benjamin	Urology Business Manager
Cudia	Joyce	Analyst, Supply Chain - Outbound
Daigle	Nancy	IDN Manager, Pharmacy Solutions
DeNicolo	Jessica	API Technical Manager
Decowski	Peter	Business Intelligence Administrator/Developer
DiBrizzi	Debbie	Director, Project Management
Eames	Kevin	Urology Business Manager
Eisele	Janell	Senior Director, National Accounts
Elakatt	Jumey	Sr Specialist, Quality Systems
Emling	Timothy	Sr. Director, Regional Sales- East
Engelhardt	Shelly	Manager, Regulatory Affairs - Labeling
Epstein	Eileen	Regional Business Manager
Falk	Megan	Senior Manager, Regional Sales Training
Fisher	Yelena	VP, Global Alliance Management
Flugum	Greg	Sr. Development Scientist, Analytical
Fox	Chad	Regional Business Manager
Fox	Thomas	Urology Business Manager
Fusha	Jana	Validated Systems Analyst, IT
Gajera	Ronakkumar	Specialist, Quality Assurance -Change Control
Gavrilyuk	Vitaliy	Senior Manager, Quality Engineering
Ghneim	Lana	Associate, Regulatory Affairs - Labeling
Gibson	Amy	Sr Manager, Sales Ops - Pharmacy Solutions
Greve	Jeffrey	EVP, Global Finance
Grover	Kazuhiro	VP, Integration Project Management
Hamilton	Amanda	Operations Information Analyst, Supply Chain
Hammond	Kevin	IDN Manager, Pharmacy Solutions
Hansen	Elene	Sr Associate, RA - Post Approval
Hartmann	Ronald	VP, Pharmacy Solutions
Hedge	Michael	National Sales Manager, Pharmacy Solutions

Herman	Robert	Regional Business Manager
Hoehn	Kara	Director, Human Resources
Horger	James	VP, Quality and Regulatory Compliance
Hussaini	Khudija	Senior Manager, RA - Publishing
Iuni	Gina	Urology Business Manager
Jackson	Brynn	Regional Business Manager
Jeffries	Jason	TrackWise Application Developer
Jensen	Peter	VP, Financial Planning
Johnson	Linda	Senior Administrator
Johnson	Michelle	Financial Systems Analyst, IT
Johnson	Michelle	Regional Business Manager
Johnston	Clayton	Regional Business Manager
Kaemmerer	Peter	Chief Executive Officer
Kean	James	Regional Business Manager
Keilhack	Thomas	Director, Tax
Kemov	Stanislav	Optimization Analyst, Supply Chain
Kessenich	Charles	Regional Business Manager
Kim	Yumi	Manager, RA - Product Development
Knudson	Elizabeth	Specialist, Quality Assurance -Change Control
Lazar	Erin	Senior Analyst, Tax
Lewis	Susan	VP, Regulatory Affairs
Lim	Douglas	Software Engineer
Lockhart	Angela	Urology Business Manager
Lope	Amy	Senior Manager, Marketing Communications
Love	Michael	Regional Business Manager
Lust	Elizabeth	IDN Manager, Pharmacy Solutions
Maraone	Steven	Senior Manager, Marketing
Mark	William	Sr Manager, IT Infra Strategy and Delivery
McClellan	Katherine	Specialist, Quality Systems
McClory	Amy	Sr Director, Marketing
McKenny	Wanda	VP, Human Resources
Michalik	Mariusz	Customer Service Analyst, Pharmacy Solutions
Miller	Christina	Mgr, Quality Systems & Regulatory Compliance
Morano	John	Technician, IT Support
Morrison	Mary	Regional Business Manager
Murray	Dale	Network Engineer
Nemec	Jeanne	Associate, Regulatory Affairs - Labeling
Nowels	Bradley	VP, Sales & National Accounts - PS
Ortmann	Brad	Senior Manager, Financial Planning
Pabis	Magdalena	Sr Associate, RA - Post Approval
Parker	Wonderlyn	Associate Director, Contracting
Patel	Komal	Specialist, Quality Assurance - Batch Release
Perez	Anali	Coordinator, Contracts
Perez	Penny	Urology Business Manager
Peterman	Richard	Sr. Director Contracting, Pricing & Analytics
Petzke	Jennifer	Regional Business Manager
Pfeiffer	Michael	Project Manager, Commercial
Quesinberry	Robert	VP, Operations Specialty Pharmaceuticals
Rahman	ATM	Analyst, JDE Manufacturing Systems

Rahman	Sajid	Director, Quality Operations
Ram	Edward	Senior Director, Supply Chain
Rivera	Yolanda	Coordinator, Accounts Payable
Roberts	Amber	Dir, Program Management & Global API
Rosanova	Isabella	HR Assistant/Receptionist
Santiago	Vanessa	Area Sales Manager
Satoh	Tomonori	Integration Liason/Quality Engineer
Schafer	Grace	Coordinator, Marketing
Schier	Eric	Senior Director, Regional Sales West
Schipp	Edward	VP, IT
Schwartz	Renee	Specialist, Quality Assurance - Batch Release
Scott	Heather	Operations Information Analyst, Supply Chain
Segreti	Michelle	Manager, Accounting
Shanmugam	Balaji	Associate Director, Pro Dev & Pro Mgt
Shareef	Zaynah	Associate, Regulatory Affairs - Publishing
Simms	Cynthia	Administrator, IT Support
Simpson	Rebecca	Global Training and Systems Manager
Sorapuru	Amy	Senior Specialist, Payroll
Stone	Stephen	VP, Trade Relations
Szurgot	Robert	VP, Specialty Pharmaceuticals
Szwec	Janice	Manager, Product Quality
Tart	Benny	Regional Business Manager
Thompson	Marie	Finance Specialist
Tinkoff	Cynthia	Director, Medical Affairs
Trusler	Jason	IDN Manager, Pharmacy Solutions
Vega	Raymond	IDN Manager, Pharmacy Solutions
Venegas	Kara	VP, Controller
Vogt	Kimberly	Director, Quality Systems
Vuligonda	Narender	Manager, Regulatory Affairs -Post Approval
Webb	Jerry	EVP, Global Operations
Weiss	Margaret	Director, Supply Chain Planning
Welch	Susan	Regional Business Manager
Welling	Niels	VP, Program Management
Widanapathirana	Lakmini	Sr Scientist, Prod Dev - Formulations
Wilburth	John	Urology Business Manager
Wilson	David	Regional Business Manager
Woods	Madeline	Urology Business Manager
Young	George	Quality Consultant
Zawadzki	Christopher	Sr. Manager, RA - Product Dev & Post Approval

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: UPS Supply Chain Solutions, Inc.

Physical Address: 2235 Route 322, Suite 100

City: Woolwich Township State: NJ Zip: 08085

Mailing Address (if different from physical address): same as physical address

City: _____ State: _____ Zip: _____

Telephone: 856-351-6623 Website: www.ups.com

Name of Designated Representative (DR): Roger McLaughlin

Licensing Company Email: ralicensing@ups.com DR Email: rogermclaughlin@ups.com

Entities the Wholesaler will Serve (✔ all applicable)	Products to be Handled or Wholesaled (✔ all applicable)	Type of Wholesaling (✔ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
▣ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Prescription Human & Veterinary drugs Over the Counter (OTC) Human & Veterinary drugs	☐ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge See Attachment #1				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

24 Jul 2023
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Medtronic
Address: 710 Medtronic Parkway City: Minneapolis State: MN Zip: 55432
Name: Medtronic Logistics, LLC
Address: 4340 Swinnea Rd City: Memphis State: TN Zip: 38118
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

N/A Date 02-Aug-2023

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): United Parcel Service of America, Inc.
Corporation/Organization Name: UPS Supply Chain Solutions, Inc.
Mailing Address: 12380 Morris Road
City: Alpharetta State: GA Zip: 30005
Telephone: 678-746-4100 Email: ralicensing@ups.com
Contact Person Name: Felix X. Chang

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A Date 02-Aug-2023

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

UPS Supply Chain Solutions, Inc.
Facility Name

Roger McLaughlin
Print Name of Authorized Person Submitting Application

Original ~~signature~~ of Authorized Person (copies or stamps not accepted)

24 Jul 2023
Date

Board Use Only	Date Received: 8/5/23	Amount: 1000-CK-1112772

Attachment #1

Disciplinary Statement
UPS Supply Chain Solutions, Inc. ("UPS SCS")

WHOLESALE LICENSE

Matters Related to Colorado Order
1645 Satellite Blvd, Duluth, GA

Final
As previously disclosed by UPS Supply Chain Solution, Inc. (UPS SCS), to your agency in 2010, the Colorado Board of Pharmacy's Stipulation and Final Agency Order ("Colorado Order") was effective October 18, 2010, with regard to UPS SCS's Duluth, GA facility's Colorado Out-of-State Wholesaler License # WHO-7462. UPS SCS's Duluth facility did not file Colorado's required notice of change of Designated Representative within Colorado's required 14-day timeframe to file such notice. UPS SCS implemented corrective actions and has successfully completed the terms of the Colorado order. Please note, UPS SCS's Colorado Out-of-State Wholesaler License # WHO-7462 was not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Colorado Case No. 2011-000273 documentation related to the Colorado Order on file with the UPS SCS Regulatory Affairs Department.

Final
On November 15, 2011, UPS SCS informed your agency of the Iowa Board of Pharmacy's (IBoP) action concerning Iowa Wholesale Drug License #5820 and which became effective November 11, 2011. This Iowa Stipulation and Consent Order (the "Iowa Order") relates to the Colorado Order and the untimely filing of notice regarding the Colorado Order to the IBoP. UPS SCS has successfully completed the terms of the Iowa Order and Iowa Wholesale Drug License #5820 has not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Iowa Case No. 2010-162 documentation on file with the UPS SCS Regulatory Affairs Department. Note: This Iowa matter is a spin-off of the Colorado matter summarized above. It is based on the same underlying facts that gave rise to the Colorado matter. It is **not** based on an independent set of facts.

Final
On October 18, 2013, UPS SCS informed your agency of the Consent Order and Stipulation between the Michigan Board of Pharmacy (BOP) and UPS SCS based on the underlying Colorado matter summarized above, which was executed by the Michigan BOP on October 9, 2013 (the "Michigan Order"). As previously disclosed to you, pursuant to this Consent Order, UPS SCS paid a fine of two thousand five hundred dollars. The Consent Order and Stipulation specifically provided that "no patient safety issues were involved," and the BOP did not impose any other penalty. UPS SCS's Michigan licenses have not been restricted, modified, revoked, or limited in any way. Note: The Michigan Order is directly related to the Colorado matter summarized above. It is based on the same underlying facts that gave rise to the Colorado matter. It is not based on an independent set of facts.

PHARMACY LICENSE

Matters Related to Kentucky Agreed Orders
1860 Outer Loop Road, Louisville, KY

Final

UPS SCS dispenses medical devices, including diabetes-related pumps, to consumers from its Kentucky licensed pharmacy facility. Not all states recognize the Durable Medical Equipment or Home Medical Equipment provider category for entities that dispense medical devices rather than drugs. Those states that do not recognize these categories require a non-resident or out of state pharmacy permit for dispensing medical devices. Accordingly, UPS SCS obtained a home-state pharmacy permit in Kentucky and numerous non-resident pharmacy permits and DME/HME permits in other states. On September 12, 2012, the Kentucky Board of Pharmacy ("KYBoP") and UPS SCS executed final Agreed Orders relating to minor violations under Kentucky Administrative Regulations 2:270 and Kentucky Revised Statutes Sec. 315.121(6) in connection with late filing of pharmacy technician registrations at UPS SCS's Louisville, Kentucky facility (the "Kentucky Orders"). UPS SCS and the KYBoP agreed to address the Kentucky Orders informally by entering in the aforementioned Agreed Orders in lieu of the KYBoP filing a formal complaint. UPS SCS self-reported this action to your agency on September 18, 2012. UPS SCS takes this and all regulatory matters seriously and has implemented corrective action. Moreover, UPS SCS has instituted internal safeguards to ensure that applicable regulatory compliance is maintained in the future. UPS SCS's Kentucky pharmacy license (Kentucky Pharmacy License #P07277) remains current and in good standing and was not and has not been restricted, modified, revoked, or limited in any way.

Final

On May 14, 2013, UPS SCS informed your agency of the Texas Board of Pharmacy's (TXBoP) action concerning UPS SCS Texas Class E Nonresident Pharmacy License #26160 and which became effective May 7, 2013. As already disclosed to you, on May 14, 2013, the Texas Board of Pharmacy (TXBoP) and UPS SCS executed a final Agreed Board Order (the "Texas Order") relating to the above-mentioned Kentucky Pharmacy License Agreed Orders. Pursuant to the Texas Agreed Board Order, the TXBoP reprimanded UPS SCS's Nonresident Pharmacy License. The Texas Board of Pharmacy did not levy a fine or any other penalty on the License. The License was not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Texas Agreed Board Order # L-13-004 on file with the UPS SCS Regulatory Affairs Department. Note: The Texas Order is directly related to the Kentucky pharmacy license matter summarized above. It is based on the same underlying facts that gave rise to the Kentucky matter. It is **not** based on an independent set of facts.

Final

On April 22, 2014, UPS SCS informed your agency of the Consent Order and Stipulation between the Michigan Board of Pharmacy (BOP) and UPS SCS based on the Kentucky Order summarized above, which was adopted by the Michigan BOP on April 9, 2014 (the "Michigan Order"). As previously disclosed to you, pursuant to this Consent Order, UPS SCS paid a fine of two hundred fifty dollars. The Consent Order and Stipulation specifically provided that "no patient safety issues were involved," and the BOP did not impose any other penalty. UPS SCS's Michigan licenses have not been restricted, modified, revoked, or limited in any way. Note: The Michigan Order is directly related to the Kentucky matter summarized above. It is based on the same underlying facts that gave rise to the Kentucky matter. It is not based on an independent set of facts.

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2011-000273

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG WHOLESALER REGISTRATION OF UPS SUPPLY CHAIN SOLUTIONS, INC., REGISTRATION NO. WHO-7462,

Respondent.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and UPS Supply Chain Solutions, Inc. ("Respondent") to resolve all matters pertaining to Board Case Number 2011-000273, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent, its registration as a non-resident prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Respondent was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on December 8, 2008, being issued registration number WHO-7462, and has been so registered at all times relevant to this disciplinary action.

3. Respondent does not contest these findings and hereby waives any further proof in this proceeding before the Board regarding the following findings.

4. Respondent failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, forty-six (46) days transpired between the date the previous designated representative ceased the position and the date the application and fee were received.

5. Respondent states and affirms that it was never without the proper oversight of a designated representative but failed to timely submit the change application to the Board because of human error. Further, Respondent states and affirms that it has identified the cause of the error and has implemented corrective actions.

6. Respondent does not contest that the conduct described above constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drug.

12-22-802. Wholesaler license requirements

(2)(b) An applicant for a license shall pay any reasonable fee required by the accreditation body or the board and comply with any rules promulgated by the board;

(3) (VII) The name of the applicant's designated representative for the facility, the fingerprints of the designated representative, and a personal information statement for the designated representative that includes information as required by the board, including but not limited to the information in subsection (5) of this section; and

(5)(i) Update all of the information required in this part 8 whenever changes occur.

Regulation 15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by CRS 12-22-803. And

(9) Wholesalers that distribute animal drugs exclusively are exempt from the requirements of 15.01.11(a)(8).

(b) Changes in any information in section 15.01.11 shall be submitted to the Colorado Board of Pharmacy within fourteen calendar days thereof.

Regulation 15.01.14 Change of name, location, or ownership, or designated representative

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

7. The Board finds and concludes, and Respondent agrees, that based upon the above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-22-125.2(5), C.R.S., Respondent shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Respondent understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent submits this signed Final Agency Order to the Board.

9. **Compliance.** Respondent shall submit all future applications detailing a change in designated representative and fee to the Board within fourteen (14) days of the previous designated representative ceasing the position.

10. **Other Requirements.** Respondent acknowledges and agrees that, as a condition of this Final Agency Order, Respondent shall:

a. promptly pay all Respondent's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Respondent enters into this Final Agency Order freely and voluntarily, whether or not Respondent has consulted with legal counsel. Respondent acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges;

c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

d. to appeal this Final Agency Order.

Respondent freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent to the sanctions imposed herein.

12. **Acknowledgments.** Respondent has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent has consulted with legal counsel, that Respondent understands its legal consequences and agrees that none of its terms or conditions are unconscionable. Respondent is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent to take all appropriate steps to comply fully with this Final Agency Order. Respondent acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Effective Date.** This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent

_____ Dated: 10/1/10
Authorized Representative / Title

Subscribed and sworn to before me in the County of Fulton, State of Georgia, this 1 day of October, 2010 by Daniel Silvernale, authorized representative of UPS Supply Chain Solutions, Inc.

My commission expires: Sept 21, 2013

DALE BANKS NOTARY PUBLIC FULTON COUNTY, GEORGIA MY COMMISSION EXPIRES SEPT 21 2013

Notary Public

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 18th day of October, 2010.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 29th day of September 2010, addressed as follows:

UPS Supply Chain Solutions, Inc.
Attn: Joy Roberts
1645 Satelite Blvd.
Duluth, GA 30097
(via email: joyroberts@ups.com)

/s/ John Steele
John C. Steele

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 18th day of October 2010, addressed as follows:

UPS Supply Chain Solutions, Inc.
Attn: Joy Roberts
1645 Satelite Blvd.
Duluth, GA 30097

Catie Ranguist
Agent of the Board

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	Case No. 2010-162
Wholesale Drug License of	)	
UPS SUPPLY CHAIN	)	**STIPULATION**
SOLUTIONS, L.L.C.,	)	**AND CONSENT**
License No. 5820	)	**ORDER**
Respondent	)	

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), The Iowa Board of Pharmacy (hereinafter, the "Board") and UPS Supply Chain Solutions, L.L.C. (hereinafter, "Respondent"), have agreed to settle a contested case currently on file with the Board. The Statement of Charges filed against Respondent on September 13, 2011, and the licensee disciplinary proceeding related to the charges shall be resolved without a hearing, as the Board and Respondent have agreed to the following Stipulation and Consent Order:

1. Respondent's license to operate a wholesale drug business was renewed November 19, 2010, as evidenced by Wholesale Drug License Number 5820, recorded in the permanent records of the Board.

2. Wholesale Drug License Number 5820 issued to and held by Respondent is current and in force until December 31, 2011.

3. The Board has jurisdiction over the parties and the subject matter herein.

4. A Statement of Charges was filed against Respondent on September 13, 2011. The Statement of Charges alleges Respondent violated the pharmacy laws of the State of Colorado and failed to timely report the violation to the Board.

5. The records of the investigation indicate that Respondent has successfully

RECEIVED
OCT 2 8 2011
IOWA BOARD OF PHARMACY

completed the terms of the Colorado Stipulation and Final Agency Order.

6. Respondent has chosen not to contest the allegations set forth in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.

7. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall be assessed a civil penalty in the amount of $1000. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa and mailed to the executive director of the Board within 10 days after Respondent's receipt of notice of the Board's approval of this Stipulation and Consent Order. All civil penalty payments shall be deposited into the State of Iowa general fund. Upon the Board's receipt of the civil penalty, this disciplinary proceeding shall be concluded without further order of the Board.

8. The Board does not mandate any further corrective action.

9. Respondent agrees to obey all federal and state laws, rules, and regulations substantially related to the operation of a wholesale drug business.

10. Should Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate action to revoke or suspend Respondent's Iowa license to operate a wholesale drug business or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 Iowa Administrative Code § 36.1.

11. This Stipulation and Consent Order is the resolution of a contested case. By entering into this stipulation, Respondent waives all rights to a contested case

hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

12. This Stipulation and Consent Order is a proposed settlement subject to approval by a majority of the full Board. If the Board fails to approve this Stipulation and Consent Order, it shall be of no force or effect to either party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

13. The Board's approval of this Stipulation and Consent Order shall constitute a FINAL ORDER of the Board in a disciplinary action.

This Stipulation and Consent Order is voluntarily submitted by UPS Supply Chain Solutions, L.L.C., to the Iowa Board of Pharmacy for its consideration on this 31st day of October 2011.

UPS SUPPLY CHAIN SOLUTIONS, L.L.C.,
Respondent
By DANIEL SILVERNALE, Vice President, Finance and Healthcare Compliance

Subscribed and sworn to before me by Daniel Silvernale, who has stated to me that he is the VP, Finance - Healthcare Compliance of UPS Supply Chain Solutions, L.L.C., and is authorized to sign this Stipulation and Consent Order on behalf of UPS Supply Chain Solutions, L.L.C., on this 31st day of October 2011.

LINDA P BOWDEN NOTARY PUBLIC FULTON COUNTY, GEORGIA MY COMMISSION EXPIRES AUGUST 30, 2015

Linda P. Bowden
NOTARY PUBLIC IN AND FOR THE STATE OF GEORGIA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on this 11th day of November 2011.

SUSAN FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

UPS Supply-settle 9-11.doc

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

UPS SUPPLY CHAIN SOLUTIONS INC.
License Numbers: 53-06-002764
53-15-027264

File Number: 53-10-118763
CONSENT ORDER AND STIPULATION

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on September 23, 2011, charging UPS Supply Chain Solutions Inc., hereafter Respondent Wholesaler, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent Wholesaler neither admits nor denies the facts alleged in the Complaint dated September 23, 2011, but agrees that the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support of the allegations; and

WHEREAS, the Disciplinary Subcommittee reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now, therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true for the purposes of this Consent Order and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly,

IT IS HEREBY ORDERED that for the cited violation of the Public Health Code, Respondent Wholesaler is FINED in the amount of $2,500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Bureau of Health Care Services, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-10-118763.**

IT IS FURTHER ORDERED that in the event Respondent violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R338.1632 and section 16221(h) of the Public Health Code, supra.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 10/9/13

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. Respondent Wholesaler neither admits nor denies the facts alleged in the Complaint dated September 23, 2011, but agrees that the Disciplinary Subcommittee shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support thereof.

2. Respondent Wholesaler understands and intends that by signing this Stipulation, Respondent Wholesaler is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Wholesaler is waiving the right to appear with an attorney and such witnesses as Respondent Wholesaler may desire to present a defense to said charges.

3. Factors taken into consideration in the formulation of the within Consent Order are as follows:

> Subsequent to the adverse actions, Respondent Wholesaler submitted information about steps implemented by Respondent Wholesaler, in the state of Colorado, to ensure that this type of action will not recur, including establishing strategy groups and tactical teams which ensure regulations are met and all locations are compliant. Respondent Wholesaler indicated that a single manager coordinates the local teams to ensure all information is consistently distributed. No patient safety issues were involved in Respondent Wholesaler's actions.
>
> Respondent Wholesaler was cooperative in resolution of this matter. Respondent Wholesaler has been licensed in the state of Michigan since 2008 and has no other complaints against its license.

4. Patricia A. Smeelink, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the foregoing Consent Order.

5. The foregoing Consent Order is approved as to form and substance by Respondent Wholesaler and the Department and may be entered as the final order of the Disciplinary Subcommittee in said cause.

CONTINUED ON NEXT PAGE

6. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Wholesaler and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department of Licensing and
Regulatory Affairs

Dated: 8-7-13

AGREED TO BY:

Daniel Silvernale, Vice President
Authorized Representative for
UPS Supply Chain Solutions Inc.
Respondent Wholesaler

Dated: 6/28/13

Approved as to form by:

Max R. Hoffman, Jr. by Mary Ruwitz (P67550)
Attorney for Respondent Wholesaler

This is the last page of a Consent Order and Stipulation in the matter of UPS Supply Chain Solutions Inc., File Number 53-10-118763, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of five pages, this page included.

BH/PB

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 11-0062A

IN RE: PHARMACY PERMIT NO. P07277 HELD BY UPS SUPPLY CHAIN SOLUTIONS, INC.

AGREED ORDER

Come the parties, the Kentucky Board of Pharmacy ("the Board") and UPS Supply Chain Solutions, Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned pharmacy permit no. P07277.

(2) (a) An investigation of Respondent's pharmacy revealed that numerous technicians worked on various dates in 2010, without being timely registered with the Board. The Respondent assured the technicians that it would take care of ensuring they were properly registered. Respondent subsequently properly registered the technicians. Nonetheless, the Respondent was in violation of KRS 315.121(1)(g).
(b) The technicians that worked without being appropriately registered with the Board were: Chelsea Hutchins, Alisha Netherton, Brittany Barger, Lauren Fisher, Karen Millay, Meghan Rae Yates, Michelle Green, Amanda Gracie, Faith Joway, Taylor Parker, Manoj Bhandari, Jonathan Pruitt, Whitney Wilson, Dustin R. Harris, Fabrice Mboya, Lauren Howell, Coco Boards, Benjamin Bickett, Jessica Horlander, Jason Cope, William Robert Bennett Jr, Thomas Hicks, Nimo Muhumed Mohamud, Harold Keith Newcom, Rodrick G Parrish, Johnathan Borho, Antoya Blackburn, Jonathan Graves, and Leilani Roach.
(c) The above facts subject Respondent to discipline pursuant to KRS 315.121(1) (h).

(3) Respondent takes compliance with KRS 315 seriously and as part of its corporate compliance program presented to the Board a detailed corrective action plan intended to ensure on-going compliance with KRS 315.121(1)(g).

(4) This matter is considered a violation pursuant to KRS 315.121(6) and 201 KAR 2:270.

(5) The Board and Respondent have agreed to address this matter informally by

entering into this Agreed Order, in lieu of the Board filing a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $2900.00 ($100 per technician) payable by September 5, 2012. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that Respondent fully understands those rights, and that Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Joel Thornbury, President
Kentucky Board of Pharmacy

9/12/12
Date

UPS Supply Chain Solutions, Inc.
Respondent

8/14/12
Date

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 11-0061A

RECEIVED
KY BOARD OF PHARMACY
2012 AUG 29 P 1:18

IN RE: PHARMACY PERMIT NO. P07277 HELD BY UPS SUPPLY CHAIN SOLUTIONS INC.

AGREED ORDER

Come the parties, the Kentucky Board of Pharmacy ("the Board") and UPS Supply Chain Solutions Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned pharmacy permit no. P07277.

(2) (a) An investigation of Respondent's pharmacy revealed that Sherry Rich worked as a pharmacy technician from April 1, 2010 through November 19, 2010, without being timely registered with the Board. The Respondent assured Ms. Rich that it would take care of ensuring she was properly registered. Respondent subsequently properly registered Ms. Rich with the Board. Nonetheless, the Respondent was in violation of KRS 315.121(1)(g).

(b) The above facts subject Respondent to discipline pursuant to KRS 315.121(1) (h).

(3) Respondent takes compliance with KRS 315 seriously and as part of its corporate compliance program presented to the Board a detailed corrective action plan intended to ensure on-going compliance with KRS 315.121(1)(g).

(4) This matter is considered a violation pursuant to KRS 315.121(6) and 201 KAR 2:270.

(5) The Board and Respondent have agreed to address this matter informally by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $125.00 payable by September 5, 2012. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky

Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that Respondent fully understands those rights, and that Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Joel Thornbury, President
Kentucky Board of Pharmacy

8/12/12
Date

UPS Supply Chain Solutions Inc.
Respondent

8/14/12
Date

AGREED BOARD ORDER #L-13-004

RE: IN THE MATTER OF
UPS SUPPLY CHAIN SOLUTIONS, INC.
(CLASS E NONRESIDENT
PHARMACY LICENSE #26160)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy ("Board") the matter of Class E nonresident pharmacy license number 26160 issued to UPS Supply Chain Solutions, Inc. ("Respondent"), 1860 Outer Loop Road, Louisville, Kentucky 40219.

On September 8, 2012, Respondent self-reported to the Board the entry of two Agreed Orders by the Kentucky Board of Pharmacy, as described below in Counts (1) and (2).

By letter dated February 22, 2013, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Section 565.002 (a)(13); and Section 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011), as alleged in the Counts below.

The conduct described in the Kentucky Board of Pharmacy's Agreed Orders is substantially similar to conduct described in:

> Section 565.002(a)(3); and Section 568.002(a) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011); and
>
> Section 297.3(a)(1) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2012).

COUNTS

(1) On or about September 12, 2012, the Kentucky Board of Pharmacy entered an Agreed Order in case number 11-0061A against the Kentucky pharmacy permit number P07277 held by UPS Supply Chain Solutions, Inc. The Order was based on allegations that from April through November of 2010, the pharmacy allowed an unregistered individual to perform duties of a pharmacy technician without being registered with the Kentucky Board of Pharmacy. The Order imposed an administrative penalty of $125.

(2) On or about September 12, 2012, the Kentucky Board of Pharmacy entered an Agreed Order in case number 11-0062A against the Kentucky pharmacy permit number P07277 held by UPS Supply Chain Solutions, Inc. The Order was based on allegations that, on various dates in 2010, the pharmacy allowed twenty-nine (29) unregistered individuals to

perform duties of a pharmacy technician without being registered with the Kentucky Board of Pharmacy. The Order imposed an administrative penalty of $2900.

An informal conference was held in the office of the Texas State Board of Pharmacy on April 2, 2013. Phillip Vowels, R.Ph., Pharmacist-in-Charge of Respondent; Sue Young, Director, Global Healthcare Compliance, for Respondent; Amy Carney, Regulatory Affairs Manager, for Respondent; Maureen O'Brien, Senior Quality Assurance Manager, for Respondent; Emily Johnson, Legal Counsel for Respondent; Hannah Heck, Legal Counsel for Respondent; and Michelle Williams, Legal Counsel for Respondent, appeared via teleconference. The informal conference was heard by a Board panel comprised of: Jeanne D. Waggener, R.Ph., Board Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin E. Arnold, General Counsel. Stacy E. Martyak, Staff Attorney, was also in attendance.

By signing this Order, Daniel Silvernale, Vice President, for and on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that Respondent's license is hereby reprimanded.

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 7th day of May, 2013.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Daniel Silvernale, Vice President of UPS Supply Chain Solutions, Inc.

APPROVED AS TO FORM:

Kerstin E. Arnold, General Counsel
Texas State Board of Pharmacy

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

UPS SUPPLY CHAIN SOLUTIONS INC.
License Number: 53-01-008968

File Number: 53-13-129412
CONSENT ORDER AND STIPULATION

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on September 27, 2013, charging UPS Supply Chain Solutions Inc., hereafter Respondent Pharmacy, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent neither admits nor denies the facts alleged in the Complaint dated September 27, 2013, but agrees that the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and argument were presented in support of the allegations; and

WHEREAS, the Disciplinary Subcommittee has reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now, therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true, for purposes of this Consent Order, and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly, IT IS HEREBY ORDERED, that for the cited violation of the Public Health Code, Respondent Pharmacy is REPRIMANDED.

IT IS FURTHER ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is FINED in the amount of $250.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909.** The fine shall be paid by check or money order made payable to the state of Michigan, and the check or money order shall clearly display the file number **53-13-129412.**

IT IS FURTHER ORDERED that in the event Respondent Pharmacy violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R 338.1632 and section 16221(h) of the Public Health Code, supra.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 4/9/14

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. Respondent Pharmacy neither admits nor denies the facts alleged in the Complaint dated September 27, 2013, but agrees that the Disciplinary Subcommittee shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support thereof.

2. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Pharmacy is waiving the right to appear with an attorney and such witnesses as Respondent Pharmacy may desire to present a defense to the charges.

3. Factors taken into consideration in the formulation of the within Consent Order are as follows:

> Respondent Pharmacy acknowledges the Kentucky Board of Pharmacy disciplinary action which precipitated the Complaint.

4. Harvey Schmidt, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in this Consent Order.

5. The foregoing Consent Order is approved as to form and substance by Respondent Pharmacy and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

CONTINUED ON NEXT PAGE

6. The foregoing proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Pharmacy and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department Licensing and
Regulatory Affairs

Dated: 1-29-14

AGREED TO BY:

UPS Supply Chain Solutions Inc.
Respondent

Dated: 1/21/14

This is the final page of a Consent Order and Stipulation in the matter of UPS Supply Chain Solutions Inc., File Number 53-13-129412, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of five pages, this page included.

PB

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
UPS Supply Chain Solutions, Inc.
2235 Route 322
Suite 100
Woolwich Township, NJ 08085
Registration Number: 3026674679
FEI Number*: 3026674679
Status: Active
Date Of Registration Status: 2023

Owner/Operator:
UPS Supply Chain Solutions, Inc.
1920 Outer Loop
Louisville, KY US 40219
Owner/Operator Number: 10038314

Official Correspondent:
Tim Bishop
1920 Outer Loop
Louisville, KY 40219
Phone: 502-6436852

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

√ verified
6/18/23

Page Last Updated: 08/14/2023
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

ATTACHMENT #2

Amy Muller

From: inspections@nabp.pharmacy
Sent: Tuesday, May 23, 2023 4:32 PM
To: RA Licensing
Cc: Roger McLaughlin
Subject: [EXTERNAL] Cleared for NABP Supply Chain Inspection - UPS Supply Chain Solutions, Inc., Woolwich Township, NJ
Attachments: Documents Required at Inspection - Advance Notification (v4).pdf

Categories: Muller

CAUTION! This email originated outside of the organization. Please do not open attachments or click links from an unknown or suspicious origin.

Dear Amy,

This notification is to inform you that UPS Supply Chain Solutions, Inc. in Woolwich Township, NJ has been cleared for its Supply Chain Inspection. **The unannounced inspection of your facility may occur any time within the next eight weeks, without notice.** This timeframe is an estimate and is subject to change pending inclement weather, a significant number of blackout dates for your facility, or other unforeseen circumstances. As a reminder of NABP's and your facility's inspection responsibilities reference the previously emailed *Follow Up Requests* communication. Please note, that any changes submitted including additional blackout dates or application changes will be subject to administrative fees and/or travel change fees, if applicable.

Attached you will find a list of items that your facility must have available during the inspection. Because it is unannounced, NABP recommends sharing the location of these documents or files with multiple staff to ensure there is sufficient awareness in the facility of the impending inspection if you, the contact, are unavailable. If these items and documents are not available, **NABP's inability to access them and complete the inspection in its entirety will be reflected in the report provided to the State Boards of Pharmacy.**

Please visit our FAQ page for information on What are the next steps after I have the inspection [nabp.pharmacy]?

Other questions can be directed to inspections@nabp.pharmacy or 847/391-4539.

Cordially,

Carla P. Aldama
Submissions Specialist, Inspection Programs
847/391-4457

National Association of Boards of Pharmacy
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy [nabp.pharmacy] | inspections@nabp.pharmacy
[facebook.com] [twitter.com]
[linkedin.com] [youtube.com]

Attachment #4

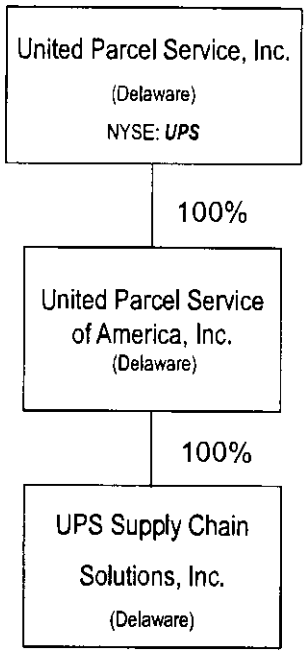
UPS Supply Chain Solutions, Inc.
12380 Morris Road
Alpharetta, GA 30005
Phone ~ (678) 746 4100
State of Incorporation: Delaware
Date of Incorporation: 8/29/88
FEIN ~ 94-3083515

Name/Title	Work Address	Work Phone	Work Fax	Email
John Bolla **President**	12380 Morris Road Alpharetta, GA 30005	(919) 455-8564	(678) 746-8650	jbolla@ups.com
Stephen Hydrick **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-4404	(678) 746-8650	shydrick@ups.com
Felix Chang **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-3452	(678) 746-8650	fxchang@ups.com
Seth Bruckner **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-7413	(678) 746-8650	sbruckner@ups.com
William M. Jacques **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-8718	(678) 746-8650	wjacques@ups.com

Parent Company Information:
United Parcel Service of America, Inc.
55 Glenlake Parkway NE
Atlanta, GA 30328
P ~ (404) 828 6022
FEIN ~ 95-1732075
State/Date of Incorporation ~ DE 5/9/30

Attachment #5

Organizational Chart
UPS SUPPLY CHAIN SOLUTIONS, INC.



THIS REPORT IS SUBMITTED IN CONFIDENCE AND APPLICABLE EXEMPTIONS TO THE FREEDOM OF INFORMATION ACT ARE TO BE INVOKED TO WITHHOLD IT FROM PUBLIC DISCLOSURE

Attachment #6

State Of Delaware

Entity Details

5/31/2023 1:56:19PM

File Number: 2170882
Entity Name: UPS SUPPLY CHAIN SOLUTIONS, INC.
Entity Kind: Corporation
Residency: Domestic
Status: Good Standing

Incorporation Date / Formation Date: 8/29/1988
Entity Type: General
State: DELAWARE
Status Date: 8/29/1988

Registered Agent Information

Name: CORPORATION SERVICE COMPANY
Address: 251 LITTLE FALLS DRIVE
City: WILMINGTON
State: DE
Phone: 302-636-5401

Country:
Postal Code: 19808

ATTACHMENT #8

State of New Jersey
DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
PO BOX 369
TRENTON, N.J. 08625-0369
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA
Commissioner

September 12, 2022

Re: Third Party Logistics Providers

Per H.R. 3204, DQSA, Uniform National Policy, Sec. 585 (b)(2) New Jersey does not regulate third-party logistics providers as wholesale distributors. To qualify for a wholesale drug or medical device registration, a facility must conduct regulated wholesale distribution or manufacturing activity as defined in N.J.A.C. 8:21-3A.3, therefore New Jersey does not issue or require registration of third party logistics providers.

Sincerely,
Eric B. Lieberman, Esq.
Project Coordinator, Wholesale Drug Project
Public Health and Food Protection Program

Attachment #9

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 5/15/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Liberty Mutual Insurance Co. Nat'l Ins Northeast
500 N 3rd St, Suite 300
Wausau, WI 54403

www.LibertyMutual.com

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS: CMeCertProduction@LibertyMutual.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Liberty Mutual Fire Insurance Company	23035
INSURER B : LM Insurance Corporation	33600
INSURER C : Liberty Insurance Corporation	42404
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
UPS SUPPLY CHAIN SOLUTIONS, INC.
12380 MORRIS ROAD
ALPHARETTA GA 30005

COVERAGES **CERTIFICATE NUMBER:** 74387002 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	✓ COMMERCIAL GENERAL LIABILITY			TB2-C21-095741-143	1/1/2023	1/1/2024	EACH OCCURRENCE	$ 1,000,000
A	☐ CLAIMS-MADE ✓ OCCUR			TB2-C21-095741-133	1/1/2023	1/1/2024	DAMAGE TO RENTED PREMISES (Ea occurrence)	$
B				TB5-C21-095741-153	1/1/2023	1/1/2024	MED EXP (Any one person)	$
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$ 1,000,000
	✓ POLICY ☐ PRO-JECT ☐ LOC						GENERAL AGGREGATE	$ 1,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$ 1,000,000
								$
A	AUTOMOBILE LIABILITY			AI2-C21-092036-583	1/1/2023	1/1/2024	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
A	✓ ANY AUTO			AI2-C21-092036-023	1/1/2023	1/1/2024	BODILY INJURY (Per person)	$
A	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS			AI2-C21-092036-943	1/1/2023	1/1/2024	BODILY INJURY (Per accident)	$
B	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY			AI5-C21-092036-873	1/1/2023	1/1/2024	PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			WC5-C25-095741-063	1/1/2023	1/1/2024	✓ PER STATUTE ☐ OTH-ER	
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [N]	N / A		WA5-C2D-095741-073	1/1/2023	1/1/2024	E.L. EACH ACCIDENT	$ 1,000,000
C	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			WA7-C2D-095741-083	1/1/2023	1/1/2024	E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: Mira Loma I facility in Nevada.

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Joshua Cleveland

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74387002 | 2-0041U5 | 1/21-1.21 - UPS SCS - All Lines - LM | Epic Celine | 5/15/2023 1:51:20 PM (GMT) | Page 2 of 2

AGENCY CUSTOMER ID: 2-004105

LOC #:

ACORD

ADDITIONAL REMARKS SCHEDULE

Page ____ of ____

AGENCY	NAMED INSURED
Liberty Mutual Insurance Co. Nat'l Ins Northeast	UPS SUPPLY CHAIN SOLUTIONS, INC. 12380 MORRIS ROAD ALPHARETTA GA 30005
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability (03/16)

HOLDER: Nevada State Board of Pharmacy

ADDRESS: 985 Damonte Ranch Parkway, Suite 206 Reno NV 89521

If changes/revisions to this certificate are necessary, you may email your request to CMeCertProduction@libertymutual.com.

If you no longer require this certificate and do not need on an annual basis, please email the certificate to our office and instruct us to delete from our database.

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ATTACHMENT

Attachment #3

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. E708225

Application/License No. _____

UPS Supply Chain Solutions, Inc., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
2235 Route 322 Suite 100 Woolwich Township, NJ 08085, as
Address of Applicant/Principal
PRINCIPAL, and Great American Insurance Company, a
Surety Company
corporation organized under the laws of the state of Ohio
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
2235 Route 322 Suite 100 Woolwich Township, NJ 08085 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 12/16/2022.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of December, 2022

APPLICANT/PRINCIPAL

Authorized Representative

Patrick D. Power VP

SURETY COMPANY

Surety Company's Representative

Michael S Brown, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Lynda M. Scott

Witness Samuli Kilpi

SIGNED and SEALED in the presence of:

Christina Rinozzi
Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

GREAT AMERICAN INSURANCE COMPANY®

Administrative Office: 301 E 4TH STREET • CINCINNATI, OHIO 45202 • 513-369-5000 • FAX 513-723-2740

The number of persons authorized by
this power of attorney is not more than one

Bond No. E708225

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the GREAT AMERICAN INSURANCE COMPANY, a corporation organized and existing under and by virtue of the laws of the State of Ohio, does hereby nominate, constitute and appoint the person or persons named below its true and lawful attorney-in-fact, for it and in its name, place and stead to execute on behalf of the said Company, as surety, the specific bond, undertaking or contract of suretyship referenced herein; provided that the liability of the said Company on any such bond, undertaking or contract of suretyship executed under this authority shall not exceed the limit stated below. The bond number on this Power of Attorney must match the bond number on the bond to which it is attached or it is invalid.

Name	Address	Limit of Power
Michael S Brown	150 Northwest Point Blvd. Elk Grove Village, IL 60007	$25000--

IN WITNESS WHEREOF the GREAT AMERICAN INSURANCE COMPANY has caused these presents to be signed and attested by its appropriate officers and its corporate seal hereunto affixed this 16th day of December , 2022 .

Attest GREAT AMERICAN INSURANCE COMPANY

Assistant Secretary

Divisional Senior Vice President

MARK VICARIO (877-377-2405)

STATE OF OHIO, COUNTY OF HAMILTON - ss:

On this 16th day of December , 2022 , before me personally appeared MARK VICARIO, to me known, being duly sworn, deposes and says that he resides in Cincinnati, Ohio, that he is a Divisional Senior Vice President of the Bond Division of Great American Insurance Company, the Company described in and which executed the above instrument; that he knows the seal of the said Company; that the seal affixed to the said instrument is such corporate seal; that it was so affixed by authority of his office under the By-Laws of said Company, and that he signed his name thereto by like authority.

SUSAN A KOHORST
Notary Public
State of Ohio
My Comm. Expires
May 18, 2025

This Power of Attorney is granted by authority of the following resolutions adopted by the Board of Directors of Great American Insurance Company by unanimous written consent dated June 9, 2008.

RESOLVED: That the Divisional President, the several Divisional Senior Vice Presidents, Divisional Vice Presidents and Divisonal Assistant Vice Presidents, or any one of them, be and hereby is authorized, from time to time, to appoint one or more Attorneys-in-Fact to execute on behalf of the Company, as surety, any and all bonds, undertakings and contracts of suretyship, or other written obligations in the nature thereof; to prescribe their respective duties and the respective limits of their authority; and to revoke any such appointment at any time.

RESOLVED FURTHER: That the Company seal and the signature of any of the aforesaid officers and any Secretary or Assistant Secretary of the Company may be affixed by facsimile to any power of attorney or certificate of either given for the execution of any bond, undertaking, contract of suretyship, or other written obligation in the nature thereof, such signature and seal when so used being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

CERTIFICATION

I, STEPHEN C. BERAHA, Assistant Secretary of Great American Insurance Company, do hereby certify that the foregoing Power of Attorney and the Resolutions of the Board of Directors of June 9, 2008 have not been revoked and are now in full force and effect.

Signed and sealed this 16th day of December , 2022 .

Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: UPS Supply Chain Solutions, Inc. MDEG License # (if applicable): N/A

Physical Address: 2235 Route 322, Suite 100

City: Woolwich Township State: NJ Zip: 08085

Mailing Address (if different from physical address): **same as physical address**

City: State: Zip:

Telephone: 856-351-6623 Website: www.ups.com

Licensing Company Email: ralicensing@ups.com

Section 2: Personal Information

First: Roger Middle: Murray Last: McLaughlin

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Petty John Road

City: Rising Sun State: MD Zip: 21911

Telephone: [redacted] Email: rogermclaughlin@ups.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
DuCastle Technical High School		9/76 - 6/81	
Address	**City**	**State**	**Zip**
1417 Newport Rd	Wilmington	DE	19804
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

N/A DSCW 02-AUG-2023

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/02 - Pres	177 Patty Jones Rd	Rising Sun	MD	21911
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

N/A DSCW 02-AUG-2023

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
UPS Supply Chain Solutions, Inc.			01/23 - 07/23 Current
Business Address	**City**	**State**	**Zip**
2235 Route 322, Suite 100	Woolwich Township	NJ	08085
Phone	**Title**	**Number of Employed Hours**	
856 351-6623	Operations Manager	1,120	
Description of Duties			
Responsible for managing the daily operations of the Woolwich NJ facility			

Business Name			From - To (MM/YY – MM/YY)
UPS Supply Chain Solutions, Inc.			03/20 - 12/22
Business Address	**City**	**State**	**Zip**
7 Gateway Blvd	Pedricktown	NJ	08067
Phone	**Title**	**Number of Employed Hours**	
856-351-6619	Operations Manager	9,900	
Description of Duties			
Responsible for managing the daily operations of the Pedricktown NJ facility			

Business Name			From - To (MM/YY – MM/YY)
UPS Supply Chain Solutions, Inc.			07/17 - 02/20
Business Address	**City**	**State**	**Zip**
1130 Commerce Blvd, Suite 100	Swedesboro	NJ	08085
Phone	**Title**	**Number of Employed Hours**	
856-975-8777	Assistant Operations Manager	5,180	
Description of Duties			
Responsible for assisting with the day to day operations for the Swedesboro, NJ facility			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

N/A

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N/A
DSW 22-AUG-2023

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

N/A
02-Aug-2023

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

24 Jul 2023
Date

I, Roger McLaughlin, **certify that as the MDEG Administrator for**

2235 Route 322, Suite 100, Woolwich Township, NJ 08085,

that I (initial that you have read and meet the following requirements):

1. RM Have a high school diploma or its equivalent;
2. RM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roger McLaughlin
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

24/01/2023
Date

Board Use Only	Date Received:

ATTACHMENT #1

UPS Supply Chain Solutions, Inc. ("UPS")
2235 Route 322, Suite 100
Woolwich Township, NJ 08085

The MDEG Administrator is a UPS SCS employee who also serves as our Designated Representative for the building.

UPS Supply Chain Solutions, Inc. ("UPS SCS") is a **Third Party Logistics Provider** that provides storage and distribution services to our contracted clients. UPS SCS does not take title or ownership of any pharmaceutical drugs and/or devices nor have responsibility to direct the sale or disposition of these products. Any customer complaints/concerns are forwarded to the contracted client upon receipt for resolution.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler UPS Supply Chain Solutions, Inc.

Pharmacy/Wholesaler License # (if applicable) Pending

Physical Address 2235 Route 322, Suite 100

City Woolwich Township State NJ Zip 08085

Mailing Address (if different from physical address) **same as above physcial address**

City _____ State _____ Zip _____

Telephone 856-351-6623 Website www.ups.com

Licensing Company Email ralicensing@ups.com

Section 2: Personal Information

First Roger Middle Murray Last McLaughlin

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Petty John Road

City Rising Sun State MD Zip 21911

Telephone [redacted] Email rogermclaughlin@ups.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Delcastle Technical High School			9/76 - 6/81	
Address		City	State	Zip
1417 Newport Rd		Wilmington	DE	19804
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

N/A
DSW 02-AMB-2023

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/07 to Pres	[redacted] Petty John Rd	Rising Sun	MD	21911
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

N/A
DSW 08-02-2023

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
UPS Supply Chain Solutions, Inc.			01/23 - 07/23 Current	
Business Address		City	State	Zip
2235 Route 322, Suite 100		Woolwich Township	NJ	08085
Phone	Title		Number of Employed Hours	
856 351-6623	Operations Manager		1,120	
Description of Duties				
Responsible for managing the daily operations of the Woolwich NJ facility				

Business Name			From - To (MM/YY – MM/YY)	
UPS Supply Chain Solutions, Inc.			03/20 - 12/22	
Business Address		City	State	Zip
7 Gateway Blvd		Pedricktown	NJ	08067
Phone	Title		Number of Employed Hours	
856-351-6619	Operations Manager		9,900	
Description of Duties				
Responsible for managing the daily operations of the Pedricktown NJ facility				

Business Name			From - To (MM/YY – MM/YY)	
UPS SupplyChain Solutions, Inc.			07/17 - 02/20	
Business Address		City	State	Zip
1130 Commerce Blvd, Suite 100		Swedesboro	NJ	08085
Phone	Title		Number of Employed Hours	
856-975-8777	Assistant Operations Manager		5,180	
Description of Duties				
Responsible for assisting with the day to day operations for the Swedesboro, NJ facility				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N/A
as of 12/4-2023

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N/A
02-AUG-2023

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
			N/A	
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
			DOW DR AUS - 2023	
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

24 Jul 2023
Date

I, Roger McLaughlin, **certify that as the designated representative for**

UPS Supply Chain Solutions, Inc., 2235 Route 322, Suite 100, Woolwich Township, NJ 08085,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JM I am at least 21 years of age;
3. JM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Roger McLaughlin
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

31-Jul-2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roger McLaughlin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-Aug-2023

Date

Please have this section completed in the presence of a Notary Public.

State of Delaware, ss. County of New Castle

I, Roger M. McLaughlin Sr., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-Aug-2023

Date

Subscribed and Sworn to before me this 10th day of August.

Carlene L. Colarantí

Notary Public Signature

(Seal)

UPS Supply Chain Solutions, Inc.
2235 Route 322, Ste 100
Woolwich Township, NJ 08085

First Name	Last Name	Position
Roger	McLaughlin	Facility Manager
Casey	Criswell	Division Manager
David	Rizzo	Associate Manager
Stephen	Foster	Associate Manager
Gary	Armour	Associate Manager
Deborah	Robertson	Compliance Manager
Myrna	Rodriguez	QA Manager
Nancy	Ewan	QA Supervisor
Suann	Alvarez	QA Supervisor
Autumn	Morenzetti	QA Specialist
Gregory	Stevens	QA Specialist
Michael	Acello	IE Specialist
Jake	Section	IE Section Manager
Megan	Smajda	IE Supervisor
Michael	Hickman	IE Supervisor
Latney	Bagby	Supervisor
Talaihia	Hobbs	Supervisor
Fred	Dauphin	Supervisor
Kenneth	Hickman	Supervisor
Joseph	Toby	Supervisor
Nicole	Neall	Supervisor
Ryan	Sensabaugh	Supervisor
Francis	Goodchild	Supervisor
Sal	Byrne	Warehouse
Tireke	Gabriel	Warehouse Lead
Gifford	George	Warehouse
Anna	Harris	Warehouse
James	Peirce	Warehouse
Lidia	Gonzalez	Warehouse
Ana	Ayala	Warehouse Lead
Alec	Kay	Warehouse
Marcelo Hernandez	Guerra	Warehouse
Jerome	Mathis	Warehouse
Jose	Ortiz	LOA
Shareefah Abdur	Rahmann	Warehouse Lead
Victor	Gomez	Warehouse
Jamahl	Eason	Warehouse
Michael	Forde	Warehouse
John	Hagan	Warehouse Lead
Deb	Hanrahan	Warehouse
Sierra	Larson	Warehouse
Ken	Maranzano	Warehouse
Shawn	Rain	Warehouse
Bruce	Averitt	Warehouse
Boris	Fokam	Warehouse
Hailey	Foraker	Warehouse
Brijesh	Raval	Warehouse
Elinnette Roman	Pabon	Warehouse
Lisa	Scott	Warehouse
Besthi	Thomas	Warehouse
Claudette	Turenne	Warehouse
Turquoise	Shockley	LOA
Patricia	Felmay	LOA
Joseph	Rohlfing	Warehouse Lead
David	Klepka	Warehouse
Augusto	Alzate	Warehouse
David	Bishop	Warehouse
Omar	Crews-Moore	Warehouse
Corrina	Foraker	Warehouse Lead
Yendy	Garcia	Warehouse
Marcus	Hill	Warehouse Lead
Clifford	Kelley	Warehouse Lead
Rosina	McKinnie	Warehouse Lead
Angel	Santa	Warehouse
Katiana	Simon	Warehouse
Jesus	Torres	Warehouse
Luis	Torres	Warehouse

First Name	Last Name	Position
Debbie	Jones	Warehouse Lead
Sobner	Joseph	Warehouse
Deaijah	Brown	Warehouse
Marlon	Brown	Warehouse
Donye	Davis	Warehouse
Lorraine	Mills	Warehouse
Jamison	Perkins	Warehouse
Margaret	Thomas	Warehouse
Edan	Quinones	Warehouse Lead
Rubin	Tidwell	Warehouse
Cynthia	Lewis	Warehouse
Robert	Long	Warehouse
Stephen	Loomis	Warehouse
Yesenia	Lopez	Warehouse Lead
Pinalben	Raval	Warehouse
Chelsea	Showalter	Warehouse
Albania	Valdez	Warehouse
Michael	Watkins	Warehouse Lead
Christian	Reinmuth	Warehouse
Tristan	Satterfield	LOA
Steve	Alvarado	Warehouse
Sandre	Belgira	Warehouse
Marco	Orellana	Warehouse Lead
Steven	Paoline	Warehouse
Dauris	Peralta	Warehouse
Troy	Miller	Warehouse
Kevin	O'Brien	Warehouse
Ana	Peralta	Warehouse Lead
Jacob	Perkins	Warehouse
Anthony	Rodriguez	Warehouse
Camila	Rodriguez	Warehouse
Woongjae	Lee	Warehouse
Rickey	Riddle	Warehouse
Michael	Boyer	Warehouse
Jessica	Gibson	Warehouse Lead
Henold	Joseph	Warehouse
Fabienne	Vilson	Warehouse
Carlos	Boria	Temp
James	Caldwell	Temp
Mariely	Landrau	Temp
Benjamin	Murrey	Temp
Angie	Osario	Temp
Matthew	Bowens	Temp
Jacob	Fuentes	Temp
Cristina Bobe	Gonzalez	Temp
Carla	Lopez	Temp
James	Harden	Temp
Ciani	Wilson	Temp
Kalia	Murray	Temp
David	Santiago	Temp
Laiza Torres	Camacho	Temp
Sean	Bennett	Temp
Andrew	Frazier	Temp
Richard	Hine	Temp
Jacqueline Perez	Torres	Temp
Vimzuly Pena	Mendoza	Temp
Zulma Pena	De Mendoza	Temp
Jadina	Santana	Temp
Marianyela Navarro	Soto	Temp
Naim	Bowick	Temp
Yury	Melendez	Temp
Amaya	Asturrizaga	Temp
Jamie	Galindo	Temp
Justice	Adams	Temp
Giovanni	Victoria	Temp
Yulett	Atencio	Temp
Mileyda Medina	Aular	Temp

4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: ViiV Healthcare Company

Physical Address: 410 Blackwell St., Suite 300

City: Durham State: NC Zip: 27701

Mailing Address (if different from physical address): 410 Blackwell St. Crowe Fowler Bld.

City: Durham State: NC Zip: 27701

Telephone: 919-302-9227 Website: N/A

Name of Designated Representative (DR): Kim Lawton

Licensing Company Email: gsklicensing@iqvia.com DR Email: kim.m.lawton@gsk.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Physicians, Government		■ Others: Virtual Manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
17-Mar-2023	15-May-2023	FL	Tallahassee	Leon County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2023-010778	State of Florida, Dept. of Buiness & Professional Regulations, Div. of Drugs, Devices

Reason/Charge
Notifying Florida Board of change of address associated with existing permit for ViiV corporate office

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
	Settlement agreement

Name of Business/Industry/Entity
ViiV Healthcare Company

Provide explanation below:

In association with ViiV Healthcare relocating its corporate headquarters from Research Triangle Park, North Carolina to Durham, North Carolina the state of North Carolina was notified of the change who then coordinated the on site inspection and issued the updated home state license. After receiving the updated home state license, subsequent notification was initiated with the state of Florida to notify them of the change in address. System limitations that coincided with trying to process annual license renewal and change of address at the same time along with extended dialogue with representatives wtihin the Department of Business & Professional Regulations prevented the change of address from being processed in a timely manner.

Original Signature (electronic, copies or stamps not accepted)

02-Jun-2023
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: GlaxoSmithKline LLC - Zebulon
Address: 1011 N. Arendell Ave. City: Zebulon State: NC Zip: 27597
Name: Pfizer Manufacturing, Deutschland GmbH
Address: Mooswaldallee 1 City: Freiburg im Breisgau State: DEU Zip: 79090
Name: Glaxo Operations UK Ltd.- Barnard Castle
Address: Harmire Rd. City: Barnard Castle, Durham State: GBR Zip: DL12 8DT
Name: Glaxo Operations UK Ltd. - Ware
Address: Priory St. City: Ware, Hertfordshire State: GBR Zip: SD12 0DJ

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): ViiV Healthcare Limited
Corporation/Organization Name: ViiV Healthcare Company
Mailing Address: 410 Blackwell St. Crowe Fowler Bld.
City: Durham State: NC Zip: 27701
Telephone: 919-302-9227 Email: gsklicensing@iqvia.com
Contact Person Name: Donna Melton

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **"Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing "Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

ViiV Healthcare Company

Facility Name

Brian Vetter

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

06-Jun-2023

Date

Board Use Only	Date Received: 7/31/23	Amount: 1000-CK-652918

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner, **Case Nos.: 2023-010778**

v.

VIIV HEALTHCARE COMPANY,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (hereinafter, "this agreement") as disposition of the alleged violations described in the Notice of Violation in case number 2023-010778 (hereinafter, "the allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereinafter, "the Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. ViiV Healthcare Company (hereinafter, "Respondent") currently holds non-resident prescription drug manufacturer permit 26:1072.

2. Respondent's address of record is 410 Blackwell Street, Suite 300, Durham, North Carolina 27701.

3. Respondent was issued a Notice of Violation on March 17, 2023, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted

pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent, by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent neither admits nor denies the allegations in the Notice of Violation issued in case 2023-010778, but enters into this agreement for the purpose of resolving the issues raised by the Department.

SETTLEMENT TERMS

6. Respondent affirms that it is currently in compliance with Chapter 499, Florida Statutes.

7. Respondent agrees to pay a settlement amount of five thousand dollars ($5,000.00). **Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047, Attention: Kimberley Johnson, Senior Legal Assistant**. Respondent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Respondent are absolute conditions precedent to the Department's execution of this agreement.

8. The Department agrees that this agreement **will not** be deemed to constitute disciplinary action against Respondent within the meaning of Section 499.066, Florida Statutes, and Rule 61N-1.024, Florida Administrative Code.

STANDARD PROVISIONS

9. It is expressly understood that a violation of the terms of this agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

10. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. **The final order shall operate to close case number 2023-010778. The final order shall be the final disposition in this proceeding and shall constitute final agency action with respect thereto.**

11. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this agreement and the final order in which this agreement is incorporated, provided the final order does not conflict with this agreement.

12. Each party waives the right to seek any attorney's fees or costs from the other party in connection with this proceeding.

13. This agreement may be executed in any number of counterparts including, without limitation, telecopies and facsimile transmission copies, all of which together shall constitute a single document.

14. The parties agree that this agreement represents a fair, appropriate, and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

15. The terms and provisions of this agreement are severable and, if any term or provision is declared or deemed void, invalid, illegal, or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

16. It is expressly understood that this agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts this

agreement and adopts it in a final order.

17. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals and, as duly designated representatives, to fully bind such principals.

VIIV HEALTHCARE COMPANY,

By: Brian Vetter

Name: Brian Vetter

Title: Vice President

Date: 15-May-2023

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION DIVISION OF DRUGS, DEVICES, AND COSMETICS,

By: _____

Name: Walter Copeland

Title: Division Director

Date: _____

Prepared by:

Anthony Coniglio
DDC Legal Chief
Division of Drugs, Devices, and Cosmetics

ViiV Healthcare Company

ADDENDUM TO CERTIFICATION

The officer responsible for the submission of the Nevada initial application is responding to all questions only to the best of his or her knowledge as it relates to ViiV Healthcare Company. ViiV Healthcare Company is one of numerous GSK-operating companies located in over 115 countries around the world as part of a global, science-led organization that researches, develops, manufactures, markets, and sells pharmaceutical, vaccines, and consumer healthcare products. The officer is not making any representations with respect to any GSK companies other than GSK/ViiV Healthcare Company.

While every endeavor has been made to ensure the statements, representations, and attestations ("Statements") provided in this application are accurate and correct, we would like to clarify the limitations in the due diligence that can reasonably be conducted in order to make such Statements. The Statements have been made in good faith based on the information available to and known by the officer of ViiV Healthcare Company at the time of submission.

In relation to any questions that refer to employees and/or agents, please note that ViiV Healthcare Company employs many thousands of people and has extensive data protection processes which precludes obtaining and reviewing the records of every employee. Therefore, while the officer cannot have personal knowledge of every ViiV Healthcare Company employee and/or agent, ViiV Healthcare Company does have employee policies imposing strict compliance with applicable laws, a comprehensive employee training curriculum that covers a wide range of employee behaviors and compliance topics and pre-employment corporate security vetting. In addition, there is a ViiV Healthcare Company initiative that encourages and safeguards employees reporting illegal or unethical behavior within the company.

In relation to any questions that refer specifically to ViiV Healthcare Company and/or any corporate officers, the officer was given confirmation that there was no information available to indicate that a different answer be given for the purposes of this application than the one provided in the Statements.

Submission of the Nevada initial application by the officer reflects this reasonable care and diligence to be expected of a properly qualified and competent member of a large corporate organization providing Statements similar in scope and character to those provided.

Corporate Officers and Owner List
ViiV Healthcare Company

Lynn M. Baxter, President - 410 Blackwell St., Durham, NC 27701; 919-475-0369; Ownership: 0%

Kimberly Yvette Smith, Vice President - 410 Blackwell St., Durham, NC 27701; 919-491-2167; Ownership: 0%

Brian Vetter, Vice President - 410 Blackwell St., Durham, NC 27701; 919-368-0633; Ownership: 0%

Rebecca Hall, Vice President Finance - 406 Blackell St., Durham NC 27701; 919-600-9294; Ownership: 0%

Crystal Baker, Secretary - 410 Blackwell St., Durham, NC 27701; 919-451-4615; Ownership: 0%

ViiV Healthcare Limited - 251 Little Falls Dr. Wilmington Delaware 19808; 919-368-0633; Ownership: 100% (July 15, 2022)

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VIIV HEALTHCARE COMPANY" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF MARCH, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "VIIV HEALTHCARE COMPANY" WAS INCORPORATED ON THE SECOND DAY OF APRIL, A.D. 2009.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4672617 8300

SR# 20230915999

Authentication: 202868848

Date: 03-08-23

You may verify this certificate online at corp.delaware.gov/authver.shtml



2023

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO
573

NOT TRANSFERABLE
STATUTE GS 81.106.113

LICENSE/CERTIFICATE: Virtual Manufacturer

TYPE

Expiration Date 12/31/2023

LICENSEE
R
CERTIFICATOR

ViiV Healthcare Company
410 BLACKWELL STREET STE 300
DURHAM NC 27701

LICENSED
2023
NORTH CAROLINA

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

STEVE TROXLER, COMMISSIONER

NC Dept. of Agriculture & Consumer Services

Food & Drug Protection Division

Firm Name: ViiV Healthcare Company

Address: 410 BLACKWELL STREET STE 300 DURHAM, NC 27701

License Type: Virtual Manufacturer

License Number: 573

Status: Active - in good standing

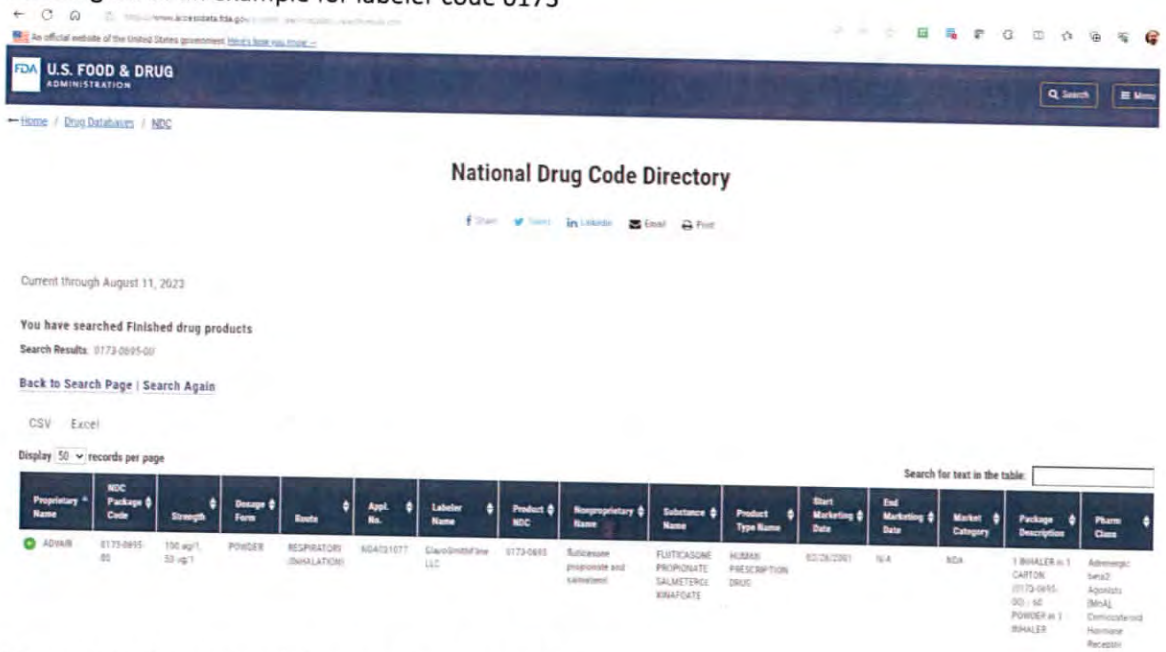
Discipline: No

Issue Date: 12/19/2022

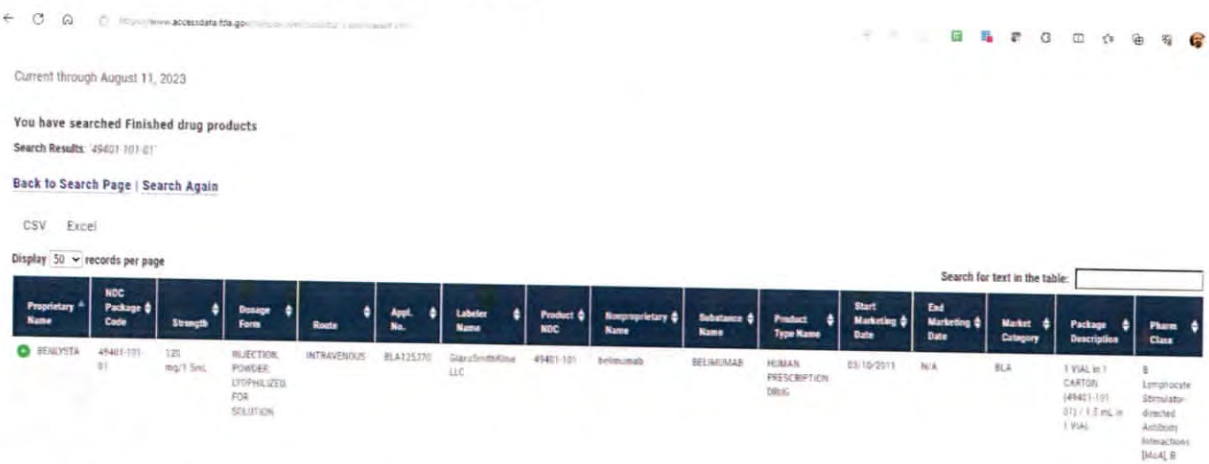
Original Issue: 12/7/2010

Expiration Date: 12/31/2023

Screen grab of an example for labeler code 0173



Screen grab of an example for labeler code 49401:



Screen grab of an example for labeler code 69656:

To Whom it May Concern,

This is to confirm that the below labeler codes are active and in use in FDA systems.

Company	Labeler Name	Included Labeler Codes
GlaxoSmithKline LLC	GlaxoSmithKline LLC	0173, 49401, 69656
	GlaxoSmithKline Biologicals SA	58160
	ID Biomedical Corporation of Quebec	19515
ViiV Healthcare Company	ViiV Healthcare Company	49702
	Agouron	63010

Please be aware that the FDA does not issue any form of official documentation for labeler codes. FDA does maintain a list of active labeler codes, but it takes you to an excel document which does not contain anything identifying the source of the information. The link to this is below.

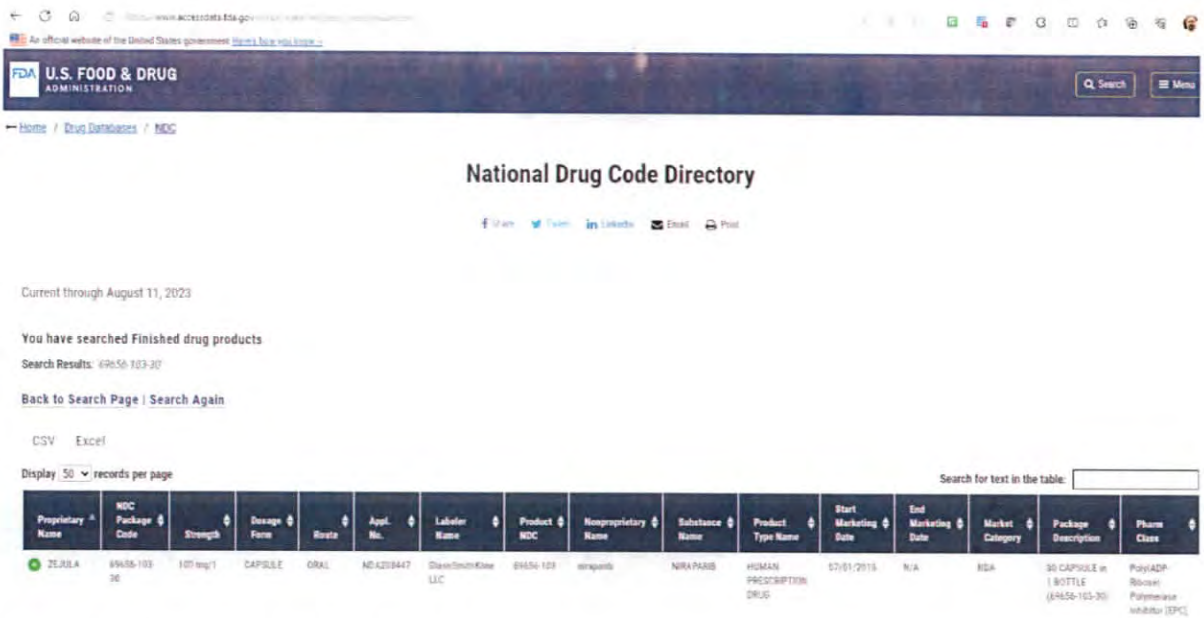
NDC/NHRIC Labeler Codes | FDA

To demonstrate that the labeler codes are active you will find below screengrabs from the FDA's National Drug Code Directory website with an example of active NDC for each of the above labeler codes. I have provided directly below the link to the FDA website that was used.

National Drug Code Directory (fda.gov)

To verify any of this, go the FDA website, for the Select Type field, choose NDC code and type in the respective NDC you wish to verify.

Verified 6/12/23



U.S. FOOD & DRUG ADMINISTRATION

Home / Drug Databases / NDC

National Drug Code Directory

Current through August 11, 2023

You have searched Finished drug products

Search Results: 69656-103-30

Back to Search Page | Search Again

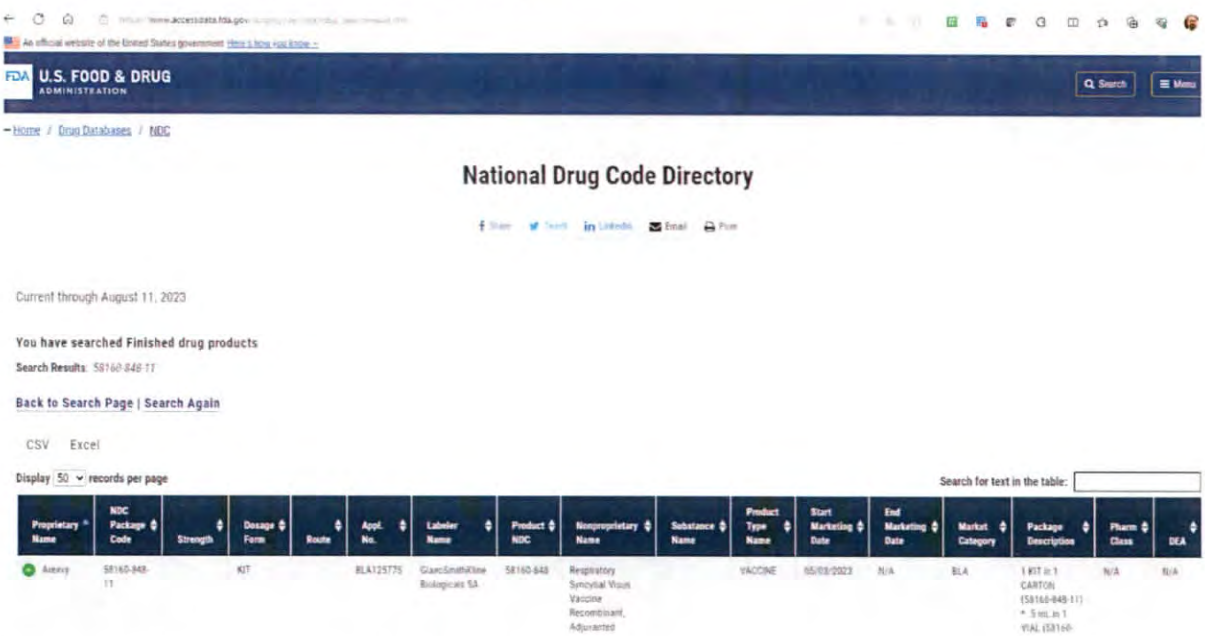
CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
ZEJULA	69656-103-30	100 mg/1	CAPSULE	ORAL	NDA208447	GlaxoSmithKline LLC	69656-103	niraparib	NIRAPARIB	HUMAN PRESCRIPTION DRUG	07/01/2015	N/A	NDA	30 CAPSULE in 1 BOTTLE (69656-103-30)	Poly(ADP-Ribose) Polymerase Inhibitor [EPC]

Screen grab of an example for labeler code 58160:



U.S. FOOD & DRUG ADMINISTRATION

Home / Drug Databases / NDC

National Drug Code Directory

Current through August 11, 2023

You have searched Finished drug products

Search Results: 58160-848-11

Back to Search Page | Search Again

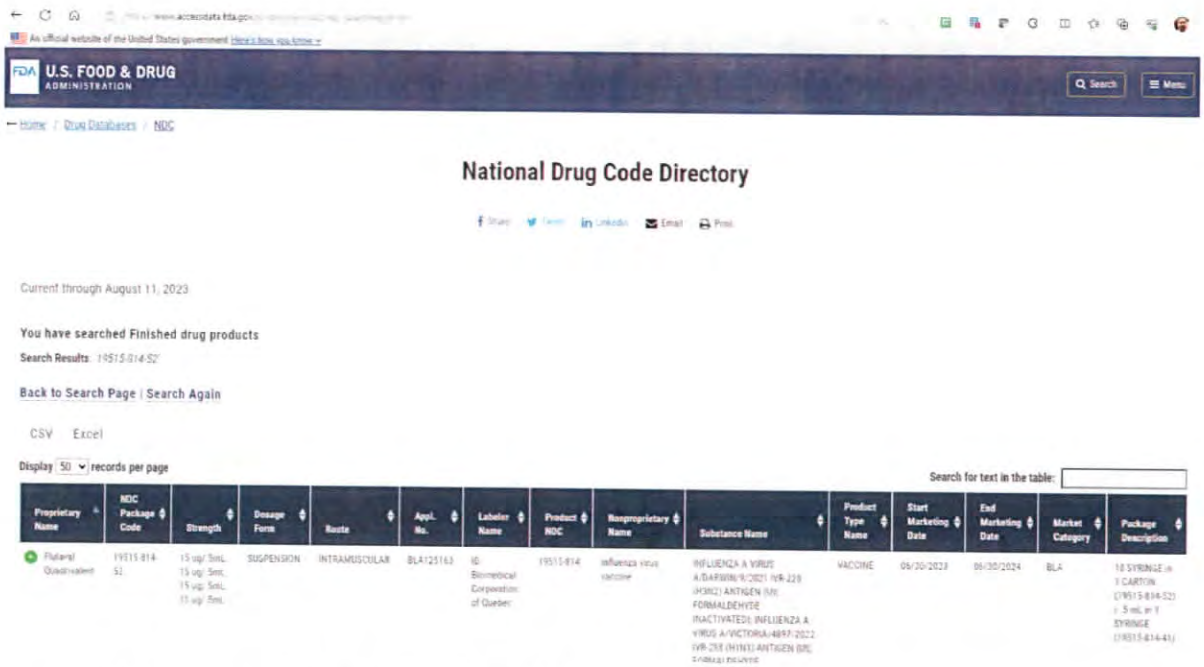
CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
Arexvy	58160-848-11		KIT		BLA125775	GlaxoSmithKline Biologicals SA	58160-848	Respiratory Syncytial Virus Vaccine Recombinant, Adjuvanted		VACCINE	05/03/2023	N/A	BLA	1 KIT in 1 CARTON (58160-848-11) * 5 mL in 1 VIAL (58160-	N/A	N/A

Screen grab of an example for labeler code 19515:



U.S. FOOD & DRUG ADMINISTRATION

Home / Drug Databases / NDC

National Drug Code Directory

Current through August 11, 2023

You have searched Finished drug products

Search Results: 19515-814-52

Back to Search Page | Search Again

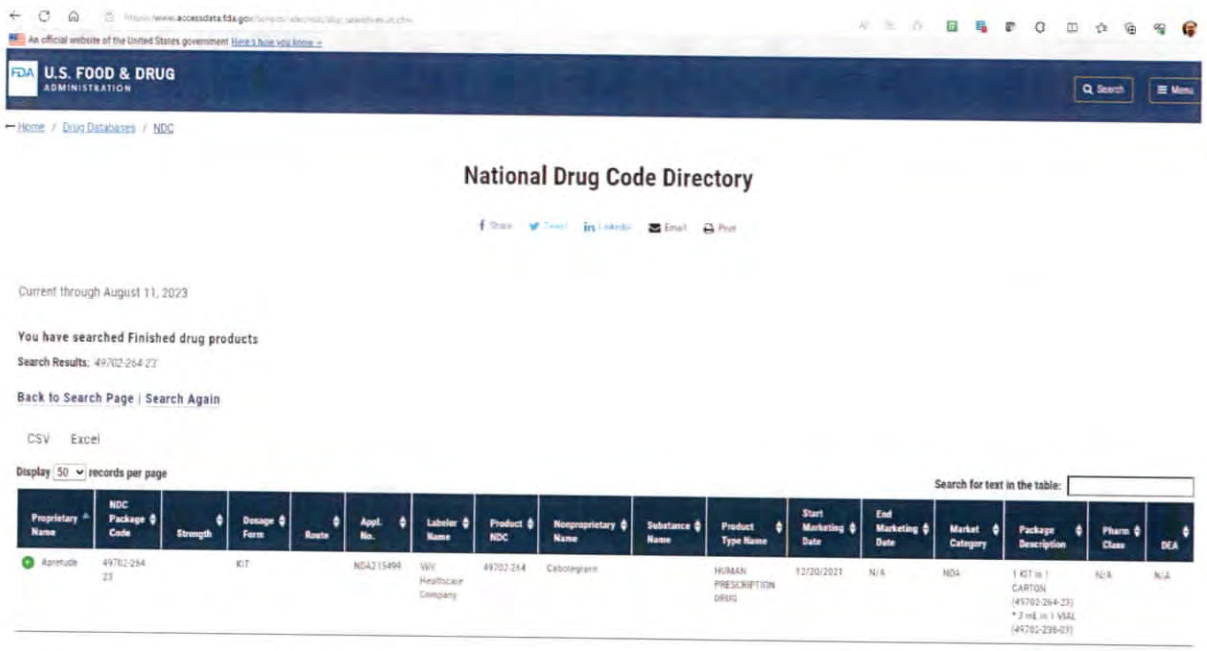
CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Fluarix Quadrivalent	19515-814-52	15 ug/ 5mL, 15 ug/ 5mL, 15 ug/ 5mL, 15 ug/ 5mL	SUSPENSION	INTRAMUSCULAR	BLA125163	ID Biomedical Corporation of Quebec	19515-814	influenza virus vaccine	INFLUENZA A VIRUS A/DARWIN/9/2021 (H3N2) ANTIGEN (MV) FORMALDEHYDE INACTIVATED) INFLUENZA A VIRUS A/VICTORIA/4897/2022 (H1N1) ANTIGEN (MV)	VACCINE	08/30/2023	08/30/2024	BLA	10 SYRINGE in 1 CARTON (19515-814-52) > 5 mL in 1 SYRINGE (19515-814-41)

Screen grab of an example for labeler code 49702:



U.S. FOOD & DRUG ADMINISTRATION

Home / Drug Databases / NDC

National Drug Code Directory

Current through August 11, 2023

You have searched Finished drug products

Search Results: 49702-264-23

Back to Search Page | Search Again

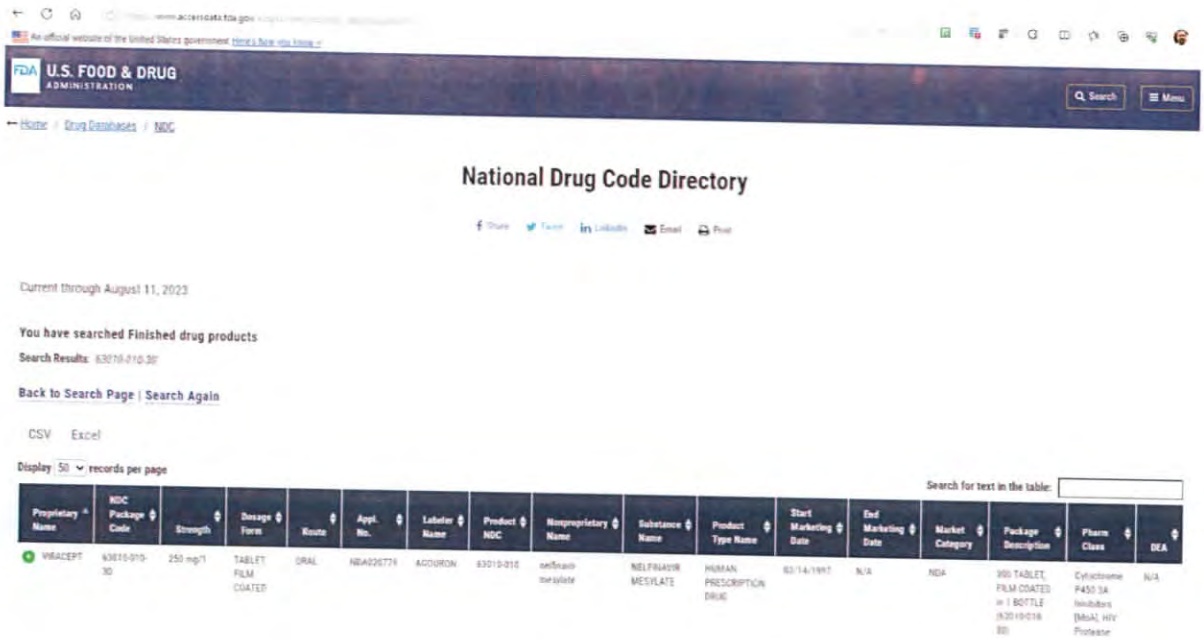
CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
Apretude	49702-264-23		KIT		NDA215499	ViiV Healthcare Company	49702-264	Cabotegravir		HUMAN PRESCRIPTION DRUG	12/20/2021	N/A	NDA	1 KIT in 1 CARTON (49702-264-23) * 3 mL in 1 VIAL (49702-236-03)	N/A	N/A

Screen grab of an example for labeler code 63010-010-30:



U.S. FOOD & DRUG ADMINISTRATION

Search Menu

Home / Drug Databases / NDC

National Drug Code Directory

Share Tweet LinkedIn Email Print

Current through August 11, 2023

You have searched Finished drug products

Search Results: 63010-010-30

Back to Search Page | Search Again

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
VIRACEPT	63010-010-30	250 mg/1	TABLET, FILM COATED	ORAL	NDA020778	ACCORD	63010-010	nelfinavir mesylate	NELFINAVIR MESYLATE	HUMAN PRESCRIPTION DRUG	03/14/1997	N/A	NDA	300 TABLET, FILM COATED in 1 BOTTLE (63010-010-30)	Cytochrome P450 3A Inhibitors [MoA], HIV Protease	N/A

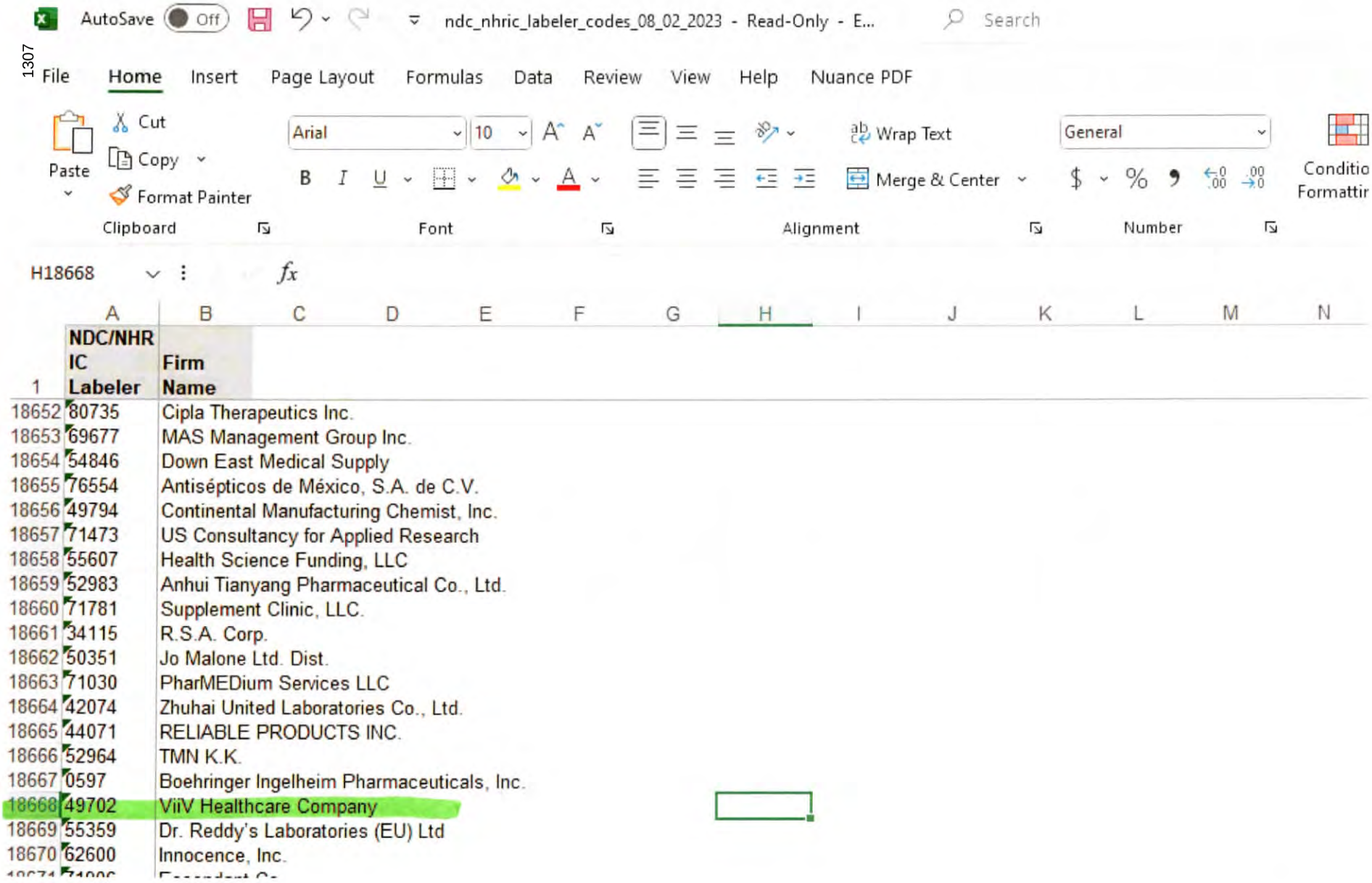
Kind regards,

Ben Harpster

QA Compliance Manager Drug Listing/ U.S. Agent

GSK US Market Supply Distribution and Quality

gsk do more feel better live longer



AutoSave Off ndc_nhric_labeler_codes_08_02_2023 - Read-Only - E... Search

1307

File Home Insert Page Layout Formulas Data Review View Help Nuance PDF

Paste Cut Copy Format Painter Arial 10 Wrap Text General Merge & Center Conditio Formattir

Clipboard Font Alignment Number

H18668

	A	B
1	NDC/NHRIC Labeler	Firm Name
18652	80735	Cipla Therapeutics Inc.
18653	69677	MAS Management Group Inc.
18654	54846	Down East Medical Supply
18655	76554	Antisépticos de México, S.A. de C.V.
18656	49794	Continental Manufacturing Chemist, Inc.
18657	71473	US Consultancy for Applied Research
18658	55607	Health Science Funding, LLC
18659	52983	Anhui Tianyang Pharmaceutical Co., Ltd.
18660	71781	Supplement Clinic, LLC.
18661	34115	R.S.A. Corp.
18662	50351	Jo Malone Ltd. Dist.
18663	71030	PharMEDium Services LLC
18664	42074	Zhuhai United Laboratories Co., Ltd.
18665	44071	RELIABLE PRODUCTS INC.
18666	52964	TMN K.K.
18667	0597	Boehringer Ingelheim Pharmaceuticals, Inc.
18668	49702	ViiV Healthcare Company
18669	55359	Dr. Reddy's Laboratories (EU) Ltd
18670	62600	Innocence, Inc.

verified
8/2/25

U.S. FOOD & DRUG ADMINISTRATION

NDA 205551/S-029
NDA 215413/S-001

SUPPLEMENT APPROVAL

ViiV Healthcare Company
c/o GlaxoSmithKline
Attention: Stephen Hyatt
Manager, Global Regulatory Affairs
410 Blackwell Street
Durham, NC 27701

Dear Mr. Hyatt:

Please refer to your supplemental new drug applications (sNDAs) dated and received April 7, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Triumeq (abacavir, dolutegravir, lamivudine) tablets and Triumeq PD (abacavir, dolutegravir, lamivudine) tablets for oral suspension.

These Prior Approval sNDAs provide for the following changes to the labeling:

- To update the USE IN SPECIFIC POPULATIONS, Pregnancy, section of the Prescribing Information (PI) with data regarding dolutegravir crossing the placenta
- To update the USE IN SPECIFIC POPULATIONS, Lactation, section of the PI with data regarding the presence of dolutegravir in human milk
- To update CLINICAL PHARMACOLOGY, Pharmacokinetics with a "Pregnant Women" subsection
- To update the Medication Guide to be consistent with the changes made to the PI

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.
Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information

---

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Kevin Allen, Regulatory Project Manager, at 301-837-7467.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

YODIT BELEW
10/07/2022 12:22:15 PM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107654560

Application/License No. _____

ViiV Healthcare Company (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 410 Blackwell Street, Suite 300, Durham, NC 27701 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square, Hartford, Connecticut 061863 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND • DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 1, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of June, 20 23.

APPLICANT/PRINCIPAL

COMPANY

ViiV Healthcare Company

Authorized Representative
Brian Vetter

CINDY L STANSBURY NOTARY PUBLIC WAKE COUNTY, NC

My Commission Expires 1/28/2026

SIGNED and SEALED in the presence of:

Witness Cindy L Stansbury
Cindy L. Stansbury

Witness
Donna Melton

SURETY

Travelers Casualty and Surety Company of America

Surety Company's Representative

Sandra Parker, print name, Attorney-in-fact

SIGNED and SEALED in the presence of:

Witness Tiffany Parker

Witness Melissa Haddick

Countersigned by:

Not Required

Nevada Resident Agent

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **SANDRA PARKER** of **HOUSTON**, **Texas**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April**, **2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April**, **2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June**, **2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **1st** day of **June**, **2023**.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ViiV Healthcare Company

Pharmacy/Wholesaler License # (if applicable) Initial

Physical Address 410 Blackwell St., Suite 300

City Durham State NC Zip 27701

Mailing Address (If different from physical address) 410 Blackwell St. Crowe Fowler Bld.

City Durham State NC Zip 27701

Telephone 919-302-9227 Website N/A

Licensing Company Email gsklicensing@iqvia.com

Section 2: Personal Information

First Kim Middle M. Last Lawton

Alias(es, nicknames, name changes, etc.) previous last names - Kraus, Silverthorne

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address 410 Blackwell St. Crowe Fowler Bld.

City Durham State NC Zip 27701

Telephone [redacted] Email gsklicensing@iqvia.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Virginia Polytechnic Institute and State University		09/84 - 05/89	
Address	**City**	**State**	**Zip**
800 Washington St. SW, Student Services Bldg., Suite 250	Blacksburg	VA	24061
Diploma/Degree obtained, if any			
BS - Industrial Engineering and Operations Research			

School Name		From - To (MM/YY – MM/YY)	
Bel Air High School		09/80-05/84	
Address	**City**	**State**	**Zip**
100 Heighe St.	Bel Air	MD	21014
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/99 - Present	[redacted] Cranborne Ln.	Cary	NC	27519
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
GlaxoSmithKline LLC			02/05 - Present	
Business Address		**City**	**State**	**Zip**
410 Blackwell St.		Durham	NC	27701
Phone	**Title**		**Number of Employed Hours**	
919-274-5055	US Serialisation Lead		48,640	
Description of Duties				
Responsible for business operational readiness ensuring compliance with the US market Drug Supply Chain Security Act and for ensuring that all corporate, product manufacturing and distribution GSK state licenses are submitted/maintained.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Kim Lawton
Original Signature (electronic, copies or stamps not accepted)

6/2/23
Date

I, Kim Lawton, **certify that as the designated representative for**

ViiV Healthcare Company,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KL I am at least 21 years of age;
3. KL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kim Lawton

Print Name (First, Last)

Kim Lawton

Original Signature (electronic, copies or stamps not accepted)

6/2/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kim Lawton

Print Name (First, Last)

Kim Lawton — 6/2/23

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of NC, ss. County of Wake

I, Philip Hallman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Kim Lawton — 6/2/23

Original Signature — **Date**

Subscribed and Sworn to before me this 2 day of June 2023.

PHILIP HALLMAN — NOTARY PUBLIC — WAKE COUNTY, NC

Notary Public Signature

My commission expires 10-09-2027

(Seal)

Employee List
ViiV Healthcare Company

- **Lynn M. Baxter**
- **Kimberly Yvette Smith**
- **Rebecca Hall**
- **Brian Vetter**
- **Crystal Baker**
- **Kim Lawson**

4FF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03058	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: VGYAAN Pharmaceuticals LLC

Physical Address: 23 Orchard Road, Suite 180

City: Skillman State: NJ Zip: 08558

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 609-452-2770 Website: www.vgyaan.com

Name of Designated Representative (DR): Nimisha Bhatt

Licensing Company Email: compliance@vgyaan.com DR Email: Nimisha.bhatt@vgyaan.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Virtual Manufaturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/22/23
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Pharmaceutics International, Inc.
Address: 10709 Gilroy Road City: Hunt Valley State: MD Zip: 21031

Name: Aizant Drug Research Solutions Pvt. Ltd.
Address: Survey No 172/173, Apparel Park Road City: Hyderabad, India State: Telang Zip: 50010

Name: N/A
Address: City: State: Zip:

Name: N/A
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey
Parent Company (if any): RK Pharma Inc
Corporation/Organization Name: VGYAAN Pharmaceuticals LLC
Mailing Address: 23 Orchard Road, Suite 180
City: Skillman State: NJ Zip: 08558
Telephone: 609-452-2770 Email: compliance@vgyaan.com
Contact Person Name: Nimisha Bhatt

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

VGYAAN Pharmaceuticals LLC

Facility Name

Nimisha Bhatt

Print Name of Authorized Person Submitting Application

Nimisha Bhatt

Original signature of Authorized Person (copies or stamps not accepted)

7/22/23

Date

Board Use Only	Date Received: 8/1/23	Amount: 1000-CK-1019

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD and NIPPON SHINYAKU CO., LTD., Plaintiffs, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC PHARMACEUTICALS, INC., VGYAAN PHARMACEUTICALS LLC, ZYDUS WORLDWIDE DMCC and ZYDUS PHARMACEUTICALS (USA) INC., Defendants.	**Civil Action No. 1:20-03859 (RMB) (KMW)**

STIPULATION OF DISMISSAL AND ORDER

Plaintiffs Actelion Pharmaceuticals Ltd and Nippon Shinyaku Co., Ltd. (collectively, "Plaintiffs") and Defendant VGYAAN Pharmaceuticals LLC ("VGYAAN" or "Defendant") by their undersigned counsel, stipulate and agree, subject to the approval of the Court, as follows:

WHEREAS, VGYAAN owns Abbreviated New Drug Application ("ANDA") No. 214055, which was filed with the United States Food and Drug Administration seeking approval to make and sell selexipag tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg and 1600 mcg ("VGYAAN's ANDA products") prior to the expiration of U.S. Patent Nos. 8,791,122 ("the '122 patent") and 9,284,280 ("the '280 patent");[1] and

[1] ANDA No. 214055 was previously owned by Aizant Drug Research Solutions Private Limited, which is, by agreement, bound by any order applicable to VGYAAN in this action. (D.I. 34.)

WHEREAS, on April 9, 2020, Plaintiffs filed suit against VGYAAN alleging that submission of ANDA No. 214055 and/or the sale and use of VGYAAN's ANDA products constitute and/or induce or contribute to acts of infringement under 35 U.S.C. §§ 271 (a), (b), (c), and (e)(2);

NOW THEREFORE, the parties hereby stipulate and agree as follows:

1. Pursuant to Rule 41(a) and 41(c) of the Federal Rules of Civil Procedure, all claims, counterclaims, and defenses as between Plaintiffs and VGYAAN concerning the '122 and '280 patents are dismissed without prejudice, and each party shall bear its own costs and attorney fees with respect to the '122 and '280 patents;

2. The case caption should be amended to remove VGYAAN as a named party to Civil Action No. 1:20-cv-03859 (RMB) (KMW).

STIPULATED AND AGREED TO BY:

s/ Keith J. Miller
Keith J. Miller
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, NJ 07102
(973) 690-5400
KMiller@rwmlegal.com

Attorneys for Plaintiffs
Actelion Pharmaceuticals Ltd
and Nippon Shinyaku Co., Ltd.

Of Counsel:

Bruce M. Wexler
Preston K. Ratliff II
Aaron P. Selikson
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

Attorneys for Plaintiffs
Actelion Pharmaceuticals Ltd
and Nippon Shinyaku Co., Ltd.

s/ Anandita Vyakarnam
Andrew J. Miller
Anandita Vyakarnam
WINDELS MARX LANE & MITTENDORF, LLP
One Giralda Farms
Madison, NJ 07940
(973) 966-3200
amiller@windelsmarx.com
avyakarnam@windelsmarx.com

Attorneys for Defendant VGYAAN
Pharmaceuticals LLC

IT IS SO ORDERED, this 27th day of January, 2021

The Honorable Renée Marie Bumb
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD and NIPPON SHINYAKU CO., LTD.,

Plaintiffs,

v.

MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC PHARMACEUTICALS, INC., VGYAAN PHARMACEUTICALS LLC, ZYDUS WORLDWIDE DMCC and ZYDUS PHARMACEUTICALS (USA) INC.,

Defendants.

Civil Action No. 1:20-03859 (RMB) (KMW)

STIPULATION OF DISMISSAL AND ORDER

Plaintiffs Actelion Pharmaceuticals Ltd and Nippon Shinyaku Co., Ltd. (collectively, "Plaintiffs") and Defendant VGYAAN Pharmaceuticals LLC ("VGYAAN" or "Defendant") by their undersigned counsel, stipulate and agree, subject to the approval of the Court, as follows:

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WHEREAS, on April 9, 2020, Plaintiffs filed suit against VGYAAN alleging that submission of ANDA No. 214055 and/or the sale and use of VGYAAN's ANDA products constitute and/or induce or contribute to acts of infringement under 35 U.S.C. §§ 271 (a), (b), (c), and (e)(2);

NOW THEREFORE, the parties hereby stipulate and agree as follows:

1. Pursuant to Rule 41(a) and 41(c) of the Federal Rules of Civil Procedure, all claims, counterclaims, and defenses as between Plaintiffs and VGYAAN concerning the '122 and '280 patents are dismissed without prejudice, and each party shall bear its own costs and attorney fees with respect to the '122 and '280 patents;

2. The case caption should be amended to remove VGYAAN as a named party to Civil Action No. 1:20-cv-03859 (RMB) (KMW).

STIPULATED AND AGREED TO BY:

s/ Keith J. Miller
Keith J. Miller
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, NJ 07102
(973) 690-5400
KMiller@rwmlegal.com

Attorneys for Plaintiffs
Actelion Pharmaceuticals Ltd
and Nippon Shinyaku Co., Ltd.

Of Counsel:

Bruce M. Wexler
Preston K. Ratliff II
Aaron P. Selikson
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

Attorneys for Plaintiffs
Actelion Pharmaceuticals Ltd
and Nippon Shinyaku Co., Ltd.

s/ Anandita Vyakarnam
Andrew J. Miller
Anandita Vyakarnam
WINDELS MARX LANE & MITTENDORF, LLP
One Giralda Farms
Madison, NJ 07940
(973) 966-3200
amiller@windelsmarx.com
avyakarnam@windelsmarx.com

Attorneys for Defendant VGYAAN
Pharmaceuticals LLC

IT IS SO ORDERED, this 27th day of January, 2021

The Honorable Renée Marie Bumb
United States District Judge

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through July 06, 2023

You have searched Finished drug products

Search Results: *'72664'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Carbamazepine	72664-218-01	200 mg/1	TABLET	ORAL	ANDA214328	VGYAAN Pharmaceuticals LLC	72664-218	Carbamazepine	CARBAMAZEPINE	HUMAN PRESCRIPTION DRUG	01/03/2022	N/A	ANDA	100 TABLET in 1 BOTTLE (72664-218-01)
+ Carbamazepine	72664-218-10	200 mg/1	TABLET	ORAL	ANDA214328	VGYAAN Pharmaceuticals LLC	72664-218	Carbamazepine	CARBAMAZEPINE	HUMAN PRESCRIPTION DRUG	01/03/2022	N/A	ANDA	1000 TABLET in 1 BOTTLE (72664-218-10)
+ Carbamazepine	72664-218-30	200 mg/1	TABLET	ORAL	ANDA214328	VGYAAN Pharmaceuticals LLC	72664-218	Carbamazepine	CARBAMAZEPINE	HUMAN PRESCRIPTION DRUG	01/03/2022	N/A	ANDA	30 TABLET in 1 BOTTLE (72664-218-30)
+ Clomipramine Hydrochloride	72664-214-30	25 mg/1	CAPSULE	ORAL	ANDA213221	VGYAAN Pharmaceuticals LLC	72664-214	Clomipramine Hydrochloride	CLOMIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	07/01/2021	N/A	ANDA	30 CAPSULE in 1 BOTTLE (72664-214-30)
+ Clomipramine Hydrochloride	72664-214-90	25 mg/1	CAPSULE	ORAL	ANDA213221	VGYAAN Pharmaceuticals LLC	72664-214	Clomipramine Hydrochloride	CLOMIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	07/01/2021	N/A	ANDA	90 CAPSULE in 1 BOTTLE (72664-214-90)

1336

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Clomipramine Hydrochloride	72664-215-30	50 mg/1	CAPSULE	ORAL	ANDA213221	VGYAAN Pharmaceuticals LLC	72664-215	Clomipramine Hydrochloride	CLOMIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	07/01/2021	N/A	ANDA	30 CAPSULE in 1 BOTTLE (72664-215-30)
+ Clomipramine Hydrochloride	72664-215-90	50 mg/1	CAPSULE	ORAL	ANDA213221	VGYAAN Pharmaceuticals LLC	72664-215	Clomipramine Hydrochloride	CLOMIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	07/01/2021	N/A	ANDA	90 CAPSULE in 1 BOTTLE (72664-215-90)
+ Clomipramine Hydrochloride	72664-216-30	75 mg/1	CAPSULE	ORAL	ANDA213221	VGYAAN Pharmaceuticals LLC	72664-216	Clomipramine Hydrochloride	CLOMIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	07/01/2021	N/A	ANDA	30 CAPSULE in 1 BOTTLE (72664-216-30)
+ Clomipramine Hydrochloride	72664-216-90	75 mg/1	CAPSULE	ORAL	ANDA213221	VGYAAN Pharmaceuticals LLC	72664-216	Clomipramine Hydrochloride	CLOMIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	07/01/2021	N/A	ANDA	90 CAPSULE in 1 BOTTLE (72664-216-90)
+ Dofetilide	72664-229-60	.125 mg/1	CAPSULE	ORAL	ANDA215323	VGYAAN Pharmaceuticals LLC	72664-229	Dofetilide	DOFETILIDE	HUMAN PRESCRIPTION DRUG	10/25/2022	N/A	ANDA	60 CAPSULE in 1 BOTTLE (72664-229-60)
+ Dofetilide	72664-230-60	.25 mg/1	CAPSULE	ORAL	ANDA215323	VGYAAN Pharmaceuticals LLC	72664-230	Dofetilide	DOFETILIDE	HUMAN PRESCRIPTION DRUG	10/25/2022	N/A	ANDA	60 CAPSULE in 1 BOTTLE (72664-230-60)
+ Dofetilide	72664-231-60	.5 mg/1	CAPSULE	ORAL	ANDA215323	VGYAAN Pharmaceuticals LLC	72664-231	Dofetilide	DOFETILIDE	HUMAN PRESCRIPTION DRUG	10/25/2022	N/A	ANDA	60 CAPSULE in 1 BOTTLE (72664-231-60)
+ Leuprolide Acetate	72664-611-28		KIT		ANDA213829	VGYAAN Pharmaceuticals LLC	72664-611	Leuprolide Acetate		HUMAN PRESCRIPTION DRUG	10/01/2021	N/A	ANDA	1 KIT in 1 CARTON (72664-611-28) * 2.8 mL in 1 VIAL, MULTI-DOSE * 1 mL in 1 PACKET

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ NADOLOL	72664-211-01	20 mg/1	TABLET	ORAL	ANDA212856	VGYAAN Pharmaceuticals LLC	72664-211	NADOLOL	NADOLOL	HUMAN PRESCRIPTION DRUG	05/19/2021	N/A	ANDA	100 TABLET in 1 BOTTLE, PLASTIC (72664-211-01)
+ NADOLOL	72664-212-01	40 mg/1	TABLET	ORAL	ANDA212856	VGYAAN Pharmaceuticals LLC	72664-212	NADOLOL	NADOLOL	HUMAN PRESCRIPTION DRUG	05/19/2021	N/A	ANDA	100 TABLET in 1 BOTTLE, PLASTIC (72664-212-01)
+ NADOLOL	72664-213-01	80 mg/1	TABLET	ORAL	ANDA212856	VGYAAN Pharmaceuticals LLC	72664-213	NADOLOL	NADOLOL	HUMAN PRESCRIPTION DRUG	05/19/2021	N/A	ANDA	100 TABLET in 1 BOTTLE, PLASTIC (72664-213-01)
+ Ursodiol	72664-217-01	300 mg/1	CAPSULE	ORAL	ANDA214329	VGYAAN Pharmaceuticals LLC	72664-217	Ursodiol	URSODIOL	HUMAN PRESCRIPTION DRUG	10/25/2020	N/A	ANDA	100 CAPSULE in 1 BOTTLE, PLASTIC (72664-217-01)

Showing 1 to 17 of 17 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

VGYAAN Pharmaceuticals LLC

23 Orchard Road, Suite 180, Skillman, NJ 08558
Phone Number: 609-452-2770

Officers:

Full Name: Nailesh Bhatt
Title/Position: CEO
23 Orchard Road, Suite 180, Skillman, NJ 08558

Full Name: Nimisha Bhatt
Title/Position: COO
23 Orchard Road, Suite 180, Skillman, NJ 08558

Ownership:

Name of Company: **RK Pharma Inc**
Percentage Owned: 100%
FEIN: 82-4714511
State of Incorporation: Delaware
Address: 401 North Middletown Road, Building 215/215A, Pearl River, NY 10965
Phone Number: 732-529-6987

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

VGYAAN PHARMACEUTICALS LLC
0600406976

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on January 24, 2014.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

NAILESH A BHATT
23 CORNFLOWER CT
SUITE 200
BELLE MEAD, NJ 08502

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 16th day of March, 2023

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6141286744

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0748620

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department **written notice** prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: [X] **manufacturer** [X] **wholesaler** **which conducts business at the following locations in this State:**

23 ORCHARD RD, STE 180 SKILLMAN, NJ 08558-

Reg. No.
5005560

VGYAAN PHARMACEUTICALS LLC
23 ORCHARD RD, STE 180
SKILLMAN, NJ 08558-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2024

Establishment Copy

VGYAAN Pharmaceuticals LLC

Trading Partners :

CMO:

Aizant Drug Research Solutions Pvt. Ltd.
Address of CMO:
Survey No 172/173, Apparel Park Road, Dulapally Village,
Dundigal-Gandimaisamma Mandal, Medchal-Malkhajgiri District,
Hyderabad, Telangana 500100, India

Pharmaceutics International, Inc.
10709 Gilroy Road
Hunt Valley, MD 21031

Third Party Logistics Provider:

Eversana Life Sciences Services, LLC
Address of 3PL: 4580 Mendenhall Road, Memphis, TN 38141

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. BX0035975

Application/License No. _____

VGYAAN Pharmaceuticals LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is

23 Orchard Road STE 180, Skillman, NJ 08558 (Address of Applicant/Principal), as PRINCIPAL, and Jet Insurance Company (Surety Company), a corporation organized under the laws of the state of North Carolina (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is

11440 Carmel Commons Blvd Ste 207 Charlotte, NC 28226 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 08/01/2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this

24th day of August, 2023.

APPLICANT/PRINCIPAL COMPANY

VGYAAN Pharmaceuticals LLC

Authorized Representative

SURETY

Jet Insurance Company

Surety Company's Representative

JET INSURANCE COMPANY CORPORATE SEAL NORTH CAROLINA

David Gonsalves, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Nick Brady
Witness

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Countersigned by: **David Gonsalves** **3349773**

Nevada Resident Agent

Bond Number: BX0035975

JET INSURANCE COMPANY

POWER OF ATTORNEY

NOW ALL BY THESE PRESENTS: That **JET INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of North Carolina, having its principal office in Charlotte, North Carolina does hereby constitute and appoint

Name	Limit of Liability per Bond
David Gonsalves	**$100,000.00**

its true and lawful Attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds, undertakings, contracts of indemnity, recognizances and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, provided that the liability of such shall not exceed the limit stated above.

The execution of such instrument(s) in pursuance of these presents, shall be as binding upon **JET INSURANCE COMPANY** as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at the principal office.

The Power of Attorney is executed and may be certified so, and may be revoked, pursuant to and by authority of the following resolutions adopted by the Board of Directors of **JET INSURANCE COMPANY** by unanimous written consent dated August 03, 2018, of which the following is a true excerpt:

RESOLVED that the President, or any Vice President, acting with any Secretary or Assistant Secretary, shall have power and authority to appoint Attorney(s)-in-fact, and to authorize them to execute on behalf of the Company, attach the Seal of the Company thereto and deliver, bonds, undertakings, contracts of indemnity, recognizances and other writings obligatory in the nature thereof; to prescribe their respective duties and the respective limits of their authority; and to revoke, at any time, any such Attorney-in-fact and revoke the authority given.

Further, this Power of Attorney is signed and sealed by facsimile pursuant to resolution of the Board of Directors of the Company adopted by unanimous written consent dated August 3, 2018, of which the following is a true excerpt:

RESOLVED that the signature of any authorized officer and the Seal of the Company may be affixed by facsimile to any Power of Attorney or certification thereof authorizing the execution on behalf of the Company and delivery of any bond, undertaking, contract of indemnity, recognizance and other writings obligatory in the nature thereof, and such signature and seal when so used shall have the same force and effect as though manually affixed.

IN WITNESS WHEREOF, **JET INSURANCE COMPANY** has caused this instrument to be signed and its corporate seal to be affixed by its authorized officer, this 17th day of May, 2023.

SEAL

JET INSURANCE COMPANY

Spencer Silno, President

Richard Popp, Secretary

STATE OF NORTH CAROLINA
County of Mecklenburg

On this 17th day of May, 2023 before me came the individuals who executed the preceding instrument, to me personally known, and being by me duly sworn, said that each is the herein described and authorized officer of Jet Insurance Company; that the seal affixed to said instrument is the Corporate Seal of said Company; that the Corporate Seal and each signature were duly affixed by order of the Board of Directors of said Company.

Sara C. Holt
Notary Public, State of North Carolina
County of Mecklenburg
My Commission Expires 09/11/2027

IN WITNESS WHEREOF, I have hereunto set my hand at Jet Insurance Company offices the day and year above written.

SARA C. HOLT
Notary Public, North Carolina
Mecklenburg County
My Commission Expires
September 11, 2027

I, Richard Popp, Secretary of **JET INSURANCE COMPANY**, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney executed by **JET INSURANCE COMPANY**, which is still in full force and effect.

SEAL

IN WITNESS WHEREOF, I have thereunto set my hand and attached the seal of said Company this 24th day of August, 2023.

Richard Popp, Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler VGYAAN Pharmaceuticals LLC

Pharmacy/Wholesaler License # (if applicable) WH03058

Physical Address 23 Orchard Road, Suite 180

City Skillman State NJ Zip 08558

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 609-452-2770 Website www.vgyaan.com

Licensing Company Email compliance@vgyaan.com

Section 2: Personal Information

First Nimisha Middle Vyas Last Bhatt

Alias(es, nicknames, name changes, etc.) Nimisha Vyas

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address 23 Orchard Road, Suite 180

City Skillman State NJ Zip 08558

Telephone [redacted] Email compliance.vgyaan.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Yale University		09/95-05/97	
Address	City	State	Zip
	New Haven	CT	
Diploma/Degree obtained, if any			
MPH			
School Name		From - To (MM/YY – MM/YY)	
University of PA		09/91-05/95	
Address	City	State	Zip
	Philadelphia	PA	
Diploma/Degree obtained, if any			
BA			
School Name		From - To (MM/YY – MM/YY)	
Frederick High School		09/87-06/91	
Address	City	State	Zip
	Frederick	MD	
Diploma/Degree obtained, if any			
HS Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/15-Current	[redacted] Cornflower Ct	Belle Mead	NJ	08502
10/01-07/15	[redacted] Sapphire Lane	Franklin Park	NJ	08823
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.2395) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
VGYAAN Pharmaceuticals LLC		01/14-Current	
Business Address	**City**	**State**	**Zip**
23 Orchard Road, Suite 180	Skillman	NJ	08558
Phone	**Title**	**Number of Employed Hours**	
609-452-2770	COO	40	
Description of Duties			
Oversee company operations, including supply chair, finance, compliance and HR.			

Business Name		From - To (MM/YY – MM/YY)	
Proximare Inc.		06/11-12/13	
Business Address	**City**	**State**	**Zip**
100 Overlook Center, 2nd Floor	Princeton	NJ	08540
Phone	**Title**	**Number of Employed Hours**	
	VP	30	
Description of Duties			
Provide consulting services for global life sciences clients, including strategy development and execution, market research and analysis along with coordination of all activities with external consultants and advisors.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2020-04-09	2021-01-27	NJ		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
1:20- cv-03859	NJ District Court

Reason/Charge
Infringement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Defendant	Lawsuit

Name of Business/Industry/Entity
VGYAAN Pharmaceuticals LLC

Provide explanation below:

VGYAAN Pharmaceuticals was named as one of multiple defendants in a patent infringement lawsuit filed by Plaintiffs Actelion Pharmaceuticals Ltd and Nippon Shinyaku Co., Ltd on April 9, 2020

All claims, counterclaims, and defenses as between Plaintiffs and VGYAAN concerning the patents were dismissed without prejudice on January 27, 2021.

See attached Stipulation of Dismissal and Order.

Nicholas Bluett

Original Signature (electronic, copies or stamps not accepted)

7/26/2023

Date

I, Nimisha Bhatt, **certify that as the designated representative for**

VGYAAN Pharmaceuticals LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. NB I am at least 21 years of age;
3. NB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. NB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. NB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. NB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. NB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Nimisha Bhatt

Print Name (First, Last)

Nimisha Bhatt

Original Signature (electronic, copies or stamps not accepted)

7/26/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nimisha Bhatt

Print Name (First, Last)

Nimisha Bhatt

Original Signature (electronic, copies or ~~stamps not accepted~~)

7/26/23

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Somerset

I, NIMISHA BHATT, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Nimisha Bhatt

Original Signature

7/26/23

Date

Subscribed and Sworn to before me this 26th day of July 2023

Notary Public Signature

MAGGIE DAWOUD
Notary Public - State of New Jersey
My Commission Expires May 22, 20?

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: VGYAAN Pharmaceuticals LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH03058

Physical Address: 23 Orchard Road, Suite 180

City: Skillman State: NJ Zip: 08558

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 609-452-2770 Website: www.vgyaan.com

Licensing Company Email: compliance@vgyaan.com

Section 2: Personal Information

First: Nailesh Middle: A. Last: Bhatt

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 23 Orchard Road, Suite 180

City: Skillman State: NJ Zip: 08558

Telephone: [redacted] Email: nailesh.bhatt@vgyaan.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ross University School of Medicine		09/94 - 04/95	
Address	City	State	Zip
	Portsmouth	Dominica	
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Boston University		09/92 - 06/94	
Address	City	State	Zip
	Boston	MA	
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
Rutgers University		09/90 - 06/92	
Address	City	State	Zip
	New Brunswick	NJ	
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Fairlawn High School		09/88 - 06/90	
Address	City	State	Zip
	Fairlawn	NJ	
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/15 - current	[redacted]Cornflower Court	Belle Mead	NJ	08502
10/01 - 07/15	[redacted]Sapphire Lane	Franklin Park	NJ	08823
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials NB

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
VGYAAN Pharmaceuticals LLC			01/14 - current
Business Address	**City**	**State**	**Zip**
23 Orchard Road, Suite 180	Skillman	NJ	08558
Phone	**Title**		
609-452-2770	CEO		
Description of Duties			
Responsible for overseeing all aspects of the business.			

Business Name			From - To (MM/YY – MM/YY)
CoreRx, Inc.			01/21 - present
Business Address	**City**	**State**	**Zip**
14205 Myerlake Circle	Clearwater	FL	33760
Phone	**Title**		
	Member, Board of Directors		
Description of Duties			
Serve as Member of the Board			

Business Name			From - To (MM/YY – MM/YY)
Azurity Pharmaceuticals			04/18 - present
Business Address	**City**	**State**	**Zip**
8 Cabot Road, Suite 2000	Woburn	MA	01801
Phone	**Title**		
	Member, Board of Directors		
Description of Duties			
Serve as Member of the Board			

Business Name			From - To (MM/YY – MM/YY)
Sonnet BioTherapeutics, Inc.			06/18 - present
Business Address	**City**	**State**	**Zip**
100 Overlook Center	Princeton	NJ	
Phone	**Title**		
	Member, Board of Directors		
Description of Duties			
Serve as Member of the Board			

Business Name			From - To (MM/YY – MM/YY)
Proximare Inc.			09/01 - present
Business Address	**City**	**State**	**Zip**
100 Overlook Center, 2nd Floor	Princeton	NJ	08540
Phone	**Title**		
	Founder & Managing Director		
Description of Duties			
Provide strategic advisory services for global pharmaceuticals, life sciences and healthcare clients.			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2020-04-09	2021-01-27	NJ		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
1:20-cv-03859	New Jersey District Court

Reason/Charge
Infringement of intellectual property.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Defendant	Lawsuit

Name of Business/industry/Entity
VGYAAN Pharmaceuticals LLC

Provide explanation below:

VGYAAN Pharmaceuticals was named as one of multiple defendants in a patent infringement lawsuit filed by Plaintiffs Actelion Pharmaceuticals Ltd and Nippon Shinyaku Co., Ltd. on April 9, 2020.

All claims, counterclaims, and defenses as between Plaintiffs and VGYAAN concerning the patents were dismissed without prejudice on January 27, 2021.

See attached Stipulation of Dismissal and Order.

Original Signature (electronic, copies or stamps not accepted)

7/22/2023
Date

Applicant's initials NB

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nailesh Bhatt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/22/2023
Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Middlesex

I, Nailesh A. Bhatt, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

07/22/23
Date

Subscribed and Sworn to before me this 22nd day of July 2023.

Notary Public Signature

TALHA T AHMED
Commission # 50207758
Notary Public, State of New Jersey
My Commission Expires
03/15/2028

(Seal)

Applicant's initials NB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site VGYAAN Pharmaceuticals LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH03058

Physical Address 23 Orchard Road, Suite 180

City Skillman State NJ Zip 08558

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 609-452-2770 Website www.vgyaan.com

Licensing Company Email compliance@vgyaan.com

Section 2: Personal Information

First Nimisha Middle Vyas Last Bhatt

Alias(es, nicknames, name changes, etc.) Nimisha Vyas

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 23 Orchard Road, Suite 180

City Skillman State NJ Zip 08558

Telephone [redacted] Email compliance@vgyaan.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Yale University		09/95 - 05/97	
Address	City	State	Zip
	New Haven	CT	
Diploma/Degree obtained, if any			
MPH			
School Name		From - To (MM/YY – MM/YY)	
University of Pennsylvania		09/91 - 05/95	
Address	City	State	Zip
	Philadelphia	PA	
Diploma/Degree obtained, if any			
BA			
School Name		From - To (MM/YY – MM/YY)	
Frederick High School		09/87 - 06/91	
Address	City	State	Zip
	Frederick	MD	
Diploma/Degree obtained, if any			
HS Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/15 - current	[redacted] Cornflower Court	Belle Mead	NJ	08502
From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/01 - 07/15	[redacted] Sapphire Lane	Franklin Park	NJ	08823
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials NB

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
VGYAAN Pharmaceuticals LLC			01/14 - current (06/21)
Business Address	**City**	**State**	**Zip**
23 Orchard Road, Suite 180	Skillman	NJ	08558
Phone	**Title**		
609-452-2770	COO		
Description of Duties			
Oversee company operations, including supply chain, finance, compliance and HR.			

Business Name			From - To (MM/YY – MM/YY)
Proximare Inc.			06/11 - 12/13
Business Address	**City**	**State**	**Zip**
100 Overlook Center, 2nd Floor	Princeton	NJ	08540
Phone	**Title**		
	Vice President		
Description of Duties			
Provide consulting services for global life sciences clients, including strategy development & execution, market research & analysis and coordination of all activities with external consultants and advisors.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials NB

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Applicant's initials NB

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2020-04-09	2021-01-27	NJ		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
1:20-cv-03859	New Jersey District Court

Reason/Charge
Infringement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Defendant	Lawsuit

Name of Business/Industry/Entity
VGYAAN Pharmaceuticals LLC

Provide explanation below:

VGYAAN Pharmaceuticals was named as one of multiple defendants in a patent infringement lawsuit filed by Plaintiffs Actelion Pharmaceuticals Ltd and Nippon Shinyaku Co., Ltd. on April 9, 2020.

All claims, counterclaims, and defenses as between Plaintiffs and VGYAAN concerning the patents were dismissed without prejudice on January 27, 2021.

See attached Stipulation of Dismissal and Order.

Nicholas Bluett

Original Signature (electronic, copies or stamps not accepted)

7/22/2023

Date

Applicant's initials NB

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nimisha Bhatt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/22/23

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Middlesex

I, NIMISHA BHATT, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/22/23

Date

Subscribed and Sworn to before me this 22nd day of July 2023

Notary Public Signature

(Seal)

TALHA T AHMED
Commission # 50207758
Notary Public, State of New Jersey
My Commission Expires
03/15/2028

Applicant's initials NB

EMPLOYEE LIST
JULY 2023

VGYAAN PHARMACEUTICALS

1. Nailesh Bhatt
2. Nimisha Bhatt

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **pharmaceutics international**

CSVExcel

Filter: 1000513101

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Pharmaceutics International, Inc.	1000513101	878265586	ANALYSIS; MANUFACTURE; PACK;	10819 Gilroy Road, Hunt Valley, Maryland (MD) 21031, United States (USA)	12/31/2023

Showing 1 to 1 of 1 entries (filtered from 2 total entries)
Previous1Next
Data Current through: Wednesday, Jul 5, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

1369

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **aizant**

CSVExcel

Filter: 3025169808

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
AIZANT DRUG RESEARCH SOLUTION PRIVATE LIMITED	3025169808	931838152	ANALYSIS;	Maitrivihar Commercial Complex, Block Nos.101-107 & 201 to 206, Ameerpet, Hyderabad, Telangana 500016, India (IND)	12/31/2023

Showing 1 to 1 of 1 entries (filtered from 2 total entries)
Previous1Next
Data Current through: Wednesday, Jul 5, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

1370

NABP ACCREDITED

DRUG DISTRIBUTOR

Eversana Life Science Services, LLC

located at

4580 Mendenhall Rd, Memphis, TN 38141

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

10/17/2021 - 10/16/2024

Period of Accreditation

1371

RKPHA-1 OP ID: SC 1372

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 07/26/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER 732-548-2727 The Schenck Agency, Inc. 495 Main St., P.O. Box 351 Metuchen, NJ 08840-0351	CONTACT NAME: PHONE (A/C, No, Ext): 732-548-2727 FAX (A/C, No): 732-548-2404 E-MAIL ADDRESS:
INSURED Vgyaan Pharmaceuticals LLC 23 Orchard Road Skillman, NJ 08558	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Hartford Fire Ins Company — 19682 INSURER B: Hartford Casualty Ins Co — 29424 INSURER C: Continental Casualty Co — 20443 INSURER D: Columbia Casualty Company — 31127 INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR			13UUNBL6977	11/01/2022	11/01/2023	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ excluded
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
B	X UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$ 9,000,000
	EXCESS LIAB CLAIMS-MADE			13RHUBL6780	11/01/2022	11/01/2023	AGGREGATE	$ 9,000,000
	DED X RETENTION $ 10000							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
C	Products Liab			ADT6080047361	01/01/2023	01/01/2024	EachClaim	5,000,000
D	Excess Products			ADE6080067996	01/01/2023	01/01/2024	Excess	5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

NVBDOFP

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

S R Cocco-Angstrom

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The ACORD name and logo are registered marks of ACORD

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Westmed Inc.

Physical Address: 5580 S. Nogales Hwy

City: Tucson State: AZ Zip: 85706

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 520-294-7987 Website: www.myairlife.com

Name of Designated Representative (DR): Peter Tountas

Licensing Company Email: info@myairlife.com DR Email: ptountas@myairlife.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Air Support Medical Co
Address: 199 RAYMOND STREET City: HOPE State: IN Zip: 47246

Name: Cardinal Health 200, LLC
Address: 7000 Cardinal Place City: Dublin State: OH Zip: 43017

Name: Flexible Technologies, Inc
Address: 528 Carwellyn Road City: Abbeville State: SC Zip: 29620

Name: A-1 Fab Inc.
Address: 3214 E. 46th Street City: Tucson State: AZ Zip: 85713

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Michigan
Parent Company (if any): SunMed Group Holdings (dba Airlife)
Corporation/Organization Name:
Mailing Address: 2710 Northridge Dr. NW Suite A
City: Grand Rapids State: MI Zip: 49544
Telephone: 800.433.2797 Email: info@myairlife.com
Contact Person Name: Rob Yamashita

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Westmed Inc.

Facility Name

Peter Tountas

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8/18/2023

Date

Board Use Only	Date Received: 8/23/23	Amount: 1000-CC 5/31/23

AirLife

September 19, 2023

RE: Nevada Temporary Wholesale License Application

Dear Nevada State Board of Pharmacy,

SunMed Group Holdings, LLC *dba* AirLife, on behalf of its subsidiary Westmed Inc., seeks a temporary license with the State of Nevada to distribute its medical devices to hospitals and medical facilities in Nevada.

AirLife has applied to obtain the "wholesaler license" for its subsidiary company Westmed Inc. This application is in the final stages of review with the Nevada State Board of Pharmacy, and we hope to have the approval in the upcoming weeks. We have ceased selling products into Nevada and did not contest and paid the $5,000 administrative fine based on case number 23-235-O (see FedEx tracking # 6843 5296 7672 for payment confirmation). In the meantime, we have a tremendous amount of demand from the local distribution channels in the State of Nevada. Any further disruption to the supply of our life-saving medical devices (which include nasal suction devices, medicinal delivery devices, and oxygen administration supplies) into the State of Nevada could result in hospitals and clinicians being hindered in their ability to help their patients, the citizens of Nevada.

We are kindly asking for a temporary license so we can meet the Nevada medical community's demand for our life saving products. AirLife is committed to compliance with all state and federal regulations and laws, including Nevada's.

If you have questions, please feel free to contact me. Thank you.

Sincerely,

Rob Yamashita

VP of Regulatory Affairs
269-873-0502
ryamashita@myairlife.com
2710 Northridge Dr. NW, Suite A | Grand Rapids, MI 49544 | USA

TAWP
APPROVED
9/25/23

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260,
Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Westmed Inc.
Address :	5580 S. Nogales Tucson AZ 85706
Registration No :	M002161
Permit Type :	Manufacturer
Sub Type :	Manufacturer
Date Issued :	02/11/2023
Expiration Date :	10/31/2024
Status :	OPEN
Discipline :	No

Kam Gandhi

Kam Gandhi

AirLife

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521
(775)850-1440

August 21, 2023

To Whom It May Concern,

Corresponding to the Wholesaler Applications for SunMed Group Holdings, LLC and Westmed, Inc, here is the required list of all the Officers and Directors:

Westmed, Inc.

Directors:

- Hendrik Struik
- Jon Singer

Officers:

- Hendrik Struik – Chief Executive Officer
- Jon Singer – Chief Financial Officer
- Caitlin Anderson – Chief Administrative Officer, General Counsel & Secretary

SunMed Group Holdings, LLC

Directors:

- Member-managed by FH Sunrise Purchaser, Inc.

Officers:

- Hendrik Struik – Chief Executive Officer
- Jon Singer – Chief Financial Officer
- Caitlin Anderson – Chief Administrative Officer, General Counsel & Secretary

Best Regards,

Valerie Decker

International Regulatory Specialist

AirLife | SunMed | Salter Labs | Westmed | Ventlab | Ethox

Toll Free 800.433.2797
T 616.259.8400
F 616.647.3430

www.myAirLife.com
2710 Northridge Dr NW, Ste. A
Grand Rapids, MI 49544

Establishment Registration & Device Listing

Establishment:
WESTMED, INC.
5580 S NOGALES HWY
TUCSON, AZ 85706
Registration Number: 2028807
FEI Number*: 1000374126
Status: Active
Date Of Registration Status: 2023

Owner/Operator:
WESTMED, INC.
5580 S. NOGALES HIGHWAY
Tucson, AZ US 85706
Owner/Operator Number: 9006543

Official Correspondent:
Rob Yamashita
5580 S. NOGALES HIGHWAY
Tucson, AZ 85706
Phone: 520-2947987

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

√verified
6/21/23

Page Last Updated: 08/28/2023
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

WESTMED, INC.

ACC file number: 05261373

was incorporated under the laws of the State of Arizona on 02/12/1992;

That all annual reports owed to date by said corporation have been filed or delivered for filing, and all annual filing fees owed to date have been paid; and

That, according to the records of the Arizona Corporation Commission, said corporation is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **04/12/2023**

Douglas Clark, Executive Director

Help (./help/index.html)

DRLM Home (mainMenu.htm) > View Your Registrations and Listings

Registration Information

Facility

Registration Number
2028807

FEI Number
1000374126

Registration Status
Active

Registration Status Reason
Legacy Data - Registration activated

Initial Importer
N

Facility Name
WESTMED, INC.

Legal Name

Facility Address
5580 S NOGALES HWY
TUCSON, ARIZONA, 85706, UNITED STATES

DUNS Number
092673953

Foreign Trade Zone
N

Facility URL

Other Business Trade Name(s)

Establishment located on a campus

Owner/Operator

Owner/Operator Number
9006543

Contact Name
ROB YAMASHITA

Business Name
WESTMED, INC.

Address
5580 S. NOGALES HIGHWAY
TUCSON, ARIZONA, 85706, UNITED STATES

Phone Number
520 - 2947987

Fax Number
520 - 2946061

E-mail ryamashita@sun-med.com

DUNS Number

Official Correspondent

Contact Name
ROB YAMASHITA

Business Name
WESTMED, INC.

Address
5580 S. NOGALES HIGHWAY
TUCSON, ARIZONA, 85706, UNITED STATES

Phone Number
520 - 2947987

Fax Number
520 - 2946061

E-mail ryamashita@sun-med.com

DUNS Number

Registration Status

Expiration Date
2023-12-31

PIN - PCN
50378620 - 23546987

< Previous (drlm.htm?_flowExecutionKey=_c5DE6B01C-FE1F-5EB1-7EB6-CF24CAD11B68_kC58631EE-EABF-15CF-FA37-1C9AFF96221C&_eventId=back)

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

12/31/2023

DATE (MM/DD/YYYY) 6/1/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	Lockton Companies 3280 Peachtree Road NE, Suite #1000 Atlanta GA 30305 (404) 460-3600	CONTACT NAME:	
		PHONE (A/C, No, Ext):	FAX (A/C, No):
		E-MAIL ADDRESS:	
		INSURER(S) AFFORDING COVERAGE	NAIC #
		INSURER A : Great Northern Insurance Company	20303
INSURED 1493635	Salter Labs, LLC 272 E. Deerpath Rd Suite 302 Lake Forest IL 60045	INSURER B : Federal Insurance Company	20281
		INSURER C : Chubb Indemnity Insurance Company	12777
		INSURER D :	
		INSURER E :	
		INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** 18018543 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY ☐ CLAIMS-MADE ☒ OCCUR X STOP GAP X $1,000,000 GEN'L AGGREGATE LIMIT APPLIES PER: ☐ POLICY ☐ PRO-JECT ☐ LOC ☐ OTHER:	N	N	36057113	12/31/2022	12/31/2023	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
							GENERAL AGGREGATE	$ 2,000,000
							PRODUCTS - COMP/OP AGG	$ XXXXXXX
								$
A	AUTOMOBILE LIABILITY X ANY AUTO ☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS ☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY	N	N	73618786	12/31/2022	12/31/2023	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
							BODILY INJURY (Per person)	$ XXXXXXX
							BODILY INJURY (Per accident)	$ XXXXXXX
							PROPERTY DAMAGE (Per accident)	$ XXXXXXX
								$ XXXXXXX
B	X UMBRELLA LIAB X OCCUR ☐ EXCESS LIAB ☐ CLAIMS-MADE ☐ DED X RETENTION $ $0	N	N	78181821	12/31/2022	12/31/2023	EACH OCCURRENCE	$ 10,000,000
							AGGREGATE	$ 10,000,000
								$ XXXXXXX
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A	N	71776686	12/31/2022	12/31/2023	X PER STATUTE ☐ OTH-ER	
							E.L. EACH ACCIDENT	$ 1,000,000
							E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
B	Products/E&O-Claims Made	N	N	99497228	12/31/2022	12/31/2023	Occurrence Limit: $10,000,000 Deductible: 100,000 Aggregate: $10,000,000	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

18018543
For Informational Purposes Only

CANCELLATION See Attachments

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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Attachment Code: D591967 Master ID: 1493635, Certificate ID: 18018543

Named Insureds

1. FH Sunrise Purchaser, Inc.
2. SunMed Group Holdings, LLC
3. SunMed Holdings, LLC
4. Omega Medical Products, LLC
5. Blue Jay Holding, LLC
6. SunMed, LLC
7. Bay Medical Products, LLC
8. Mainline Medical Products, LLC
9. Ventlab, LLC
10. VL International Limited
11. SunMed AP, LTD
12. Salter Labs, LLC
13. Salter Labs Texas, LLC
14. Ethox Medical, LLC
15. Salter Labs de Mexico S.A. de C.V.
16. Salter Labs UK Limited
17. Parker Medical, LLC
18. Westmed Holding Company
19. Westmed, Inc.
20. VBT, LLC
21. Westmed de Mexico S.A. de C.V
22. Cookgas, LLC

Miscellaneous Attachment: M604030 Master ID: 1493635, Certificate ID: 18018543

VALUED CERTIFICATE HOLDER

To whom it may concern:

In our continuing effort to provide timely certificate delivery, Lockton Companies is transitioning to paperless delivery of Certificates of Insurance.

To ensure electronic delivery for future renewals of this certificate, we need your email address. Please contact us via the methods below, referencing Certificate Number that is listed in the Certificate Holder box just above the Certificate Holder Name or in middle section just below the Insured box towards the top **"CERTIFICATE NUMBER: ".**

- Email: **SE-EDelivery@lockton.com**
- **Include the Certificate ID number**
- **Subject line: TSU E-Delivery**

If you no longer need this certificate, please contact us at the email address above, reference the Certificate Holder ID number and use this subject line: "Certificate Removal"

The above inbox is for automating electronic delivery of certificates only. Please do NOT send future certificate requests to this inbox.

Thank you for your cooperation and willingness in reducing our environmental footprint.

Lockton Companies

Lockton Companies
3280 Peachtree Road NE, Ste. 250
Atlanta, GA 30305

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. SU 1196422

Application/License No. _____

Westmed, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5580 S. Nogales Highway, Tucson, AZ 85706 (Address of Applicant/Principal), as PRINCIPAL, and Arch Insurance Company (Surety Company), a corporation organized under the laws of the state of MO (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is Harborside 3, 210 Hudson Street, Suite 300, Jersey City, NJ 07311-1107 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 08/30/2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 30th day of August, 2023.

APPLICANT/PRINCIPAL
Westmed, Inc.

Authorized Representative

SURETY COMPANY
Arch Insurance Company

Surety Company's Representative

Stephen A. Vann, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Ryan Norman

Witness Emma Bryant

Countersigned by:

N/A
Nevada Resident Agent

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated. Not valid for Note, Loan, Letter of Credit, Currency Rate, Interest Rate or Residential Value Guarantees.

POWER OF ATTORNEY

Know All Persons By These Presents:
That the Arch Insurance Company, a corporation organized and existing under the laws of the State of Missouri, having its principal administrative office in Jersey City, New Jersey (hereinafter referred to as the "Company") does hereby appoint:

Bradley Mapes, Oana Dimulescu, Sarah C. Belcastro and Stephen A. Vann of Atlanta, GA (EACH)

its true and lawful Attorney(s)in-Fact, to make, execute, seal, and deliver from the date of issuance of this power for and on its behalf as surety, and as its act and deed: Any and all bonds, undertakings, recognizances and other surety obligations, in the penal sum not exceeding One Hundred Fifty Million Dollars ($150,000,000.00). This authority does not permit the same obligation to be split into two or more bonds In order to bring each such bond within the dollar limit of authority as set forth herein.

The execution of such bonds, undertakings, recognizances and other surety obligations in pursuance of these presents shall be as binding upon the said Company as fully and amply to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at its principal administrative office in Jersey City, New Jersey.

This Power of Attorney is executed by authority of resolutions adopted by unanimous consent of the Board of Directors of the Company on August 31, 2022, true and accurate copies of which are hereinafter set forth and are hereby certified to by the undersigned Secretary as being in full force and effect:
"**VOTED**, That the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, or the Secretary shall have the power and authority to appoint agents and attorneys-in-fact, and to authorize them subject to the limitations set forth in their respective powers of attorney, to execute on behalf of the Company, and attach the seal of the Company thereto, bonds, undertakings, recognizances and other surety obligations obligatory in the nature thereof, and any such officers of the Company may appoint agents for acceptance of process."

This Power of Attorney is signed, sealed and certified by facsimile under and by authority of the following resolution adopted by the unanimous consent of the Board of Directors of the Company on August 31, 2022:

VOTED, That the signature of the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, and the signature of the Secretary, the seal of the Company, and certifications by the Secretary, may be affixed by facsimile on any power of attorney or bond executed pursuant to the resolution adopted by the Board of Directors on August 31, 2022, and any such power so executed, sealed and certified with respect to any bond or undertaking to which it is attached, shall continue to be valid and binding upon the Company. **In Testimony Whereof**, the Company has caused this instrument to be signed and its corporate seal to be affixed by their authorized officers, this **3rd day of January, 2023**.

Attested and Certified

Regan A. Shulman, Secretary

Arch Insurance Company
CORPORATE SEAL 1971 Missouri

Arch Insurance Company

Stephen C. Ruschak, Executive Vice President

STATE OF PENNSYLVANIA SS
COUNTY OF PHILADELPHIA SS

I, **Michele Tripodi**, a Notary Public, do hereby certify that Regan A. Shulman and Stephen C. Ruschak personally known to me to be the same persons whose names are respectively as Secretary and Executive Vice President of the Arch Insurance Company, a Corporation organized and existing under the laws of the State of Missouri, subscribed to the foregoing instrument, appeared before me this day in person and severally acknowledged that they being thereunto duly authorized signed, sealed with the corporate seal and delivered the said instrument as the free and voluntary act of said corporation and as their own free and voluntary acts for the uses and purposes therein set forth.

Commonwealth of Pennsylvania - Notary Seal
MICHELE TRIPODI, Notary Public
Philadelphia County
My Commission Expires July 31, 2025
Commission Number 1160622

Michele Tripodi, Notary Public
My commission expires 07/31/2025

CERTIFICATION

I, **Regan A. Shulman**, Secretary of the Arch Insurance Company, do hereby certify that the attached **Power of Attorney dated January 3, 2023** on behalf of the person(s) as listed above is a true and correct copy and that the same has been in full force and effect since the date thereof and is in full force and effect on the date of this certificate; and I do further certify that the said Stephen C. Ruschak, who executed the Power of Attorney as Executive Vice President, was on the date of execution of the attached Power of Attorney the duly elected Executive Vice President of the Arch Insurance Company.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seal of the Arch Insurance Company on this 30th **day of** August, 2023.

Regan A. Shulman, Secretary

This Power of Attorney limits the acts of those named therein to the bonds and undertakings specifically named therein and they have no authority to bind the Company except in the manner and to the extent herein stated.

PLEASE SEND ALL CLAIM INQUIRIES RELATING TO THIS BOND TO THE FOLLOWING ADDRESS:
Arch Insurance – Surety Division
3 Parkway, Suite 1500
Philadelphia, PA 19102

Arch Insurance Company
CORPORATE SEAL 1971 Missouri

To verify the authenticity of this Power of Attorney, please contact Arch Insurance Company at SuretyAuthentic@archinsurance.com
Please refer to the above named Attorney-In-Fact and the details of the bond to which the power is attached.

AirLife

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

August 21, 2023

To Whom It May Concern,

Corresponding to the Wholesaler Application for Westmed, Inc., here is the required list of all persons employed at 5580 S. Nogales Highway, Tucson, AZ 85706:

Acosta	Laura	ASSEMBLR - Assembler
Acuna	Anthony	WRHASSOC - Warehouse Associate
Aguilar	Jose Oscar	ASMMMTCH - ASM Materials & Machine Tech
Alcantar	Josefina	MOLDDATA - Molding Lead Data Clerk
Alvarez	Blanca	MLDGOP - Molding Operator
Alvarez	Emilio	MLDMTHND - Molding Material Handler
Avila	Rosa	ASSEMBLR - Assembler
Aviles	Miranda	WRHASSOC - Warehouse Associate
Baxter	James	SHIPCLRK - Shipping Clerk
Bazan	Maria	MLDGOP - Molding Operator
Bencomo	Graciela	MLDGOP - Molding Operator
Borbon	Rafaela	MLDGOP - Molding Operator
Bracamonte	Frank	RECCLRK - Receiving Clerk
Bustos	Angel	SHIPSUP - Shipping Supervisor
Cabrera	Richard C	SHIPCLRK - Shipping Clerk
Campbell	Brianna	MLDGOP - Molding Operator
Cardenas	Claudia A	MLDLDOP - Molding Lead Operator
Carmona	Dina	SRQCINSP - Sr QC Inspector
Carrasco	Jorge	MAINTECH - Maintenance Tech II/Facilities

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Carrizosa	Christian Gabriel	ENGTECH - Engineering Technician
Casasola Zapien	Jasmine	MLDGOP - Molding Operator
Castro	Maria R	ASSEMBLR - Assembler
Chavarria	Armida	ASSEMBLR - Assembler
Contreras	Sergio	JRMLDMKR - Journeyman Mold Maker
Cournoyer	Christopher A	MLDSFSUP - Molding Shift Supervisor
Cuevas	Wendy C	WRHDCLRK - Warehouse Data Clerk
Curiel	Jose Robert	TRCKDRVR - Truck Driver
Davis	Kim	MATEXPED - Materials Expeditor
Dube	Brad R	TOLDIMKR - Tool & Die Maker
Duenas	Eva Angelina	MLDLDOP - Molding Lead Operator
Farmer	Johnathon	QALCNTIN - Quality Control Inspector
Fimbres	Alba	ASSEMBLR - Assembler
Garcia	Siria	ASSEMSUP - Assembly Supervisor
Garcia	Andrea	MLDGOP - Molding Operator
Garcia	Luz	MLDGOP - Molding Operator
Gavino	Gaudelia	QALCNTIN - Quality Control Inspector
George	Sarah B	MSTRSCHD - Master Scheduler
Gomez	Lorraine	BUYER - Buyer
Gomez	Lidya	QALCNTIN - Quality Control Inspector
Gonzalez	Candido	QALCNTIN - Quality Control Inspector
Gonzalez Lopez	Francisca	QALCNTIN - Quality Control Inspector
Guerrero	Maria	ASSEMBLR - Assembler
Haralson	Crystal M	INDDTANL - IND Data Analyst
Hoffman	Tee Jay	WRHASSOC - Warehouse Associate
Hoyos	Eusebio	TRCKDRVR - Truck Driver

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Hymbaugh	Dustin A	PMTLTECH - PM Tooling Tech
Johnson	Matthew C	SHIPCLRK - Shipping Clerk
Johnson	Annalisa A	SHIPCLRK - Shipping Clerk
Lau	Roger	MLDMTHND - Molding Material Handler
Leon Enriquez	Nelyeth	ASSEMBLR - Assembler
Liera	Susana	INCOMINS - Incoming Inspector
Lopez	Martina	MLDGOP - Molding Operator
Lopez	Anthony	WRHASSOC - Warehouse Associate
Lopez-Perea	Yolanda	ASSEMBLR - Assembler
Lorona	Isabel	MLDLDOP - Molding Lead Operator
Madero	Martha	ENGTECH - Engineering Technician
Martinez	Eliud	ASMTHND - Assembly Material Handler
Mazon	Luis	SHIPCLRK - Shipping Clerk
McSwain	David O	MLDSFSUP - Molding Shift Supervisor
Miller	Joshua	QUALSUP - Quality Supervisor
Miranda	Octavio	ASMTHND - Assembly Material Handler
Moore	Blake	PMTLTECH - PM Tooling Tech
Morales	Maritza	SCHBYPLN - Supply Chain Buyer/Planner
Morales	Sipriana L	ASSEMBLR - Assembler
Murray	Sonny	WRHCLRK - Warehouse Clerk
Narvaez Lopez	Vianeth	SRQLMGR - Senior Quality Manager
Olivarria	Reina	ASSEMBLR - Assembler
Olvera	Zulema	ASEMLEAD - Assembly Lead
Osorio De Sanchez	Baudelina	PRSHLDCL - Print Shop Lead Clerk
Pakosta	David L	WRMTRLHD - Whse Material Handler
Parmeter	Rachel	RBTSPEC - Rebate Specialist

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Perea	Luis H	PROCENG - Process Engineer
Perea Avila	Guadalupe	ASSEMBLR - Assembler
Perez	Robert	PRTSHPC - Print Shop Clerk
Phansakdy	Thiphakone	MLDSFSUP - Molding Shift Supervisor
Quintero-Cardenas	Miguel	QAINTRN - Quality Intern
Ramirez	Maria Armida	ASSEMBLR - Assembler
Ramirez	Luz	ASSEMBLR - Assembler
Rea	Hope	ASSEMBLR - Assembler
Reina	Nirma E	ASSEMBLR - Assembler
Rodriguez	Marco	MLDSFSUP - Molding Shift Supervisor
Rodriguez Ayala	Ma Del Rosario	MLDGOP - Molding Operator
Rogers	Santiago	WRHASSOC - Warehouse Associate
Roman	Jose	SRMOLD - Senior Molding Supervisor
Ruiz	Jose	WRHDCLRK - Warehouse Data Clerk
Sanchez	Daniel	WRHASSOC - Warehouse Associate
Selph	Anthony	MLDTECH - Mold Set up Technician
Sicoli	Claudio	PLTENGR - Maintenance/Plant Engineer Manager
Sierra	Juan F	FACTCH - Facility Custodian Technician
Silva	Isabel	ASMAMAGR - ASM Assistant Manager
Silva	Luis E	MLDSFSUP - Molding Shift Supervisor
Sinohui	Lessley	WRHASSOC - Warehouse Associate
Siqueiros	Maria G	ASSEMBLR - Assembler
Sison	Anne	QLSPEC - Quality Specialist
Soderholm	Paul	QALCNTIN - Quality Control Inspector
Solorzano	Gloria	MLDGOP - Molding Operator
Sounnakhone	Christina	LOGCOORD - Logistics Coordinator

AirLife

Suaso	Julian	ITSYSMGR - IT Systems Manager
Sullivan	Julianna	DCOCONSP - Document Control Specialist
Tountas	Peter M	REGAFSPE - Regulatory Affairs Specialist
Touraille	Tracy	SRWARMNG - Senior Warehouse Manager
Valdez	Lorraine O	QALCNTIN - Quality Control Inspector
Vander	Michael A	QLSYSAL - Quality Systems Analyst
Vanover	Edward	MAINTECH - Maintenance Tech II/Facilities
Varela	Elizabeth	RECCLRK - Receiving Clerk
Vega	Enrique	TRCKDRVR - Truck Driver
Veit	Conner Douglas	PRODTENG - Product Engineer
Villasenor	Victor C	WRHCLRK - Warehouse Clerk
Villasenor	Anthony	WRHCLRK - Warehouse Clerk
Walker	Marcus	WRHASSOC - Warehouse Associate
Wilson	Leroy	ASTCTRLR - Assistant Controller
Wix	Christopher L	TOOLDIR - Tooling Director
Woolbright	Michael	MLDLDOP - Molding Lead Operator
Wright	Vivian A	QALCNTIN - Quality Control Inspector
Zagelow	James	CYCCOUNT - Cycle Counter
Zuniga Penuelas	Karla	ASEMLEAD - Assembly Lead

Best Regards,

Valerie Decker

International Regulatory Specialist

AirLife | SunMed | Salter Labs | Westmed | Ventlab | Ethox

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Westmed Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5580 S. Nogales Hwy

City Tucson State AZ Zip 85706

Mailing Address (if different from physical address) N/A

City N/A State _____ Zip _____

Telephone 520-294-7987 Website www.myairlife.com

Licensing Company Email ptountas@myairlife.com

Section 2: Personal Information

First Peter Middle Michael Last Tountas

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] S Prudence Rd Apt [redacted]

City Tucson State AZ Zip 85710

Telephone [redacted] Email ptountas@myairlife.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Brookline College		01/2015-03/2016	
Address	**City**	**State**	**Zip**
300 S. Craycroft Rd	Tucson	AZ	85711
Diploma/Degree obtained, if any			
Associates in Buisness			

School Name		From - To (MM/YY – MM/YY)	
Brookline College		06/2013-02/2014	
Address	**City**	**State**	**Zip**
300 S. Craycroft Rd	Tucson	AZ	85711
Diploma/Degree obtained, if any			
Diploma-Pharmacy Technician			

School Name		From - To (MM/YY – MM/YY)	
Palo Verde High Magnet School		08/2008-05/2012	
Address	**City**	**State**	**Zip**
1302 S Avenida Vega	Tucson	AZ	85710
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/23-Present	[redacted] S Prudence Rd Apt [redacted]	Tucson	AZ	85710
02/20-02/23	[redacted] E. Cooperstown Dr	Tucson	AZ	85706
2/18-02/20	[redacted] E Mary Dr	Tucson	AZ	85730
2/16-2/18	[redacted] E Tanque Verde Rd	Tucson	AZ	85749
2/13-2/16	[redacted] N Pantano Rd	Tucson	AZ	85710
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Westmed Inc.				From - To (MM/YY – MM/YY): 06/2018- Present
Business Address: 5580 S. Nogales Hwy		City: Tucson	State: AZ	Zip: 85706
Phone: 520-664-8293	Title: Regulatory Specialist			Number of Employed Hours: 10,400
Description of Duties: Product registration, Internal/External Audits, FDA 510(k) submissions				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Peter Michael Tountas, **certify that as the designated representative for**

Westmed Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PT I am at least 21 years of age;
3. PT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Peter, Tountas
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/18/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Tountas
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/18/2023
Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Pima

I, Peter Tountas, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/18/2023
Date

Subscribed and Sworn to before me this 18th day of August 2023

Notary Public Signature

Veronica Rodriguez
Notary Public
Pima County, Arizona
My Comm. Expires 01-26-27
Commission No. 643273

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Westmed Inc. MDEG License # (if applicable): _____

Physical Address: 5580 S. Nogales Hwy

City: Tucson State: AZ Zip: 85706

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 520-294-7987 Website: www.myairlife.com

Licensing Company Email: ptountas@myairlife.com

Section 2: Personal Information

First: Peter Middle: Michael Last: Tountas

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] S Prudence Rd Apt [redacted]

City: Tucson State: AZ Zip: 85710

Telephone: [redacted] Email: ptountas@myairlife.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Brookline College		01/2015-03/2016	
Address	City	State	Zip
300 S. Craycroft Rd	Tucson	AZ	85711
Diploma/Degree obtained, if any			
Associates in Buisness			

School Name		From - To (MM/YY – MM/YY)	
Brookline College		06/2013-02/2014	
Address	City	State	Zip
300 S. Craycroft Rd	Tucson	AZ	85711
Diploma/Degree obtained, if any			
Diploma-Pharmacy Technician			

School Name		From - To (MM/YY – MM/YY)	
Palo Verde High Magnet School		08/2008-05/2012	
Address	City	State	Zip
1302 S Avenida Vega	Tucson	AZ	85710
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/23-Present	[redacted] S Prudence Rd Apt [redacted]	Tucson	AZ	85710
02/20-02/23	[redacted] E. Cooperstown Dr	Tucson	AZ	85706
02/18-02/20	[redacted] E Mary Dr	Tucson	AZ	85730
02/16-02/18	[redacted] E Tanque Verde Rd	Tucson	AZ	85749
02/13-02/16	[redacted] N Pantano Rd	Tucson	AZ	85710
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Westmed Inc.			06/2018- Present	
Business Address		**City**	**State**	**Zip**
5580 S. Nogales Hwy		Tucson	AZ	85706
Phone	**Title**		**Number of Employed Hours**	
520-664-8293	Regulatory Specialist		10,400	
Description of Duties				
Product registration, Internal/External Audits, FDA 510(k) submissions				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Peter Michael Tountas, **certify that as the MDEG Administrator for**

Westmed Inc.,

that I (initial that you have read and meet the following requirements):

1. PT Have a high school diploma or its equivalent;
2. PT Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. PT Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. PT Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter, Tountas
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/18/23
Date

Board Use Only	Date Received:

4HH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☑ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Actelion Pharmaceuticals US, Inc.

Physical Address: 1125 Trenton Harbourton Road

City: Titusville State: NJ Zip: 08560

Mailing Address (if different from physical address): Same as physical address.

City: _____ State: _____ Zip: _____

Telephone: 215-325-2519 Website: https://www.janssen.com/

Name of Designated Representative (DR): Erica Moor

Licensing Company Email: emoor@its.jnj.com DR Email: emoor@its.jnj.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer (virtual)
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): .Johnson & Johnson

Corporation Name: Actelion Pharmaceuticals US, Inc.

Mailing Address: 1125 Trenton Harbourton Road

City: Titusville State: NJ Zip: 08560

Telephone: 215-325-2519 Email: emoor@its.jnj.com

Contact Person Name: Erica Moore

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol: JNJ

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification N/A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment D		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** See Attachment D	✓			
• **List of all corporation shareholders and their percent ownership.** N/A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - applicant is a wholly-owned subsidiary of a publicly traded company		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - applicant is a wholly-owned subsidiary of a publicly traded company		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) ~~N/A~~ See Attachment D	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment C	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment F	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Actelion Pharmaceuticals US, Inc.

Facility Name

Erica Moor

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

July 27, 2023

Date

Board Use Only	Date Received: 8/28/23	Amount: 1000 - CK - 1115

Attachment A

Nature of Business

Actelion Pharmaceuticals US, Inc. (Actelion) is a virtual manufacturer. Actelion will utilize contract manufacturers to produce its products and a licensed third party logistics provider to warehouse and distribute its products. Accordingly, Actelion will never actually physically manufacture, handle, or distribute any products. Because Actelion does not manufacture or handle product, the FDA will not inspect. Provided below is the information for Actelion's third party distributor and contract manufacturer.

Contract Manufacturer

Almac Pharma Services, Ltd.
22 Seagoe Industrial Estate
BT63 5QD, United Kingdom
FDA Registration #: 3004444888

Third Party Logistics Provider

Integrated Commercialization Solutions, LLC
420 International Blvd., Suite 500
Brooks, KY 40109

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through May 02, 2023

You have searched Finished drug products

Search Results: *'ACTELION'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date
+ OPSUMIT	66215-501-15	10 mg/1	TABLET, FILM COATED	ORAL	NDA204410	Actelion Pharmaceuticals US, Inc.	66215-501	macitentan	MACITENTAN	HUMAN PRESCRIPTION DRUG	11/04/2013
+ OPSUMIT	66215-501-30	10 mg/1	TABLET, FILM COATED	ORAL	NDA204410	Actelion Pharmaceuticals US, Inc.	66215-501	macitentan	MACITENTAN	HUMAN PRESCRIPTION DRUG	11/04/2013
+ Tracleer	66215-102-03	125 mg/1	TABLET, FILM COATED	ORAL	NDA021290	Actelion Pharmaceuticals US, Inc.	66215-102	bosentan	BOSENTAN	HUMAN PRESCRIPTION DRUG	10/02/2012
+ Tracleer	66215-102-06	125 mg/1	TABLET, FILM COATED	ORAL	NDA021290	Actelion Pharmaceuticals US, Inc.	66215-102	bosentan	BOSENTAN	HUMAN PRESCRIPTION DRUG	11/20/2001
+ Tracleer	66215-101-03	62.5 mg/1	TABLET, FILM COATED	ORAL	NDA021290	Actelion Pharmaceuticals US, Inc.	66215-101	bosentan	BOSENTAN	HUMAN PRESCRIPTION DRUG	10/02/2012
+ Tracleer	66215-101-06	62.5 mg/1	TABLET, FILM COATED	ORAL	NDA021290	Actelion Pharmaceuticals US, Inc.	66215-101	bosentan	BOSENTAN	HUMAN PRESCRIPTION DRUG	11/20/2001
+ Tracleer	66215-232-56	32 mg/1	TABLET, SOLUBLE	ORAL	NDA209279	Actelion Pharmaceuticals US, Inc.	66215-232	bosentan	BOSENTAN	HUMAN PRESCRIPTION DRUG	07/29/2021
+ Tracleer	66215-103-56	32 mg/1	TABLET, SOLUBLE	ORAL	NDA209279	Actelion Pharmaceuticals US, Inc.	66215-103	bosentan	BOSENTAN	HUMAN PRESCRIPTION DRUG	11/13/2017
+ UPTRAVI	66215-604-06	400 ug/1	TABLET, COATED	ORAL	NDA207947	Actelion Pharmaceuticals US, Inc.	66215-604	Selexipag	SELEXIPAG	HUMAN PRESCRIPTION DRUG	12/21/2015
+ UPTRAVI	66215-606-06	600 ug/1	TABLET, COATED	ORAL	NDA207947	Actelion Pharmaceuticals US, Inc.	66215-606	Selexipag	SELEXIPAG	HUMAN PRESCRIPTION DRUG	12/21/2015
+ UPTRAVI	66215-718-01	1800 ug/10mL	INJECTION, POWDER, FOR SOLUTION	INTRAVENOUS	NDA214275	Actelion Pharmaceuticals US, Inc.	66215-718	Selexipag	SELEXIPAG	HUMAN PRESCRIPTION DRUG	07/29/2021
+ UPTRAVI	66215-602-06	200 ug/1	TABLET, COATED	ORAL	NDA207947	Actelion Pharmaceuticals US, Inc.	66215-602	Selexipag	SELEXIPAG	HUMAN PRESCRIPTION DRUG	12/21/2015

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date
+ UPTRAVI	66215-602-14	200 ug/1	TABLET, COATED	ORAL	NDA207947	Actelion Pharmaceuticals US, Inc.	66215-602	Selexipag	SELEXIPAG	HUMAN PRESCRIPTION DRUG	12/21/2015
+ UPTRAVI	66215-610-06	1000 ug/1	TABLET, COATED	ORAL	NDA207947	Actelion Pharmaceuticals US, Inc.	66215-610	Selexipag	SELEXIPAG	HUMAN PRESCRIPTION DRUG	12/21/2015
+ UPTRAVI	66215-616-06	1600 ug/1	TABLET, COATED	ORAL	NDA207947	Actelion Pharmaceuticals US, Inc.	66215-616	Selexipag	SELEXIPAG	HUMAN PRESCRIPTION DRUG	12/21/2015
+ UPTRAVI	66215-612-06	1200 ug/1	TABLET, COATED	ORAL	NDA207947	Actelion Pharmaceuticals US, Inc.	66215-612	Selexipag	SELEXIPAG	HUMAN PRESCRIPTION DRUG	12/21/2015
+ UPTRAVI	66215-614-06	1400 ug/1	TABLET, COATED	ORAL	NDA207947	Actelion Pharmaceuticals US, Inc.	66215-614	Selexipag	SELEXIPAG	HUMAN PRESCRIPTION DRUG	12/21/2015
+ UPTRAVI	66215-608-06	800 ug/1	TABLET, COATED	ORAL	NDA207947	Actelion Pharmaceuticals US, Inc.	66215-608	Selexipag	SELEXIPAG	HUMAN PRESCRIPTION DRUG	12/21/2015
+ UPTRAVI Titration Pack	66215-628-20		KIT		NDA207947	Actelion Pharmaceuticals US, Inc.	66215-628	Selexipag		HUMAN PRESCRIPTION DRUG	12/21/2015
+ Veletri	66215-403-01	.5 mg/10mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	NDA022260	Actelion Pharmaceuticals US, Inc.	66215-403	epoprostenol	EPOPROSTENOL	HUMAN PRESCRIPTION DRUG	04/22/2010
+ Veletri	66215-402-01	1.5 mg/10mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	NDA022260	Actelion Pharmaceuticals US, Inc.	66215-402	epoprostenol	EPOPROSTENOL	HUMAN PRESCRIPTION DRUG	04/22/2010
+ VENTAVIS	66215-302-30	10 ug/mL	SOLUTION	RESPIRATORY (INHALATION)	NDA021779	Actelion Pharmaceuticals US, Inc.	66215-302	iloprost	ILOPROST	HUMAN PRESCRIPTION DRUG	05/07/2005
+ VENTAVIS	66215-303-30	20 ug/mL	SOLUTION	RESPIRATORY (INHALATION)	NDA021779	Actelion Pharmaceuticals US, Inc.	66215-303	iloprost	ILOPROST	HUMAN PRESCRIPTION DRUG	08/24/2009
+ Zavesca	66215-201-90	100 mg/1	CAPSULE	ORAL	NDA021348	Actelion Pharmaceuticals US, Inc.	66215-201	miglustat	MIGLUSTAT	HUMAN PRESCRIPTION DRUG	07/31/2003

Showing 1 to 24 of 24 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Attachment C

Personnel Information

Actelion Pharmaceuticals US, Inc. is wholly-owned by its parent company. No individual holds any ownership interest in the company.

Corporate Officers:

Samuele Butera
Worldwide Vice President

Qian Lin
Treasurer

Sherlin Simon
Vice President, Commercial Excellence

Designated Representative:

Erica Moor
Group Product Director

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ACTELION PHARMACEUTICALS US, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF APRIL, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2902350 8300

SR# 20231387730

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203116711

Date: 04-11-23

0748121

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

1125 TRENTON-HARBOURTON RD TITUSVILLE, NJ 08560-

Reg. No.
5006027

ACTELION PHARMACEUTICALS US IN
1ST FLOOR/B-WING
1125 TRENTON-HARBOURTON RD
TITUSVILLE, NJ 08560-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2024

Establishment Copy

EXHIBIT 21

SUBSIDIARIES

Johnson & Johnson, a New Jersey corporation, had the U.S. and international subsidiaries shown below as of January 1, 2023. Johnson & Johnson is not a subsidiary of any other entity.

Name of Subsidiary	Jurisdiction
U.S. Subsidiaries:	
ABD Holding Company, Inc.	Delaware
ABIOMED R&D, Inc.	Delaware
ABIOMED, Inc.	Delaware
Acclarent, Inc.	Delaware
Actelion Pharmaceuticals US, Inc.	Delaware
Albany Street LLC	New Jersey
ALZA Corporation	Delaware
Alza Land Management, Inc.	Delaware
AMO Development, LLC	Delaware
AMO Manufacturing USA, LLC	Delaware
AMO Nominee Holdings, LLC	Delaware
AMO Sales and Service, Inc.	Delaware
AMO Spain Holdings, LLC	Delaware
Anakuria Therapeutics, Inc.	Delaware
AorTx, Inc.	Delaware
Aragon Pharmaceuticals, Inc.	Delaware
Asia Pacific Holdings, LLC	New Jersey
Atrionix, Inc.	California
AUB Holdings LLC	Delaware
Auris Health, Inc.	Delaware
BeneVir BioPharm, Inc.	Delaware
BioMedical Enterprises, Inc.	Texas
Biosense Webster, Inc.	California
Breethe, Inc.	Delaware
Centocor Biologics, LLC	Pennsylvania
Centocor Research & Development, Inc.	Pennsylvania
Cerenovus, Inc.	New Jersey
Coherex Medical, Inc.	Delaware
Consumer Test Entity (TEST PURPOSE ONLY)	
CoTherix Inc.	Delaware
CRES Holdings, Inc.	Delaware
CrossRoads Extremity Systems, LLC	Tennessee
CSATS, Inc.	Washington
DePuy Mitek, LLC	Massachusetts
DePuy Orthopaedics, Inc.	Indiana
DePuy Products, Inc.	Indiana
DePuy Spine, LLC	Ohio
DePuy Synthes Institute, LLC	Delaware
DePuy Synthes Products, Inc.	Delaware
DePuy Synthes Sales, Inc.	Massachusetts
DePuy Synthes, Inc.	Delaware
Dutch Holding LLC	Delaware
ECL7, LLC	Delaware
Ethicon Endo-Surgery, Inc.	Ohio
Ethicon Endo-Surgery, LLC	Delaware
Ethicon LLC	Delaware
Ethicon US, LLC	Texas

Name of Subsidiary	Jurisdiction
Ethicon, Inc.	New Jersey
Hansen Medical International, Inc.	Delaware
Hansen Medical, Inc.	Delaware
I.D. Acquisition Corp.	New Jersey
Janssen BioPharma, LLC	Delaware
Janssen Biotech, Inc.	Pennsylvania
Janssen Global Services, LLC	New Jersey
Janssen Oncology, Inc.	Delaware
Janssen Ortho LLC	Delaware
Janssen Pharmaceuticals, Inc.	Pennsylvania
Janssen Products, LP	New Jersey
Janssen Research & Development, LLC	New Jersey
Janssen Scientific Affairs, LLC	New Jersey
Janssen Supply Group, LLC	Pennsylvania
Janssen-Cilag Manufacturing, LLC	Delaware
Jevco Holding, Inc.	New Jersey
JJHC, LLC	Delaware
JNJ International Investment LLC	Delaware
JNTL (APAC) HoldCo 2 LLC	Delaware
JNTL (APAC) HoldCo LLC	Delaware
JNTL (Japan) HoldCo Inc.	Delaware
JNTL (Middle East) HoldCo LLC	Delaware
JNTL (Thailand) HoldCo LLC	Delaware
JNTL Consumer Health (Services) LLC	Delaware
JNTL HoldCo 2 LLC	Delaware
JNTL HoldCo 3 LLC	Delaware
JNTL HoldCo 4 LLC	Delaware
JNTL HoldCo 5 LLC	Delaware
JNTL HoldCo 6 LLC	Delaware
JNTL HoldCo 7 LLC	Delaware
JNTL HoldCo 8 LLC	Delaware
JNTL HoldCo LLC	Delaware
JNTL Holdings 2, Inc.	Delaware
JNTL Holdings 3, Inc.	Delaware
JNTL Holdings, Inc.	Delaware
Johnson & Johnson	New Jersey
Johnson & Johnson (Middle East) Inc.	New Jersey
Johnson & Johnson (Singapore) Holdco LLC	Delaware
Johnson & Johnson Consumer Inc.	Nevada
Johnson & Johnson Consumer Inc.	New Jersey
Johnson & Johnson Enterprise Innovation Inc.	Delaware
Johnson & Johnson Finance Corporation	New Jersey
Johnson & Johnson Gateway, LLC	New Jersey
Johnson & Johnson Health and Wellness Solutions, Inc.	Michigan
Johnson & Johnson Health Care Systems Inc.	New Jersey
Johnson & Johnson Innovation - JJDC, Inc.	New Jersey
Johnson & Johnson Innovation LLC	Delaware
Johnson & Johnson International	New Jersey
Johnson & Johnson Medical Devices & Diagnostics Group - Latin America, L.L.C.	Florida
Johnson & Johnson S.E., Inc.	New Jersey
Johnson & Johnson Services, Inc.	New Jersey
Johnson & Johnson Surgical Vision, Inc.	Delaware
Johnson & Johnson Urban Renewal Associates	New Jersey
Johnson & Johnson Vision Care, Inc.	Florida

Name of Subsidiary	Jurisdiction
JOM Pharmaceutical Services, Inc.	Delaware
Kenvue Inc.	Delaware
LTL Management LLC	North Carolina
McNeil Consumer Pharmaceuticals Co.	New Jersey
McNeil Healthcare LLC	Delaware
McNeil LA LLC	Delaware
McNEIL MMP, LLC	New Jersey
McNeil Nutritionals, LLC	Delaware
Medical Device Business Services, Inc.	Indiana
Medical Devices & Diagnostics Global Services, LLC	Delaware
Medical Devices International LLC	Delaware
MegaDyne Medical Products, Inc.	Utah
Mentor Partnership Holding Company I, LLC	Delaware
Mentor Texas GP LLC	Delaware
Mentor Texas L.P.	Delaware
Mentor Worldwide LLC	Delaware
Middlesex Assurance Company Limited	Vermont
Momenta Pharmaceuticals, Inc.	Delaware
NeoStrata Company, Inc.	Delaware
Netherlands Holding Company	Delaware
NeuWave Medical, Inc.	Delaware
Novira Therapeutics, LLC	Delaware
NuVera Medical, Inc.	Delaware
OMJ Pharmaceuticals, Inc.	Delaware
Omrix Biopharmaceuticals, Inc.	Delaware
Ortho Biologics LLC	Delaware
Ortho Biotech Holding LLC	Pennsylvania
Patriot Pharmaceuticals, LLC	Delaware
Peninsula Pharmaceuticals, LLC	Delaware
Percivia LLC	Delaware
preCARDIA, Inc.	Delaware
Princeton Laboratories, Inc.	Delaware
Prosidyan, Inc.	Delaware
Pulsar Vascular, Inc.	New Jersey
Regency Urban Renewal Associates	North Carolina
Royalty A&M LLC	New Jersey
Rutan Realty LLC	Delaware
Scios LLC	Minnesota
SterilMed, Inc.	Delaware
Synthes USA Products, LLC	Delaware
Synthes USA, LLC	Delaware
Synthes, Inc.	Delaware
TARIS Biomedical LLC	Delaware
TearScience, Inc.	Florida
The Anspach Effort, LLC	Florida
The Vision Care Institute, LLC	Delaware
Tibotec, LLC	Delaware
Torax Medical, Inc.	Delaware
Verb Surgical Inc.	Delaware
Vogue International LLC	Georgia
WH4110 Development Company, L.L.C.	Delaware
Zarbee's, Inc.	

Name of Subsidiary	Jurisdiction
International Subsidiaries:	
3Dintegrated ApS	Denmark
Actelion Ltd	Switzerland
Actelion Pharmaceuticals Ltd	Switzerland
Actelion Pharmaceuticals Trading (Shanghai) Co., Ltd.	China
Actelion Treasury Unlimited Company	Ireland
AMO (Hangzhou) Co., Ltd.	China
AMO (Shanghai) Medical Devices Trading Co., Ltd.	China
AMO ASIA LIMITED	Hong Kong
AMO Australia Pty Limited	Australia
AMO Canada Company	Canada
AMO Denmark ApS	Denmark
AMO France	France
AMO Germany GmbH	Germany
AMO Groningen B.V.	Netherlands
AMO International Holdings Unlimited Company	Ireland
AMO Ireland	Cayman Islands
AMO Italy SRL	Italy
AMO Japan K.K.	Japan
AMO Netherlands BV	Netherlands
AMO Norway AS	Norway
AMO Puerto Rico Manufacturing, Inc.	Cayman Islands
AMO Singapore Pte. Ltd.	Singapore
AMO Switzerland GmbH	Switzerland
AMO United Kingdom, Ltd.	United Kingdom
AMO Uppsala AB	Sweden
Apsis	France
Backsvalan 6 Handelsbolag	Sweden
Beijing Dabao Cosmetics Co., Ltd.	China
Berna Rhein B.V.	Netherlands
Biosense Webster (Israel) Ltd.	Israel
C Consumer Products Denmark ApS	Denmark
Carlo Erba OTC S.r.l.	Italy
ChromaGenics B.V.	Netherlands
Ci:z. Labo Co., Ltd.	Japan
Cilag AG	Switzerland
Cilag GmbH International	Switzerland
Cilag Holding AG	Switzerland
Cilag Holding Treasury Unlimited Company	Ireland
Cilag-Biotech, S.L.	Spain
ColBar LifeScience Ltd.	Israel
Cordis de Mexico, S.A. de C.V.	Mexico
Corimmun GmbH	Germany
Debs-Vogue Corporation (Proprietary) Limited	South Africa
DePuy Hellas SA	Greece
DePuy International Limited	United Kingdom
DePuy Ireland Unlimited Company	Ireland
DePuy Mexico, S.A. de C.V.	Mexico
EES Holdings de Mexico, S. de R.L. de C.V.	Mexico
EES, S.A. de C.V.	Mexico
EIT Emerging Implant Technologies GmbH	Germany
Ethicon Endo-Surgery (Europe) GmbH	Germany
Ethicon Sarl	Switzerland
Ethicon Women's Health & Urology Sarl	Switzerland

Name of Subsidiary	Jurisdiction
Ethnor (Proprietary) Limited	South Africa
Ethnor del Istmo S.A.	Panama
Ethnor Farmaceutica, S.A.	Venezuela, Bolivarian Republic of
Finsbury (Development) Limited	United Kingdom
Finsbury (Instruments) Limited	United Kingdom
Finsbury Medical Limited	United Kingdom
Finsbury Orthopaedics International Limited	United Kingdom
Finsbury Orthopaedics Limited	United Kingdom
FMS Future Medical System SA	Switzerland
GATT Technologies B.V.	Netherlands
GH Biotech Holdings Limited	Ireland
Global Investment Participation B.V.	Netherlands
GMED Healthcare BV	Belgium
Guangzhou Bioseal Biotech Co., Ltd.	China
Hansen Medical Deutschland GmbH	Germany
Hansen Medical UK Limited	United Kingdom
Healthcare Services (Shanghai) Ltd.	China
Innomedic Gesellschaft f✔r innovative Medizintechnik und Informatik mbH	Germany
J & J Company West Africa Limited	Nigeria
J&J Argentina S.A.	Argentina
J&J Pension Trustees Limited	United Kingdom
J&J Productos Medicos & Farmaceuticos del Peru S.A.	Peru
J.C. General Services BV	Belgium
Janssen Biologics (Ireland) Limited	Ireland
Janssen Biologics B.V.	Netherlands
Janssen Cilag Farmaceutica S.A.	Argentina
Janssen Cilag S.p.A.	Italy
Janssen Cilag SPA	Algeria
Janssen Cilag, C.A.	Venezuela, Bolivarian Republic of
Janssen Development Finance Unlimited Company	Ireland
Janssen Egypt LLC	Egypt
Janssen Farmaceutica Portugal Lda	Portugal
Janssen France Treasury Unlimited Company	France
Janssen Holding GmbH	Switzerland
Janssen Inc.	Canada
Janssen Irish Finance Unlimited Company	Ireland
Janssen Japan Treasury Unlimited Company	Japan
Janssen Korea Ltd.	Korea, Republic of
Janssen Mexico Treasury Unlimited Company	Ireland
Janssen Pharmaceutica (Proprietary) Limited	South Africa
Janssen Pharmaceutica NV	Belgium
Janssen Pharmaceutica S.A.	Peru
Janssen Pharmaceutical K.K.	Japan
Janssen Pharmaceutical Sciences Unlimited Company	Ireland
Janssen Pharmaceutical Unlimited Company	Ireland
Janssen R&D Ireland Unlimited Company	Ireland
Janssen Sciences Ireland Unlimited Company	Ireland
Janssen Vaccines & Prevention B.V.	Netherlands
Janssen Vaccines Corp.	Korea, Republic of
Janssen-Cilag	France
Janssen-Cilag (New Zealand) Limited	New Zealand
Janssen-Cilag A/S	Denmark
Janssen-Cilag AG	Switzerland
Janssen-Cilag Aktiebolag	Sweden

Name of Subsidiary	Jurisdiction
Janssen-Cilag AS	Norway
Janssen-Cilag B.V.	Netherlands
Janssen-Cilag d.o.o. Beograd	Serbia
Janssen-Cilag de Mexico S. de R.L. de C.V.	Mexico
Janssen-Cilag Farmaceutica Lda.	Portugal
Janssen-Cilag Farmaceutica Ltda.	Brazil
Janssen-Cilag GmbH	Germany
Janssen-Cilag International NV	Belgium
Janssen-Cilag Kft.	Hungary
Janssen-Cilag Limited	United Kingdom
Janssen-Cilag Limited	Thailand
Janssen-Cilag NV	Belgium
Janssen-Cilag OY	Finland
Janssen-Cilag Pharma GmbH	Austria
Janssen-Cilag Pharmaceutical S.A.C.I.	Greece
Janssen-Cilag Polska, Sp. z o.o.	Poland
Janssen-Cilag Pty Ltd	Australia
Janssen-Cilag S.A.	Colombia
Janssen-Cilag s.r.o.	Czech Republic
Janssen-Cilag, S.A.	Spain
Janssen-Cilag, S.A. de C.V.	Mexico
Janssen-Pharma, S.L.	Spain
J-C Health Care Ltd.	Israel
JJ Surgical Vision Spain, S.L.	Spain
JJC Acquisition Company B.V.	Netherlands
JJSV Belgium BV	Belgium
JJSV Manufacturing Malaysia SDN. BHD.	Malaysia
JJSV Norden AB	Sweden
JJSV Produtos Oticos Ltda.	Brazil
JNJ Global Business Services s.r.o.	Czech Republic
JNJ Holding EMEA B.V.	Netherlands
JNTL (APAC) HoldCo 3 Pte. Ltd.	Singapore
JNTL (APAC) HoldCo Pte. Ltd.	Singapore
JNTL (Malaysia) Sdn. Bhd.	Malaysia
JNTL (Puerto Rico) HoldCo GmbH	Switzerland
JNTL (Shanghai) Investment Co., Ltd.	China
JNTL (Switzerland) HoldCo GmbH	Switzerland
JNTL (UK) HoldCo Limited	United Kingdom
JNTL Consumer Health (Vietnam) Co. Ltd.	Vietnam
JNTL Consumer Health (Belgium) BV	Belgium
JNTL Consumer Health (Brazil) Ltda.	Brazil
JNTL Consumer Health (Czech Republic) s.r.o.	Czech Republic
JNTL Consumer Health (Dominican Republic), S.A.S.	Dominican Republic
JNTL Consumer Health (Finland) Oy	Finland
JNTL Consumer Health (France) SAS	France
JNTL Consumer Health (Hungary) Kft	Hungary
JNTL Consumer Health (India) Private Limited	India
JNTL Consumer Health (New Zealand) Limited	New Zealand
JNTL Consumer Health (Norway) AS	Norway
JNTL Consumer Health (Philippines) Inc.	Philippines
JNTL Consumer Health (Poland) sp. z o.o.	Poland
JNTL Consumer Health (Portugal) Limitada	Portugal
JNTL Consumer Health (Slovakia), s.r.o.	Slovakia
JNTL Consumer Health (Spain), S.L.	Spain

Name of Subsidiary	Jurisdiction
JNTL Consumer Health (Taiwan) Limited	Taiwan (Province of China)
JNTL Consumer Health General Services BV	Belgium
JNTL Consumer Health I (Ireland) Limited	Ireland
JNTL Consumer Health I (Switzerland) GmbH	Switzerland
JNTL Consumer Health II (Switzerland) GmbH	Switzerland
JNTL Consumer Health LLC	Egypt
JNTL Consumer Health Mexico, S. de R.L. de C.V.	Mexico
JNTL Consumer Health Middle East FZ-LLC	United Arab Emirates
JNTL Holdings B.V.	Netherlands
JNTL Ireland HoldCo 2 B.V.	Netherlands
JNTL Netherlands HoldCo B.V.	Netherlands
JNTL Turkey T✔ketici Sağlığı Limited Şirketi	Turkey
Johnson & Johnson - Societa' Per Azioni	Italy
Johnson & Johnson (Angola), Limitada	Angola
Johnson & Johnson (Australia) Pty Ltd	Australia
Johnson & Johnson (Canada) Inc.	Canada
Johnson & Johnson (China) Investment Ltd.	China
Johnson & Johnson (Ecuador) S.A.	Ecuador
Johnson & Johnson (Egypt) S.A.E.	Egypt
Johnson & Johnson (Hong Kong) Limited	Hong Kong
Johnson & Johnson (Ireland) Limited	Ireland
Johnson & Johnson (Jamaica) Limited	Jamaica
Johnson & Johnson (Kenya) Limited	Kenya
Johnson & Johnson (Mozambique), Limitada	Mozambique
Johnson & Johnson (Namibia) (Proprietary) Limited	Namibia
Johnson & Johnson (New Zealand) Limited	New Zealand
Johnson & Johnson (Philippines), Inc.	Philippines
Johnson & Johnson (Private) Limited	Zimbabwe
Johnson & Johnson (Thailand) Ltd.	Thailand
Johnson & Johnson (Trinidad) Limited	Trinidad and Tobago
Johnson & Johnson (Vietnam) Co., Ltd	Vietnam
Johnson & Johnson AB	Sweden
Johnson & Johnson AG	Switzerland
Johnson & Johnson Bulgaria EOOD	Bulgaria
Johnson & Johnson China Ltd.	China
Johnson & Johnson Consumer (Hong Kong) Limited	Hong Kong
Johnson & Johnson Consumer (Thailand) Limited	Thailand
Johnson & Johnson Consumer B.V.	Netherlands
Johnson & Johnson Consumer Holdings France	France
Johnson & Johnson Consumer NV	Belgium
Johnson & Johnson Consumer Saudi Arabia Limited	Saudi Arabia
Johnson & Johnson Consumer Services EAME Ltd.	United Kingdom
Johnson & Johnson d.o.o.	Slovenia
Johnson & Johnson de Argentina S.A.C. e. I.	Argentina
Johnson & Johnson de Chile S.A.	Chile
Johnson & Johnson de Colombia S.A.	Colombia
Johnson & Johnson de Mexico, S.A. de C.V.	Mexico
Johnson & Johnson de Uruguay S.A.	Uruguay
Johnson & Johnson de Venezuela, S.A.	Venezuela, Bolivarian Republic of
Johnson & Johnson del Ecuador, S.A.	Ecuador
Johnson & Johnson Del Paraguay, S.A.	Paraguay
Johnson & Johnson del Peru S.A.	Peru
Johnson & Johnson do Brasil Industria E Comercin de Produtos Para Saude Ltda.	Brazil
Johnson & Johnson Dominicana, S.A.S.	Dominican Republic

Name of Subsidiary	Jurisdiction
Johnson & Johnson European Treasury Unlimited Company	Ireland
Johnson & Johnson Finance Limited	United Kingdom
Johnson & Johnson Financial Services GmbH	Germany
Johnson & Johnson for Export and Import LLC	Egypt
Johnson & Johnson Gesellschaft m.b.H.	Austria
Johnson & Johnson GmbH	Germany
Johnson & Johnson GT, Sociedad Anónima	Guatemala
Johnson & Johnson Guatemala, S.A.	Guatemala
Johnson & Johnson Hellas Commercial and Industrial S.A.	Greece
Johnson & Johnson Hellas Consumer Products Commercial Societe Anonyme	Greece
Johnson & Johnson Hemisferica S.A.	Puerto Rico
Johnson & Johnson Holding GmbH	Germany
Johnson & Johnson Holdings (Austria) GmbH	Austria
Johnson & Johnson Inc.	Canada
Johnson & Johnson Industrial Ltda.	Brazil
Johnson & Johnson Innovation Limited	United Kingdom
Johnson & Johnson International (Singapore) Pte. Ltd.	Singapore
Johnson & Johnson International Financial Services Unlimited Company	Ireland
Johnson & Johnson Irish Finance Company Limited	Ireland
Johnson & Johnson K.K.	Japan
Johnson & Johnson Kft.	Hungary
Johnson & Johnson Korea Selling & Distribution LLC	Korea, Republic of
Johnson & Johnson Korea, Ltd.	Korea, Republic of
Johnson & Johnson Limited	United Kingdom
Johnson & Johnson LLC	Russian Federation
Johnson & Johnson Luxembourg Finance Company Sarl	Luxembourg
Johnson & Johnson Management Limited	United Kingdom
Johnson & Johnson Medical (China) Ltd.	China
Johnson & Johnson Medical (Proprietary) Ltd	South Africa
Johnson & Johnson Medical (Shanghai) Ltd.	China
Johnson & Johnson Medical (Suzhou) Ltd.	China
Johnson & Johnson Medical B.V.	Netherlands
Johnson & Johnson Medical GmbH	Germany
Johnson & Johnson Medical Greece Single Member S.A.	Greece
Johnson & Johnson Medical Korea Ltd.	Korea, Republic of
Johnson & Johnson Medical Limited	United Kingdom
Johnson & Johnson Medical Mexico, S.A. de C.V.	Mexico
Johnson & Johnson Medical NV	Belgium
Johnson & Johnson Medical Products GmbH	Austria
Johnson & Johnson Medical Pty Ltd	Australia
Johnson & Johnson Medical S.A.	Argentina
Johnson & Johnson Medical S.p.A.	Italy
Johnson & Johnson Medical SAS	France
Johnson & Johnson Medical Saudi Arabia Limited	Saudi Arabia
Johnson & Johnson Medical Taiwan Ltd.	Taiwan (Province of China)
Johnson & Johnson Medical, S.C.S.	Venezuela, Bolivarian Republic of
Johnson & Johnson Medikal Sanayi ve Ticaret Limited Sirketi	Turkey
Johnson & Johnson MedTech (Thailand) Ltd.	Thailand
Johnson & Johnson Medtech Colombia S.A.S.	Colombia
Johnson & Johnson Middle East FZ-LLC	United Arab Emirates
Johnson & Johnson Morocco Societe Anonyme	Morocco
Johnson & Johnson Nordic AB	Sweden
Johnson & Johnson Pacific Pty Limited	Australia
Johnson & Johnson Pakistan (Private) Limited	Pakistan

Name of Subsidiary	Jurisdiction
Johnson & Johnson Panama, S.A.	Panama
Johnson & Johnson Personal Care (Chile) S.A.	Chile
Johnson & Johnson Pharmaceutical Ltd.	China
Johnson & Johnson Poland Sp. z o.o.	Poland
Johnson & Johnson Private Limited	India
Johnson & Johnson Pte. Ltd.	Singapore
Johnson & Johnson Pty. Limited	Australia
Johnson & Johnson Romania S.R.L.	Romania
Johnson & Johnson S.E. d.o.o.	Croatia
Johnson & Johnson Sante Beaute France	France
Johnson & Johnson SDN. BHD.	Malaysia
Johnson & Johnson Surgical Vision India Private Limited	India
Johnson & Johnson Taiwan Ltd.	Taiwan (Province of China)
Johnson & Johnson UK Treasury Company Limited	United Kingdom
Johnson & Johnson Ukraine LLC	Ukraine
Johnson & Johnson Vision Care (Australia) Pty Ltd	Australia
Johnson & Johnson Vision Care (Shanghai) Ltd.	China
Johnson & Johnson Vision Care Ireland Unlimited Company	Ireland
Johnson & Johnson Vision Korea, Ltd.	Korea, Republic of
Johnson & Johnson, Lda	Portugal
Johnson & Johnson, S.A.	Spain
Johnson & Johnson, S.A. de C.V.	Mexico
Johnson & Johnson, s.r.o.	Slovakia
Johnson & Johnson, s.r.o.	Czech Republic
Johnson and Johnson (Proprietary) Limited	South Africa
Johnson and Johnson Sihhi Malzeme Sanayi Ve Ticaret Limited Sirketi	Turkey
Johnson Y Johnson de Costa Rica, S.A.	Costa Rica
La Concha Land Investment Corporation	Philippines
McNeil AB	Sweden
McNeil Denmark ApS	Denmark
McNeil Healthcare (Ireland) Limited	Ireland
McNeil Healthcare (UK) Limited	United Kingdom
McNeil Iberica S.L.U.	Spain
McNeil Panama, LLC	Panama
McNeil Products Limited	United Kingdom
McNeil Sweden AB	Sweden
Medos International Sarl	Switzerland
Medos Sarl	Switzerland
Menlo Care De Mexico, S.A. de C.V.	Mexico
Mentor B.V.	Netherlands
Mentor Deutschland GmbH	Germany
Mentor Medical Systems B.V.	Netherlands
Momenta Ireland Limited	Ireland
NeoStrata UG (haftungsbeschränkt)	Germany
Neuravi Limited	Ireland
Obtech Medical Mexico, S.A. de C.V.	Mexico
OBTECH Medical Sarl	Switzerland
OGX Beauty Limited	United Kingdom
OMJ Holding GmbH	Switzerland
Omrix Biopharmaceuticals Ltd.	Israel
Omrix Biopharmaceuticals NV	Belgium
Orthospin Ltd.	Israel
Orthotaxy	France
Pharmadirect Ltd.	Canada

Name of Subsidiary	Jurisdiction
Pharmedica Laboratories (Proprietary) Limited	South Africa
Productos de Cuidado Personal y de La Salud de Bolivia S.R.L.	Bolivia
Proleader S.A.	Uruguay
PT Integrated Healthcare Indonesia	Indonesia
PT Johnson & Johnson Indonesia	Indonesia
PT Johnson and Johnson Indonesia Two	Indonesia
RespiVert Ltd.	United Kingdom
Review Manager Test Entity 2	France
Serhum S.A. de C.V.	Mexico
Shanghai Elsker Mother & Baby Co., Ltd	China
Shanghai Johnson & Johnson Ltd.	China
Shanghai Johnson & Johnson Pharmaceuticals Ltd.	China
Sodiac ESV	Belgium
Spectrum Vision Limited Liability Company	Russian Federation
Spectrum Vision Limited Liability Company	Ukraine
Spectrum Vision Limited Liability Partnership	Kazakhstan
Surgical Process Institute Deutschland GmbH	Germany
Synthes Costa Rica S.C.R., Limitada	Costa Rica
SYNTHES GmbH	Germany
Synthes GmbH	Switzerland
Synthes Holding AG	Switzerland
Synthes Holding Limited	United Arab Emirates
SYNTHES Medical Immobilien GmbH	Germany
Synthes Medical Surgical Equipment & Instruments Trading LLC	United Arab Emirates
Synthes Produktions GmbH	Switzerland
Synthes Proprietary Limited	South Africa
Synthes S.M.P., S. de R.L. de C.V.	Mexico
Synthes Tuttlingen GmbH	Germany
UAB "Johnson & Johnson"	Lithuania
Vania Expansion	France
Vision Care Finance Unlimited Company	Ireland
Xian Janssen Pharmaceutical Ltd.	China
XO1 Limited	United Kingdom

Attachment D

Parent Company SEC Documentation and Shareholder Information

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended January 1, 2023

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from to**

Commission file number 1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza **New Brunswick, New Jersey**	**08933**
(Address of principal executive offices)	(Zip Code)

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)

Registrant's telephone number, including area code: **(732) 524-0400**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
0.650% Notes Due May 2024	JNJ24C	New York Stock Exchange
5.50% Notes Due November 2024	JNJ24BP	New York Stock Exchange
1.150% Notes Due November 2028	JNJ28	New York Stock Exchange
1.650% Notes Due May 2035	JNJ35	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes o No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☑ No o

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. o

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $472 billion.

On February 10, 2023, there were 2,604,286,303 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III:	Portions of registrant's proxy statement for its 2023 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

Item		Page
	PART I	
1	Business	1
	General	1
	Segments of Business	1
	Geographic Areas	2
	Raw Materials	2
	Patents	2
	Trademarks	3
	Seasonality	3
	Competition	3
	Environment	3
	Regulation	3
	Employees and Human Capital Management	5
	Available Information	7
1A.	Risk Factors	8
1B.	Unresolved Staff Comments	16
2	Properties	16
3	Legal Proceedings	16
4	Mine Safety Disclosures	16
	Executive Officers of the Registrant	17
	PART II	
5	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	20
6	(Reserved)	20
7	Management's Discussion and Analysis of Results of Operations and Financial Condition	21
7A.	Quantitative and Qualitative Disclosures About Market Risk	39
8	Financial Statements and Supplementary Data	39
9	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	108
9A.	Controls and Procedures	108
9B.	Other Information	108
9C.	Disclosures Regarding Foreign Jurisdictions That Prevent Inspections	108
	PART III	
10	Directors, Executive Officers and Corporate Governance	108
11	Executive Compensation	109
12	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	109
13	Certain Relationships and Related Transactions, and Director Independence	109
14	Principal Accountant Fees and Services	109
	PART IV	
15	Exhibits and Financial Statement Schedules	110
16	Form 10-K Summary	110
	Signatures	111
	Exhibit Index	113

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the Company) also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; impact and timing of restructuring initiatives, including associated cost savings and other benefits; the planned separation of the Company's Consumer Health business; the Company's strategy for growth; product development activities; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing generic, biosimilar or other products and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Pateot and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- The impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;

- The impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;
- Increased scrutiny of the healthcare industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;
- Failure to meet compliance obligations in compliance agreements with governments or government agencies, which could result in significant sanctions;
- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of healthcare products; access to, and reimbursement and pricing for, healthcare products and services; environmental protection; and sourcing of raw materials;
- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets, including requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;
- Changes in domestic and international tax laws and regulations, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and
- The issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives, Healthcare Market Trends and the Planned Separation of the Company's Consumer Health Business

- Pricing pressures resulting from trends toward healthcare cost containment, including the continued consolidation among healthcare providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payers of healthcare expenses, significant new entrants to the healthcare markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;
- Restricted spending patterns of individual, institutional and governmental purchasers of healthcare products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected;
- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected;
- The Company's ability to consummate the planned separation of the Company's Consumer Health business on a timely basis or at all;
- The Company's ability to successfully separate the Company's Consumer Health business and realize the anticipated benefits from the planned separation; and
- The New Consumer Health Company's ability to succeed as a standalone publicly traded company.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- The risks associated with global operations on the Company and its customers and suppliers, including foreign governments in countries in which the Company operates;
- The impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- The impact of global public health crises and pandemics, including the novel coronavirus (COVID-19) pandemic;

- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and
- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world, including social and economic disruptions and instability of financial and other markets.

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally, through third-party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors, which could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;
- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products; and
- The potential that the expected benefits and opportunities related to restructuring actions contemplated for the global supply chain may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities.

Investors also should carefully read the Risk Factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I

Item 1. BUSINESS

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 152,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. Johnson & Johnson is a holding company, with operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's three business segments: Consumer Health, Pharmaceutical and MedTech (previously referred to as Medical Devices). Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of Business

The Company is organized into three business segments: Consumer Health, Pharmaceutical and MedTech. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under: "Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition" of this Report; and Note 17 "Segments of Business and Geographic Areas" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Consumer Health

The Consumer Health segment includes a broad range of products focused on personal healthcare used in the Skin Health/Beauty, Over-the-Counter medicines, Baby Care, Oral Care, Women's Health and Wound Care markets. Major brands in Skin Health/Beauty include the AVEENO; CLEAN & CLEAR; DR. CI:LABO; NEUTROGENA and OGX product lines. Over-the-Counter (OTC) medicines include the broad family of TYLENOL acetaminophen products; SUDAFED cold, flu and allergy products; BENADRYL and ZYRTEC allergy products; MOTRIN IB ibuprofen products; NICORETTE smoking cessation products outside the U.S.; ZARBEE'S products, inspired by nature, and the PEPCID line of acid reflux products. Baby Care includes the JOHNSON'S and AVEENO Baby line of products. Oral Care includes the LISTERINE product line. Major brands in Women's Health outside of North America are STAYFREE and CAREFREE sanitary pads and o.b. tampon brands. Wound Care brands include the BAND-AID Brand Adhesive Bandages and NEOSPORIN First Aid product lines. These products are marketed to the general public and sold online (eCommerce) and to retail outlets and distributors throughout the world.
In November 2021, the Company announced its intention to separate the Company's Consumer Health business (Kenvue as the name for the planned New Consumer Health Company), with the intention to create a new, publicly traded company by the end of the fiscal year 2023.

Pharmaceutical

The Pharmaceutical segment is focused on the following therapeutic areas: Immunology (e.g., rheumatoid arthritis, psoriatic arthritis, inflammatory bowel disease and psoriasis), Infectious Diseases (e.g., HIV/AIDS), Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia), Oncology (e.g., prostate cancer, hematologic malignancies, lung cancer and bladder cancer), Cardiovascular and Metabolism (e.g., thrombosis, diabetes and macular degeneration) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. Key products in the Pharmaceutical segment include: REMICADE (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis and active polyarticular juvenile idiopathic arthritis (pJIA) in people 2 years of age and older; STELARA (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, for adults with moderately to severely active Crohn's disease and treatment of moderately to severely active ulcerative colitis; TREMFYA (guselkumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis; EDURANT (rilpivirine), PREZISTA (darunavir) and PREZCOBIX/REZOLSTA (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral products and SYMTUZA (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV; CONCERTA (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA/XEPLION (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA/TREVICTA (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA for at least four months; RISPERDAL CONSTA (risperidone long-acting injection), for the treatment of schizophrenia and the maintenance treatment of Bipolar 1 Disorder in adults; ZYTIGA

(abiraterone acetate), a treatment for patients with prostate cancer; ERLEADA (apalutamide), a next-generation androgen receptor inhibitor for the treatment of patients with prostate cancer; IMBRUVICA (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers and chronic graft versus host disease; DARZALEX (daratumumab), a treatment for multiple myeloma; DARZALEX FASPRO (daratumumab and hyaluronidase-fihj), a treatment for multiple myeloma and light chain (AL) Amyloidosis; XARELTO (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment and reduction of risk of recurrence of DVT and PE to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD) and peripheral artery disease (PAD), for the treatment and secondary prevention of thromboembolism in pediatric patients, and for thromboprophylaxis in pediatric patients following the Fontan procedure; INVOKANA (canagliflozin), for the treatment of adults with type 2 diabetes; INVOKAMET/VOKANAMET (canagliflozin/metformin HCl), a combination therapy of fixed doses of canagliflozin and metformin hydrochloride for the treatment of adults with type 2 diabetes; and INVOKAMET XR (canagliflozin/metformin hydrochloride extended-release), a once-daily, fixed-dose combination therapy of canagliflozin and metformin hydrochloride extended-release, for the treatment of adults with type 2 diabetes; OPSUMIT (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI (selexipag), the only approved oral and intravenous, selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

MedTech

The MedTech (previously referred to as Medical Devices) segment includes a broad portfolio of products used in the Interventional Solutions, Orthopaedics, Surgery and Vision categories. Interventional Solutions include Electrophysiology products (Biosense Webster) to treat cardiovascular diseases, Neurovascular care (Cerenovus) that treats hemorrhagic and ischemic stroke and the Heart Recovery portfolio (Abiomed) which includes technologies to treat severe coronary artery disease requiring high-risk PCI or AMI cardiogenic shock. The Orthopaedics portfolio (DePuy Synthes) comprises products in support of Hips, Knees, Trauma, and Spine, Sports & Other. The Surgery portfolios include advanced and general surgery offerings (Ethicon), solutions that focus on Breast Aesthetics (Mentor), and Ear, Nose and Throat (Acclarent) procedures. Johnson & Johnson Vision products include ACUVUE Brand contact lenses and ophthalmic technologies related to cataract and laser refractive surgery. These products are distributed to wholesalers, hospitals and retailers, and used predominantly in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

Geographic Areas

Johnson & Johnson and its subsidiaries (the Company) have approximately 152,700 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The products made and sold in the international business include many of those described above under "– Segments of Business – Consumer Health," "– Pharmaceutical" and "– MedTech." However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw Materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 19, "Legal Proceedings—Intellectual Property" of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, STELARA (ustekinumab), accounted for approximately 10.2% of the Company's total revenues for fiscal 2022. Accordingly, the patents related to this product are believed to be material to the

Company. Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, owns patents specifically related to STELARA. The latest expiring United States composition of matter patent expires in 2023. The latest expiring European composition of matter patent expires in 2024.

Sales of the Company's second largest product, collectively DARZALEX (daratumumab) and DARZALEX FASPRO (daratumumab and hyaluronidase-fihj), accounted for approximately 8.4% of the Company's total revenues for fiscal 2022. Accordingly, the patents related to this product are believed to be material to the Company. Genmab A/S owns two patent families related to DARZALEX, and Janssen Biotech, Inc. has an exclusive license to those patent families. The two patent families both expire in the United States in 2029. The latest expiring licensed European patent expires in 2032. Janssen Biotech, Inc. owns a separate patent portfolio related to DARZALEX FASPRO.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has typically been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for advertising and research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research. In addition, the development and maintenance of customer demand for the Company's consumer products involve significant expenditures for advertising and promotion.

Environment

The Company is subject to a variety of U.S. and international environmental protection measures. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation and enforcement. The Company is subject to costly and complex U.S. and foreign laws and governmental regulations and any adverse regulatory action may materially adversely affect the Company's financial condition and business operations. In the U.S., the drug, device and cosmetic industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the U.S. FDA) continues to result in increases in the amounts of testing and documentation required for U.S. FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S. The new medical device regulatory framework and the evolving privacy, data localization, and emerging cyber security laws and regulations around the world are examples of such increased regulation. Five U.S. States (California, Connecticut, Colorado, Utah and Virginia) now have comprehensive privacy laws in place and China introduced broad personal information protection and data security regulations in 2022. With other jurisdictions enacting similar privacy laws, local data protection authorities will force greater accountability on the collection, access and use of personal data in the healthcare industry.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls regardless of whether it has been required or directed to.

The U.S. FDA and regulatory agencies around the globe are also increasing their enforcement activities. If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our drugs or medical

devices are ineffective or pose an unreasonable health risk, the U.S. FDA could ban such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending applications for marketing authorization or require certificates of foreign governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The U.S. FDA may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis, or enjoin and/or restrain certain conduct resulting in violations of applicable law. The U.S. FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future clearances or approvals, and could result in a substantial modification to our business practices and operations. Equivalent enforcement mechanisms exist in different countries in which we conduct business.

The costs of human healthcare have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused by states, regulatory agencies and Congress on prices, profits, overutilization and the quality and costs of healthcare generally. Laws and regulations have been enacted to require adherence to strict compliance standards and prevent fraud and abuse in the healthcare industry. There is increased focus on interactions and financial relationships between healthcare companies and healthcare providers. Various transparency laws and regulations require disclosures of payments and other transfers of value made to physicians and teaching hospitals and, beginning with disclosures in 2022, to certain non-physician practitioners. Federal and foreign laws governing international business practices require strict compliance with anti-bribery standards and certain prohibitions with respect to payments to any foreign government official. Payers and Pharmacy Benefit Managers (PBMs) have become a more potent force in the market place and increased attention is being paid to drug pricing and appropriate drug and medical device utilization.

Our business has been and continues to be affected by federal and state legislation that alters the pricing, coverage, and reimbursement landscape. At the federal level, in August 2022, President Biden signed into law the Inflation Reduction Act (IRA), which includes provisions that effectively authorize the government to establish prices for certain high-spend single-source drugs and biologics reimbursed by the Medicare program, starting in 2026 for Medicare Part D drugs and 2028 for Medicare Part B drugs. It is not yet certain which products the federal government will select and subject to government-established prices, or how the federal government will establish prices for selected products, as the IRA specifies a ceiling price but not a minimum price. One or more of our products could be selected and subject to the government-established price.

The IRA also contains provisions that impose rebates if certain prices increase at a rate that outpaces the rate of inflation, beginning October 1, 2022, for Medicare Part D drugs and January 1, 2023, for Medicare Part B drugs. Separate IRA provisions redesign the Medicare Part D benefit in various ways, including by shifting a greater portion of costs to manufacturers within certain coverage phases and replacing the Part D coverage gap discount program with a new manufacturer discounting program. Failure to comply with IRA provisions may subject manufacturers to various penalties, including civil monetary penalties. The impact of the IRA on our business and the broader pharmaceutical industry remains uncertain, as the federal government has yet to make various IRA implementation decisions.

Additionally, we expect continued scrutiny on drug pricing and government price reporting from Congress, agencies, and other bodies at the federal and state levels.

There are a number of additional bills pending in Congress and healthcare reform proposals at the state level that would affect drug pricing, including in the Medicare and Medicaid programs. This changing legal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal and state law, and potential modification or repeal of these laws, will ultimately affect the industry. The IRA and any other federal or state legislative change could affect the pricing and market conditions for our products.

In addition, business practices in the healthcare industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties. Of note is the increased enforcement activity by data protection authorities in various jurisdictions, particularly in the European Union, where significant fines have been levied on companies for data breaches, violations of privacy requirements, and unlawful cross-border data transfers. In the U.S., the Federal Trade Commission has stepped up enforcement of data privacy with several significant settlements and there have been a material increase in class-action lawsuits linked to the collection and use of biometric data.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, are subject to increasing regulatory requirements, and may be faced with unexpected changes such as those resulting from the

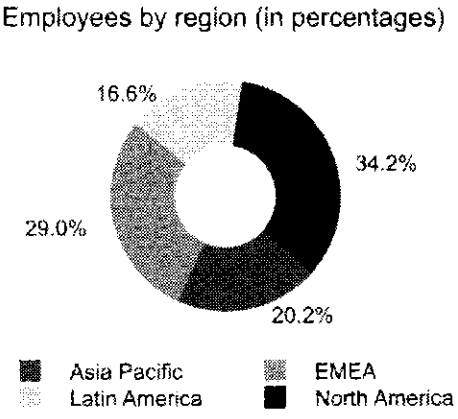
COVID-19 pandemic and Brexit that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to complex and lengthy regulatory approvals.

Employees and Human Capital Management

As of January 1, 2023, and January 2, 2022, the number of employees were approximately:

	2022	2021
Employees[1]	155,800	144,300
Full-time equivalent (FTE) positions[2]	152,700	141,700

[1]"Employee" is defined as an individual working full-time or part-time, excluding fixed term employees, interns and co-op employees. Employee data may not include full population from more recently acquired companies and individuals on long-term disability are excluded. Contingent workers, contractors and subcontractors are also excluded. Abiomed headcount has been included in the above table.
[2] FTE represents the total number of full-time equivalent positions and does not reflect the total number of individual employees as some work part-time.



Strategy

The Company believes that its employees are critical to its continued success and are an essential element of its long-term strategy. Management is responsible for ensuring that its policies and processes reflect and reinforce the Company's desired corporate culture, including policies and processes related to strategy, risk management, and ethics and compliance. The Company's human capital management strategy is built on three fundamental focus areas:

- Attracting and recruiting the best talent
- Developing and retaining talent
- Empowering and inspiring talent

Underpinning these focus areas are ongoing efforts to cultivate and foster a culture built on diversity, equity and inclusion (DEI), innovation, health, well-being and safety, where the Company's employees are encouraged to succeed both professionally and personally while helping the Company achieve its business goals.

Culture and Employee Engagement

At the Company, employees are guided by Our Credo which sets forth the Company's responsibilities to patients, consumers, customers, healthcare professionals, employees, communities and shareholders. Employees worldwide must adhere to the Company's Code of Business Conduct which sets basic requirements and serves as a foundation for the Company policies, procedures and guidelines, all of which provide additional guidance on expected employee behaviors in every market where it operates. The Company conducts global surveys that offer its employees the ability to provide feedback and valuable insight to help address potential human resources risks and identify opportunities to improve. In 2022, 92% of global employees across 77 countries participated in Our Credo Survey which was offered in 36 languages.

Growth and Development

To continue to lead in the changing healthcare landscape, it is crucial that the Company continue to attract and retain top talent. The Company believes that its employees must be equipped with the right knowledge and skills and be provided with opportunities to grow and develop in their careers. Accordingly, professional development programs and educational resources
are available to all employees. The Company's objective is to foster a learning culture that helps shape each person's unique career path while creating a robust pipeline of talent to deliver on the Company's long-term strategies. In furtherance of this objective, the Company deploys a global approach to ensure development is for everyone, regardless of where they are on their career journey. In 2022, 46.2% of employees in Manager and above job categories who had movements (including upward promotions or lateral transfers) took advantage of career opportunities by moving across functions, country or business segment lines (excluding employees in the research and development organizations). The Company's voluntary turnover rate was 9%.

Diversity, Equity, and Inclusion (DEI)

The Company is committed to workplace diversity and to cultivating, fostering, and advancing a culture of equity and inclusion. In 2022, Johnson & Johnson introduced the Company's evolved enterprise Diversity, Equity and Inclusion strategy, which recognizes how DEI accelerates the Company's ability to meet the changing needs of the communities the Company serves to deliver Our Purpose to profoundly change the trajectory of health for humanity. The Company's DEI vision is: *Be yourself, change the world.* The Company's DEI Mission is: *Make diversity, equity and inclusion how we work everyday.* Our evolved enterprise DEI Strategy is aligned to our DEI Vision and Mission and rests on four core pillars:

- Accelerate our global culture of inclusion where every individual belongs
- Build a workforce that reflects the diversity of our communities
- Transform talent and business processes to achieve equitable access and outcomes for all
- Drive innovation and growth with our business to serve diverse markets around the world

The Company's DEI strategy is guided by internal and external insights, global best practices and continual employee feedback which remind the Company that while diversity changes by location, inclusion is the same everywhere.

Compensation and Benefits

As part of the Company's total rewards philosophy, the Company offers competitive compensation and benefits to attract and retain top talent. The Company is committed to fairness and equitable treatment in its compensation and benefits for employees at all levels. The Company observes legal minimum wage provisions and exceeds them where possible. The Company's total rewards offerings include an array of programs to support its employees' well-being, including annual performance incentive opportunities, pension and retirement savings programs, health and welfare benefits, paid time off, leave programs, flexible work schedules and employee assistance programs. In recognition of the Company's commitment to help employees balance their personal and professional responsibilities, the Company extended its paid parental leave benefit globally from 8 to 12 weeks for all eligible employees. In the U.S., the benefit was effective on January 1, 2022, with retroactive coverage for new family additions as of July 1, 2021.

Health, Wellness and Safety

The Company's investment in employee health, well-being and safety is built on its conviction that advancing health for humanity starts with advancing the health of its employees. With the right awareness, focus, practices and tools, the Company ensures that all its employees around the world, as well as temporary contractors and visitors to the Company's sites, can work safely. The Company has continuously expanded health and well-being programs throughout the Company and across the globe, incorporating new thinking and technologies to keep its offerings best-in-class and to help employees achieve their personal health goals. The programs and practices the Company advances for total health—physical, mental, emotional and financial—ensure employee health protection for emerging health risks. Protecting and supporting our employees as the COVID-19 pandemic has evolved continues to be a top priority and the Company's approach includes: ensuring the health and safety of our employees in the workplace through robust layers of protection; enhanced cleaning and access to cleaning supplies and personal protective equipment; supporting employees with benefits and well-being tools. The Company continues to address our employees needs through J&J Flex, a hybrid model that empowers the Company's office-based employees to find the right productivity and balance of in-person and remote work.

Available Information

The Company's main corporate website address is *www.jnj.com*. All of the Company's SEC filings are also available on the Company's website at *www.investor.jnj.com/sec.cfm*, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

Investors and the public should note that the Company also announces information at *www.factsaboutourprescriptionopioids.com*, *www.factsabouttalc.com* and *www.LTLManagementInformation.com*.
We use these websites to communicate with investors and the public about our products, litigation and other matters. It is possible that the information we post to these websites could be deemed to be material information. Therefore, we encourage investors and others interested in the Company to review the information posted to these websites in conjunction with www.jnj.com, the Company's SEC filings, press releases, public conference calls and webcasts.

In addition, the Amended and Restated Certificate of Incorporation, By-Laws, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance & Sustainability Committee, the Science & Technology Committee and any special committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at *www.investor.jnj.com/gov.cfm* on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on *www.jnj.com*, *www.factsaboutourprescriptionopioids.com*, *www.factsabouttalc.com* and *www.LTLManagementInformation.com* is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. RISK FACTORS

An investment in the Company's common stock or debt securities involves risks and uncertainties. The Company seeks to identify, manage and mitigate risks to our business, but uncertainties and risks are difficult to predict and many are outside of the Company's control and cannot therefore be eliminated. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

Risks Related to Our Business, Industry and Operations

The Company's businesses operate in highly competitive product markets and competitive pressures could adversely affect the Company's earnings.
The Company faces substantial competition in all three operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development.

For the Company's Pharmaceutical businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's MedTech businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's Consumer Health businesses face intense competition from other branded products and retailers' private-label brands. If the Company fails to sufficiently differentiate and market its brand name consumer products, this could adversely affect revenues and profitability of those products.

Interruptions and delays in manufacturing operations could adversely affect the Company's business, sales and reputation.
The Company's manufacture of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 89 manufacturing facilities as well as sourcing from thousands of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, labor shortages, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest, terrorist attacks and epidemics or pandemics. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

The Company relies on third parties to manufacture certain of our products. Any failure by or loss of a third-party manufacturer could result in delays and increased costs, which may adversely affect our business.
The Company relies on third parties to manufacture certain of our products. We depend on these third-party manufacturers to allocate to us a portion of their manufacturing capacity sufficient to meet our needs, to produce products of acceptable quality and at acceptable manufacturing yields and to deliver those products to us on a timely basis and at acceptable prices. However, we cannot guarantee that these third-party manufacturers will be able to meet our near-term or long-term manufacturing requirements, which could result in lost sales and have an adverse effect on our business.

Other risks associated with our reliance on third parties to manufacture these products include reliance on the third party for regulatory compliance and quality assurance, misappropriation of the Company's intellectual property, limited ability to manage our inventory, possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the manufacturing agreement by the third party at a time that is costly or inconvenient for us. Moreover, if any of our third-party manufacturers suffers any damage to facilities, loses benefits under material agreements, experiences power outages, encounters financial difficulties, is unable to secure necessary raw materials from its suppliers or suffers any other reduction in efficiency, the Company may experience significant business disruption. In the event of any such disruption, the

Company would need to seek and source other qualified third-party manufacturers, likely resulting in further delays and increased costs which could affect our business adversely.

Counterfeit versions of our products could harm our patients and have a negative impact on our revenues, earnings, reputation and business.
Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet our rigorous manufacturing and testing standards. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured – often in unregulated, unlicensed, uninspected and unsanitary sites – as well as the lack of regulation of their contents.

The industry's failure to mitigate the threat of counterfeit medicines could adversely impact our business and reputation by impacting patient confidence in our authentic products, potentially resulting in lost sales, product recalls, and an increased threat of litigation. In addition, diversion of our products from their authorized market into other channels may result in reduced revenues and negatively affect our profitability.

Global health crises, pandemics, epidemics, or other outbreaks could adversely disrupt or impact certain aspects of the Company's business, results of operations and financial condition.
We are subject to risks associated with global health crises, epidemics, pandemics and other outbreaks (such incident(s), a health crisis or health crises), including the global outbreak of coronavirus and its variants (COVID-19). The COVID-19 pandemic has adversely impacted, and may continue to adversely impact, certain aspects of the Company's business, results of operations and financial condition, including lower sales and reduced customer demand and usage of certain of our products. The continued spread of COVID-19 or other health crises may cause the Company to modify its business practices, and take further actions as may be required by government authorities or as the Company determines are in the best interests of our patients, customers, employees and business partners. While the Company has robust business continuity plans in place across our global supply chain network to help mitigate the impact of health crises, these efforts may not completely prevent our business from being adversely affected and future impacts remain uncertain.

While the U.S. and other countries have substantially reopened their economies, the extent to which COVID-19, or other health crises, could impact the Company's future operations will depend on many factors which cannot be predicted with confidence, including the duration of an outbreak and impact of variants. A surge in COVID-19 or other health crises could result in the imposition of new mandates and prolonged restrictive measures implemented in order to control the spread of disease. The global spread of COVID-19 or other health crises could adversely impact the Company's operations, including, among other things, our manufacturing operations, supply chain, third-party suppliers, sales and marketing, and clinical trial operations. Any of these factors could adversely affect the Company's business, financial results, and global economic conditions generally.

We also face uncertainties related to our vaccine development programs, including uncertainties related to the risk that our continued development programs may not be successful, commercially viable or receive approval from regulatory authorities; risks associated with clinical trial and real-world data, including further analyses of its efficacy, safety and durability; the risk that continued evolution and mutation of disease and the duration of a particular outbreak may impede our ability to conduct trials within a specified time frame; the risk that data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by national immunization technical advisory groups (NITAGs) and regulatory authorities; disruptions in the relationships between us, our third-party suppliers, external manufacturers, and other third parties with whom we engage; the risk that other companies may produce superior or competitive products; the risk that demand for any products we may develop may no longer exist; risks related to the availability of raw materials to manufacture any such products; the risk that we may not be able to recoup costs associated with our R&D and manufacturing efforts and risks associated with any changes in the way we approach or provide additional research funding for potential drug development; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis, that we may continue to experience manufacturing delays once a manufacturing site is activated, or have access to logistics or supply channels commensurate with global demand for any potential approved vaccine or product candidate, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods indicated, and other challenges and risks associated with the pace of our vaccine development program; and pricing and access challenges for such products, including in the U.S.

Risks Related to Government Regulation and Legal Proceedings

Global sales in the Company's Pharmaceuticol and MedTech segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Actelion Pharmaceuticals US, Inc.

Employee First Name	Employee Last Name				
Jennifer	Battle				
Jason	Putman				
Christopher	Wright				
Sara	Barker				
Erin	McElroy				
Demetrus	Johnson				
Mary	Martina				
Christopher	Thomas				
Travis	Jensen				
Buffi	Miller				
AlDon	Brink				
Catherine	Ussery				
Robert	Schwarz				
Ana	Escobar				
Alan	Han				
Limor	Vidor				
NGA	JEFFRIES				
Amanda	Morrison				
Lisa	Bailey				
Sarah	Walden				
Monica	Gon				
Maja	Nelson				
Wendy	Hill				
Andrew	Titus				
Jennifer	Rosenberg				
Jean Paul	Barba				
Tyler	Gilbert				
Shaun	Trimble				
Vince Edward	Quiambao				
TANIA	NASIR				
Adriana	Thibodeaux				
Clarinda	Rice				
GLENDA	PANG				
John	Hartney				
Paulina	Edge				
Lindsay	Powell				
Elizabeth	Griffin				
Eduardo	De La Maza				
BENJAMIN	COLLINS				
Fabian	Guarnizo				
George	Acuna				
GREGORY	GRIFFIN				
Tracy	Stahl				
Brad	Brandenburg				
SHEILA	HICKSON-CURRAN				
Barbie	Grazier				
Jenny	Brooks				
Larisa	Ruiz Serrano				

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Employee First Name	Employee Last Name				
KIM	LEGG				
Erica	Neal				
Brett	Hinkel				
Tony	Rosquete				
Benjamin Kody	Timms				
Patricia	Adolphsen				
Lisa	Waldman				
Alim	Shabazz				
Darren	Hill				
Robyn	Zeman				
RITO	OCHOA				
MELISSA	MERZ				
JOHN	THOMAS				
Joseph	Frederick				
THOMAS	MCHUGH				
Robert	Personette				
Bryan	Boes				
Jacob	Brown				
Mark	Kennedy				
Stephanie	Rattanavongsa				
Christina	Benninger				
Roy	Moran IV				
Gregory	Watkins				
Latherio	Joseph Jr				
Spencer	Goold				
Faith	Ekanem				
Joseph	D'Avella				
Robert	De Santis				
Divya	Narayanan				
Earl	Cronan III				
Marjan	Sadegh				
Xiaoqin	Tang				
Courtney	Leslie				
Mark	Nemer				
Kristina	Atanasoski				
REGINALD	LAWRENCE				
Laura	Richardson				
Darren	Kennedy				
Ashley	Nitzkowski				
Lawrence	Ober				
Martina	Schutte				
Josephine	Garcia-Ferrer				
Kelly	Verba				
Jennifer	Boynton				
Stephanie	Perkins				
Albert	Torregroza				
NATALIE	GEARHART				
Paul	Strachan				

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Employee First Name	Employee Last Name				
Michelle	Han				
Mohammad	Rahman				
Gabriela	Gomez Rendon				
David	Lopez				
Carlos	Cruz Pena				
Jenny	Lam				
Donald	Baines				
THERESA	MALFITANO				
JOSEPH	YEN				
Marinella	Sandros				
Donna	Hodge				
ALEX	CHEN				
Catherine	Stephenson				
James	Heuck				
Justin	Porter				
Neda	Thorson				
KENDRA	HEUSINKVELD				
Kevin	East				
Carlo	Cicacci				
Michael	Morand				
Luana	Pagliani				
PAYAL	DESAI				
SHAILI	UPADHYAY				
Suann	Bidwell				
Ian	Hepburn				
Melisa	Marino				
Jessica	Sladewski				
Michael	Lorenz				
John	Hanson				
Jason	Werts				
Joseph	Youssef				
YASMEEN	SPOTWOOD				
Jessica	House				
Nicholas	Bauer				
Anisha	Johnson				
Ariana	Iacono				
Tara	Raoufi				
Lori	Mancini				
Amanda	Marshall				
Sharon	Sofield				
ELISA	KAGAN				
Robert	Treml Jr				
Sylvia	Georgi				
Kenneth	Johnson				
Thomas	Chempiel				
Natalie	Timmons				
Sean	Studer				
Isha	Williams				

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Employee First Name	Employee Last Name				
Travis	Smith				
Lacey	Buckley				
Robert	Salvatore				
Marilena	Tata				
Katarzyna	Gosek				
Elmer	Song				
Adam	Denis				
Michael F.	Murphy				
Kevin	Hohner				
Kyle	Shouler				
Laura	O'Kula				
Daniel	Woody				
Daniel	Welch				
Justin	Luciani				
Allison	Colvin				
Elise	Gerold				
John	Way				
MARLA	CHOREN				
Michelle	Kortokrax				
Anson	Hall Jr				
Heather	Kauflin				
Erin	McDermott				
KENNETH	GOTTSCHALK				
Laura	Rosenheck				
Lisa	Clark				
Abdiel	Acevedo-Santiago				
Michael	Scott				
Arthur	Colon				
Gregory	Smart				
David	Skoviak				
Sarah	Arendse				
Tobore	Tobore				
Timothy	Cunniff				
Mary	Ijomah				
Gurinderpal	Doad				
Johnny	DeSouza				
ERICA	MOOR				
Susan	Stegman				
ASIA	CARRABY				
Jason	Van Hoof				
Christopher	Brockway				
Edward	Rackowski				
THOMAS	DOWDEN IV				
Roland	Massaad				
Mary Ann	Hagan				
Kevin	Waters				
Lisa	Walker				
Ryan	Courtwright				

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Employee First Name	Employee Last Name				
Kadriye	Erkul				
Colleen	Sweeney				
MICHELLE	CHO				
Kate	Hayes				
Christopher	Amabile				
Jennifer	Sefton				
Paula	Barry				
Sonja	Grooms-Smith				
Kimberly	Kline				
Davonnetrae	Worthy				
Tyler	Burgess				
Vicki	Bynum				
Andrew	Berkowitz				
MOLLY	CHASSEY				
Jason	Pelfrey				
James	Ross				
Bruce	Neale				
Michael	Rariden				
Chad	Overman				
Keith	Lord				
kelly	medina				
Bret	Eckstein				
Tari	Garza				
Kristi	Morin				
Erika	Pierce				
Bethany	Buchanan				
Lindsey	Crockett				
Robert	Bean				
Saja	Khuder				
Sharon	Shand				
Julian	Mangano				
Kim	Beck				
Rochelle	Romer				
Stephanie	Dahle				
Chi	Chan				
Gene	Ruiz				
Serguei	Zoubkov				
Larry	Green				
Donald	Newell				
Kristin	Anderson Roseleip				
Francisco	Ruiz Serrano				

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411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	*Applicant is a wholly-owned subsidiary of a publicly traded company. ☑ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Facility Name: ARS Pharmaceuticals Operations, Inc.

Physical Address: 11682 El Camino Real, Suite 120

City: San Diego State: CA Zip: 92130

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 858-799-1840 Website: www.ars-pharma.com

Name of Designated Representative (DR): Oscar Ereso

Licensing Company Email: oereso@ars-pharma.com DR Email: oereso@ars-pharma.com

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☑ Wholesalers ☐ Veterinarians ☐ Others:	☑ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical devices, equipment, supplies, gases ☐ Others:	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☑ Others: Virtual manufacturer

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Name: N/A - no pharmaceutical products have been sold, dispensed or distributed within the past year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

State of Incorporation: Delaware

Parent Company (if any): ARS Pharmaceuticals, Inc. (publicly traded company)

Corporation Name: ARS Pharmaceuticals Operations, Inc.

Mailing Address: 11682 El Camino Real, Suite 120

City: San Diego State: CA Zip: 92130

Telephone: 858-799-1840 Email: oereso@ars-pharma.com

Contact Person Name: Brian Dorsey

Date of SEC Registration:	SEC Registration Number: 0001671858 (CIK)	Stock Exchange Symbol: SPRY

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. N/A - applicant is a wholly-owned subsidiary of a publicly traded company.		

• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

ARS Pharmaceuticals Operations, Inc.

Facility Name

Oscar Ereso

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/10/23

Date

Board Use Only	Date Received: 5/22/23	Amount: $1000 CK #1448

BOARD OF PHARMACY

LICENSING DETAILS FOR: WLS 8314

NAME: ARS PHARMACEUTICALS OPERATIONS INC

LICENSE TYPE: WHOLESALER

LICENSE STATUS: CLEAR

ADDRESS

11682 EL CAMINO REAL STE 120
SAN DIEGO CA 92130
SAN DIEGO COUNTY

ISSUANCE DATE

AUGUST 31, 2023

EXPIRATION DATE

DECEMBER 15, 2023

CURRENT DATE / TIME

SEPTEMBER 1, 2023
12:12:40 PM

LICENSE RELATIONSHIPS

NAME: ERESO, OSCAR S

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 46271 **PRIMARY STATUS:** CLEAR

FROM FDA DATABASE:

NDC/NH RIC Labeler	Firm Name
82003	PharmaCare USA LLC
66232	AVON ORGANICS LIMITED
52540	LK Consulting Group
86156	MasterVet
78927	NUVOMED,INC.
82022	Indelicare LLC
52219	GREEN LIFE
45941	DSM Fine Chemicals GMBH
69315	Leading Pharma LLC
80537	MEDREDI LLC
80006	Henry Rose LLC
73382	Natures Design Products LLC
82580	ARS Pharmaceuticals, Inc.
74627	Sugarleaf Labs Inc.
80884	Lets go Clean, LLC
78472	Temple Engineering, Inc.
77910	IDEAL ENERGY SOLUTIONS LLC
76010	VARAM INC
71454	GC US CORPORATION
11433	Shanghai Soap Co. Ltd
83124	Kairos Trading Inc
71856	NUTRIOMO LABS PTE. LTD
73239	Kanamed Inc
70165	Neos Therapeutics Brands, LLC
21839	Gordon Laboratories, Inc
66280	New Colony Farms, LLC

NDCLabelerCodeAutoReport

Attachment B

Corporation Information

ARS Pharmaceuticals Operations, Inc.
(a wholly-owned subsidiary of ARS Pharmaceuticals, Inc.)

Corporate Officers:

Richard Lowenthal
President and CEO

Sarina Tanimoto, M.D.
Chief Medical Officer

Kathleen D. Scott
Chief Financial Officer

Eric Karas
Chief Commercial Officer

Justin Chakma
Chief Business Officer

Alex Fitzpatrick, Esq.
Chief Legal Officer

Brian Dorsey
Chief Operating Officer

Attachment C

Delaware Certificate of Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ARS PHARMACEUTICALS OPERATIONS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIFTH DAY OF AUGUST, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ARS PHARMACEUTICALS OPERATIONS, INC." WAS INCORPORATED ON THE FIFTH DAY OF AUGUST, A.D. 2015.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5799877 8300

SR# 20233346340

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204041631

Date: 08-25-23

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "ARS SUBSIDIARY, INC.", CHANGING ITS NAME FROM "ARS SUBSIDIARY, INC." TO "ARS PHARMACEUTICALS OPERATIONS, INC.", FILED IN THIS OFFICE ON THE SEVENTH DAY OF MARCH, A.D. 2023, AT 6:44 O`CLOCK P.M.

Jeffrey W. Bullock, Secretary of State

5799877 8100
SR# 20230902987

Authentication: 202863062
Date: 03-08-23

Attachment D

Parent Company SEC Documentation and Shareholder Information

Harris	Lynda	Executive Director HR
Asuncion	Al	VP Supply Chain
Chakma	Justin	Chief Business Officer
Clark	Lisa	Director, Talent Acquisition/HR
De Luca	Salvatore	Controller
Dorsey	Brian	Chief Operating Officer
Ereso	Oscar	Sr Director Supply Chain, Designated Representative
Fitzpatrick	Alexander	Chief Legal Officer
Haupt	Patrick	Director QA
Lowenthal	Richard	President and CEO
Maula	Denny	Manager Legal Affairs
McNeely	Sally	Senior Accounts Payable Specialist
Paul	Tracy	I.T. Manager Consultant
Rueb	Nick	Director of SEC Reporting and Technical Accounting
Scott	Kathleen	Chief Financial Officer
Tanimoto	Sarina	Chief Medical Officer
Wills	Kristin	Sr. Director, Accounting

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

May 15, 2023
Date of Report (Date of earliest event reported)

ARS Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-39756	81-1489190
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

11682 El Camino Real, Suite 120 San Diego, California	92130
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (858) 771-9307

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**SPRY**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b–2 of the Securities Exchange Act of 1934 (§ 240.12b–2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2023, ARS Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2023 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02 of this Current Report on 8-K, including Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press Release dated May 15, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ARS PHARMACEUTICALS, INC.

Date: May 15, 2023

By: /s/ Richard Lowenthal
Richard Lowenthal, M.S., MBA
President and Chief Executive Officer

ARS Pharmaceuticals Highlights Progress and Reports First Quarter 2023 Financial Results

*FDA Advisory Committee Votes in Support of Favorable Benefit-Risk Profile for **neffy**® for the Treatment of Allergic Reactions (Type I), Including Anaphylaxis*

*New Drug and Marketing Authorization Applications for **neffy** Under Review with FDA and EMA, Respectively; FDA PDUFA Target Action Date Anticipated mid-2023*

*$264.5 Million in Cash, Cash Equivalents and Short-term Investments to Support Operating Runway for the Next Three Years, Including the Planned Commercialization of **neffy** in the United States*

SAN DIEGO – May 15, 2023 -ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions that could lead to anaphylaxis, today highlighted recent progress and reported first quarter 2023 financial results.

"For the millions of people living with Type I allergic reactions including anaphylaxis, we believe that ***neffy*** (nasal epinephrine spray), a small, needle-free and easy-to-use nasal spray, could provide a much-needed alternative to the currently approved epinephrine injection devices. Despite their effectiveness, these devices are limited in usage because many patients and caregivers do not carry, avoid using or hesitate to use them," said Richard Lowenthal, president and chief executive officer of ARS Pharmaceuticals. "Throughout the first quarter, we've made important strides toward bringing ***neffy*** to patients. We are glad to have had the opportunity to discuss ***neffy*** with the FDA's Advisory Committee during our recent meeting and are incredibly pleased with the outcome and the committee's support of ***neffy*** for adults and children."

Eric Karas, chief commercial officer added, "As we look ahead, with both our NDA and MAA for ***neffy*** currently under review by the regulators in the U.S. and EU, we are laser focused on our commercial preparedness activities. Over the last several months, we've made significant progress in our Commercial Launch Readiness. We are preparing to launch a 125-person salesforce focusing on specialists and healthcare providers who prescribe epinephrine and will have an array of patient and provider services established to ensure affordability. Access to ***neffy*** is a key focus and priority for us, and we have started to work with drug benefit plans to educate and raise awareness about new routes of administration that will help ensure the prompt use of epinephrine for severe allergic reactions, including anaphylaxis."

- **FDA Advisory Committee Supports *neffy* Potential for the Treatment of Allergic Reactions (Type I), Including Anaphylaxis, Under Review with FDA and EMA:** The U.S. Food and Drug Administration's (FDA) held a Division of Pulmonary-Allergy Drug Advisory Committee (PADAC) meeting on May 11, 2023, to review the New Drug Application (NDA) for ***neffy***. The committee voted 16:6 in favor for adults, and 17:5 in favor for children (<18 years of age and ≥30 kg), that available data support a favorable benefit-risk assessment for ***neffy*** in the treatment of severe allergic reaction (Type I), including anaphylaxis, for adults and children who weigh more than 30kg. The PADAC decision was based on a review of comprehensive data from clinical studies developed in agreement with the FDA, which support a positive risk-benefit profile for intranasal (IN) epinephrine safety and effectiveness, compared to epinephrine injection. We believe the studies demonstrated and the majority of the Committee's discussion supported that ***neffy*** shows:
    - Comparable or greater pharmacodynamic (PD) response (systolic blood pressure and heart rate) vs. intramuscular injection that is observed even at 1 minute after dosing of ***neffy***. Increases in systolic blood pressure and heart rate are the outcomes monitored by physicians to assess clinical response, and therefore ARS considered PD response to be a surrogate for efficacy. The majority conclusion of the Committee also suggests that PD was more important and informative given the high PK variability of injection products.
    - Comparable or greater pharmacokinetic (PK) data (epinephrine levels in the blood) vs. intramuscular injection at all time points based on integrated data across the three primary clinical studies. This includes a "real-world" self-administration study in allergic reaction (Type I) patients, where PK was statistically greater than intramuscular injection during the early timepoints when clinical response is observed. Importantly, exposures with ***neffy*** in all clinical studies were less than the upper limit represented by EpiPen to ensure safety.
    - Effective IN delivery of systemic epinephrine and PD response even with nasal congestion or runny nose (e.g., during allergic rhinitis or upper respiratory tract infection)
    - Comparable safety to injection that is generally mild in nature without any meaningful nasal irritation or pain, without needle-related risks
- **FDA PDUFA Target Action Date Anticipated Mid-2023:** The Company's new drug application (NDA) and marketing authorization application (MAA) for ***neffy*** for the emergency treatment of allergic reactions (Type I) including anaphylaxis in adults and children ≥30 kg (66 lbs), are under review by the FDA and the European Medicines Agency (EMA), respectively. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date anticipated mid-2023. If approved, ***neffy*** would be the first non-injectable treatment available to patients with allergic reactions (Type I) including anaphylaxis.

First Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents and short-term investments were $264.5 million as of March 31, 2023, which ARS believes are sufficient to fund its current operating plan for at least three years.
- **R&D Expenses:** Research and development (R&D) expenses were $6.6 million for the quarter ended March 31, 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were $12.2 million for the quarter ended March 31, 2023.
- **Net Loss:** Net loss was $15.0 million for the quarter ended March 31, 2023.

About Type I Allergic Reactions including Anaphylaxis

Type I severe allergic reactions are serious and potentially life-threatening events that can occur within minutes of exposure to an allergen and require immediate treatment with epinephrine, the only FDA-approved medication for these reactions. While epinephrine autoinjectors have been shown to be highly effective, there are well published limitations that result in many patients and caregivers delaying or not administering treatment in an emergency situation. These limitations include fear of the needle, lack of portability, needle-related safety concerns, lack of reliability, and complexity of the devices. There are approximately 25 to 40 million people in the United States who experience Type I severe allergic reactions. Of those, only 3.3 million currently have an active epinephrine autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector. Even if patients or caregivers carry an autoinjector, more than half either delay or do not administer the device when needed in an emergency.

About ARS Pharmaceuticals, Inc.

ARS is a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions that could lead to anaphylaxis. The Company is developing ***neffy***® (also referred to as ARS-1), an intranasal epinephrine product in clinical development for patients and their caregivers with Type I allergic reactions including food, medications and insect bites that could lead to life-threatening anaphylaxis. For more information, visit www.ars-pharma.com.

Forward-Looking Statements

Statements in this press release that are not purely historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, ARS's projected cash runway; the anticipated timing for regulatory review decisions on ***neffy*** and the potential approval of ***neffy***; the anticipated US launch of ***neffy***, if approved, and the timing thereof; ARS's strategy of pursuing potential strategic transactions or partnerships for ***neffy*** in Europe, if approved; the estimated addressable patient population for ***neffy***; ARS's plan to file a supplemental regulatory application for a ***neffy*** 1 mg product for children 15 kg to <30 kg immediately after the approval of ***neffy*** 2 mg in the United States and/or Europe; andother statements that are not historical fact. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "anticipate," "plans," "expects," "will," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the ability to obtain and maintain regulatory approval for ***neffy***; results from clinical trials may not be indicative of results that may be observed in the future; potential safety and other complications from ***neffy***; the labelling for ***neffy***, if approved; the scope, progress and expansion of developing and commercializing ***neffy***; the size and growth of the market therefor and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; ARS's ability to protect its intellectual property position; and the impact of government laws and regulations. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption "Risk Factors—Risks Related to ARS Pharma" in the company's definitive merger proxy statement filed with the Securities and Exchange Commission on October 6, 2022. This document can also be accessed on ARS's web page at ir.ars-pharma.com by clicking on the link "Financials & Filings."

The forward-looking statements included in this press release are made only as of the date hereof. ARS assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

ARS Investor Contact:
Justin Chakma
ARS Pharma
justinc@ars-pharma.com

ARS Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and par value data)

	March 31, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 87,862	$ 210,518
Short-term investments	176,687	63,863
Prepaid expenses and other current assets	2,801	3,319
Total current assets	267,350	277,700
Right-of-use asset	398	445
Fixed assets, net	584	329
Other assets	2,860	2,961
Total assets	$ 271,192	$ 281,435
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $307 and $16, respectively)	$ 9,596	$ 4,931
Lease liability, current	232	230
Contract liability, current	10	283
Total current liabilities	9,838	5,444
Lease liability, net of current portion	199	251
Contract liability, net of current portion	—	2,854
Total liabilities	10,037	8,549
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at March 31, 2023 and December 31, 2022; no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at March 31, 2023 and December 31, 2022; 94,448,028 and 93,943,316 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	9	9
Additional paid-in capital	352,977	349,408
Accumulated other comprehensive gain	68	407
Accumulated deficit	(91,899)	(76,938)
Total stockholders' equity	261,155	272,886
Total liabilities, convertible preferred stock and stockholders' equity	$ 271,192	$ 281,435

ARS Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenue under collaboration agreements	$ 20	$ 663
Operating expenses:		
Research and development (including related party amounts of $591 and $540, respectively)	6,552	5,423
General and administrative (including related party amounts of $337 and $165, respectively)	12,181	2,339
Total operating expenses	18,733	7,762
Loss from operations	(18,713)	(7,099)
Other income (expense), net	3,752	(151)
Net loss	$ (14,961)	$ (7,250)
Change in unrealized gain on available-for-sale securities	(339)	—
Comprehensive loss	$ (15,300)	$ (7,250)
Net loss per share, basic and diluted	$ (0.16)	$ (0.24)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	94,227,313	30,369,413

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☑ New Wholesaler	* If making a change, provide current license number:	☑ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Bristol Myers Squibb

Physical Address: 38 Jackson Rd.

City: Devens State: MA Zip: 01434

Mailing Address (if different from physical address): 1 Squibb Drive

City: New Brunswick State: NJ Zip: 08901

Telephone: (978) 784-6001 Website: usdc@bms.com

Name of Designated Representative (DR): Joe Clarke

Licensing Company Email: usdc@bms.com DR Email: joe.clarke@bms.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Manufacturers, Clinics		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attached, no shipping at this time!
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____
Name: _____
Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): _____
Corporation Name: Bristol Myers Squibb
Mailing Address: 1 Squibb Drive
City: New Brunswick, NJ 08901 State: NJ Zip: 08901
Telephone: _____ Email: usdc@bms.com
Contact Person Name: Cindy Blue

Date of SEC Registration: 8/11/1933 | SEC Registration Number: 0000014272 | Stock Exchange Symbol: BMY

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A
Parent Company (if any): _____
Corporation/Organization Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 6: Partnership

Partnership Name: N/A
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A
Business Name: _____
Business Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Bristol Myers Squibb

Facility Name

Kimberly M. Jablonski

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/30/2023

Date

Board Use Only	Date Received: 8/2/23	Amount: 1000-CK-652541

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Bristol-Myers Squibb Compan**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Bristol-Myers Squibb Company	3008455069	860967566	ANALYSIS; API MANUFACTURE;	38 Jackson Road, Devens, Massachusetts (MA) 01434, United States (USA)	12/31/2023

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Wednesday, Apr 5, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Verified
4/15/23

Corporate Officer Information

Bristol Myers Squibb Company
38 Jackson Road
Devens, MA 01434
FEIN: 22-0790350

Bristol Myers Squibb Company – Home Office
Address: 430 E. 29th Street, 14th Floor New York, NY 10016
Ownership: 100%

Kimberly M. Jablonski– **Vice President & Secretary**
Business Address: Route 206 & Province Line Road, Princeton, NJ 08648
Business Phone: 609-252-4774
Home Address: [redacted]Sked Street, Pennington, NJ 08534
Home Phone: [redacted]
SSN:
DOB:

Sandra Ramos-Alves– **Senior Vice President & Treasurer**
Business Address: 406 Riverside Drive, Princeton, NJ 08540
Business Phone: 908-219-0460
Home Address: [redacted]Riverside Drive, Princeton, NJ 08540
Home Phone: [redacted]
SSN:
DOB:

The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the
Commonwealth

Date: July 03, 2023

To Whom It May Concern :

I hereby certify that according to the records of this office,

BRISTOL-MYERS SQUIBB COMPANY

a corporation organized under the laws of

DELAWARE

on **August 11, 1933** was qualified to do business in this Commonwealth on

August 26, 1982 under the provisions of the General Laws, and I further certify that said corporation is still qualified to do business in this Commonwealth.

I also certify that said corporation is not delinquent in the filing of any annual reports required to date.

In testimony of which,
I have hereunto affixed the
Great Seal of the Commonwealth
on the date first above written.

William Francis Galvin

Secretary of the Commonwealth

Certificate Number: 23070032110
Verify this Certificate at: http://corp.sec.state.ma.us/CorpWeb/Certificates/Verify.aspx
Processed by: bod

Massachusetts Office of Health and Human Services (EOHHS)
Health Professions License Verification Site

Home Page > Profile > MA0093663 - BRISTOL MYERS SQUIBB

License Information

License Type:	Drug Manufacturer or Drug Distributor Controlled Substance Registration
License Number:	MA0093663
Status:	Current
Organization Name:	BRISTOL MYERS SQUIBB
Expiration Date:	June 20, 2024
Address:	38 JACKSON ROAD DEVENS, MA 01434
Drug Schedules:	VI

Compliance Actions/Fines

There are no public compliance actions or fines against this license/registration record.

<< Back to Search Page

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Drug Manufacturer or Drug Distributor Controlled Substance Registration to:

BRISTOL MYERS SQUIBB
38 JACKSON ROAD
DEVENS, MA 01434

Margret R. Cooke
Commissioner - Department of Public Health

Registration Number: MA0093663

Type: Manufacture, Distribute

Schedules: VI

Issue Date: 03/27/2023

Expiration Date: 06/20/2024

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

How to Get Help:

Mass.gov Resources

- eLicensing User Guide
- Bureau of Health Professions Licensure
- Office of Local and Regional Health
- Department of Public Health

BHPL eLicensing Support Resources

Online: eLicensing Support Request Form

Email: dph.elicensing_support@mass.gov

Phone: (617) 973-0935

TTY Line: (617) 973-0988

DO NOT provide your Social Security Number or **Date of Birth** when contacting the eLicensing Support Desk online or by email

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Did you find what you were looking for on this webpage? Please provide your feedback here.

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Bristol Myers Squibb

Facilities Listing for Bristol Myers Squibb, 38 Jackson Rd, Devens, MA 01434:

Juno Therapeutics, Inc., at 1522 217th Pl, SE, Bothell, WA 98021

Contact: Karlika Cintron-Garcia (206)829-3803

Celgene Corporation, at 556 Morris Ave, Bldg. S12, Summit, NJ 07901

Contact: Anthony Patuto (908)673-9000

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107746539

Application/License No. _____

Bristol Myers Squibb (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 38 Jackson Road , Devens, MA 01434 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square , Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 21, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of July, 2023.

APPLICANT/PRINCIPAL

Bristol Myers Squibb
COMPANY

By: _____
Authorized Representative

SURETY

Travelers Casualty and Surety Company of Am

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA
HARTFORD, CONN.

By: _____
Surety Company's Representative

Michelle Anne McMahon, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Jennifer Godere

_____
Witness Gentry Stewart

Countersigned by:

_____
Non ~~Nevada~~ Resident Agent Kathryn Pryor
Non-Resident License No. 3549033

Posted February 20, 2020

TRAVELERS	**Travelers Casualty and Surety Company of America** **Travelers Casualty and Surety Company** **St. Paul Fire and Marine Insurance Company** **Farmington Casualty Company**

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, St. Paul Fire and Marine Insurance Company, and Farmington Casualty Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint Michelle Anne McMahon of Short Hills , NJ , their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge the following bond:

Surety Bond No.: 107746539
OR
Project Description: NV Pharmaceutical Wholesaler Bond

Principal: Bristol Myers Squibb
Obligee: Nevada State Board of Pharmacy

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April, 2021.**

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April, 2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Cheirman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attestad and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 21st day of July , 2023 .

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

Telephone: +1 860-241-4437
Website: wtwco.com
E-mail: melissa.stanton@wtwco.com

July 24, 2023

Bristol Myers Squibb
38 Jackson Road
Devens, MA 01434

Re: **Bond Number: 107746539**
Obligee: Nevada State Board of Pharmacy
Description: NV Pharmaceutical Wholesaler Bond
Commission: 0%

We are pleased to enclose the above referenced bond you requested. This bond was executed based upon the information you provided. We urge you to check all of the information enclosed, including the Power of Attorney, signatures, dates, amounts, description, bond form and any other attachments.

Please be sure to affix the bond with the proper signature and seal.

If a premium is charged, our invoice for this bond is enclosed or will be sent to you under separate cover. Please note the premium payment for this bond is due upon receipt.

Willis Towers Watson negotiates commission rates with certain insurers on a corporate level. If the rate on your placement is lower than the negotiated rate, Willis Towers Watson can collect the difference directly from the insurer. These payments will not increase the cost of your bonds or otherwise impact your premium or rates. Details of these arrangements where there is compensation beyond the base compensation detailed in your commission schedule can be found at: http://www.willis.com/About_Willis/The_Willis_Way/Commission_Rates/.

Thank you for the opportunity to service your surety needs. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Melissa Stanton

Bristol Myers Squibb Employee List at Devens, MA

name	Title
Mani Bhadra Mohapatra	Senior Manager, Global Regulatory CMC Cell Therapy
Scott Clark	Director, IT Cell Therapy Manufacturing Site Lead, Devens, MA
Cory Robert Gierczak	Senior Manager - Cell Therapy Manufacturing Systems
Wallas Vieira	Senior Manager, Manufacturing Execution System Engineer - Cell Therapy IT
Anthony Berninzon	Manufacturing Execution System (MES) Engineer - Cell Therapy IT
Laura Beth Maguire	IT Quality and Compliance Engineer, Cell Therapy Senior Specialist
Dominique Geraldine Schiraldi	Cell Therapy Network - Recipe Analyst
Vishwesh Sankholkar	Associate Director, Cell Therapy MES IT Business Partner
Pankaj Sinha	Associate Director, IT - Cell Therapy Global Manufacturing Digital Factory Lead
Tine Van Nunen	HR Business Partner, Devens Cell Therapy Operations
PASQUALE JOSEPH PERFETTO	Executive Director, GMQ Network Compliance Excellence and Strategy
Gregory Bassett	Vice President, Cell Therapy Internal Manufacturing Quality
Bradley C. Warsen	Executive Director, Quality, Cell Therapy Manufacturing Facility
Kunal Ahalpara	Associate Director, Quality Business Operations Cell Therapy
Patience Kinyanjui	Senior Project Manager, Cell Therapy Quality
Vaibhav Dixit	Sr. Manager, Operational Excellence
Antonio Moran	Manager, Operational Excellence
Michael Call	Director, Compliance and Quality Systems Cell Therapy
David Smith	Specialist, Learning and Development, Cell Therapy
Alissa Dougherty	Specialist, Training Cell Therapy
Sabina Wojtyna	Senior Manager, Document Control - Cell Therapy
Michele Gadoua	Senior Specialist, Document Control Cell Therapy
Micheal Neeley	Senior Specialist, Document Control Cell Therapy
Deanna Broderick	Senior Manager, Compliance Cell Therapy
Jeffrey White	Senior Manager, Quality Assurance Material Operations, Cell Therapy
Hir Patel	Manager, Incoming Quality Assurance Disposition Cell Therapy
Brenden Knight	Specialist, Quality Assurance Incoming Material Disposition, Cell Therapy
Navy Sree	Specialist, Quality Assurance Incoming Material Disposition, Cell Therapy
Navy Mak	Senior Specialist, Quality Assurance Incoming Material Disposition, Cell Therapy
Todd Stowell	Manager, Incoming Material Inspection and Disposition, Cell Therapy
Fadi Nasr	Manager, QA SAP Master Data, Cell Therapy
Chelsea Warren	Senior Manager, Quality Assurance Drug Product Disposition, Cell Therapy

Matthew Liberty	Manager, Quality Assurance Drug Product Disposition, Cell Therapy
Heliana Downing	Manager, Quality Assurance Drug Product Disposition Cell Therapy
Alessandra M Mastrullo	Manager, Quality Assurance Drug Product Disposition Cell Therapy
Jacob Chase	Specialist, Quality Assurance Drug Product Disposition, Cell Therapy
Laurie Richard	Sr. Specialist, Quality Assurance Drug Product Disposition Cell Therapy
Elizabeth Cleveland	Manager, Quality Assurance Drug Product Disposition, Cell Therapy
Timothy Trettel	Senior Manager, QA Disposition, Material Review Board Coordinator, Cell Therapy
Bill Lyon	Director, Quality Control Operations Cell Therapy
Thomas Bullock	Senior Specialist, Quality Control Investigations, Cell Therapy
Patrick Bousquet	Scientist, Quality Control Investigations, Cell Therapy
Philippe Chalvire	Senior Manager, Quality Control Sample Management and Planning Cell Therapy
Maria Cascio	Manager, Night Shift Cell Therapy Quality Control
William Guillemette	Senior Manager, LIMS Cell Therapy
James Mostone	Scientist, QC Equipment Lifecycle Management, Cell Therapy
Christine Stanney	Senior Manager, Quality Control Investigations, Cell Therapy
Jessica Hamilton	Senior Scientist, Quality Control Molecular Cell Therapy
Lori Desmond	Senior Manager, QC Microbiology Lab Operations, Cell Therapy
Kelvin Wong	Manager, QC Microbiology, Cell Therapy
Severiano Ramos	Senior Specialist, Quality Control Microbiology, Cell Therapy
Payton Giles	Associate, QC Microbiology, Cell Therapy
Adonis Ramirez-Matos	Associate, QC Microbiology, Cell Therapy
Zurwa Razaq	Associate, QC Microbiology, Cell Therapy
John Henry	Associate, QC Microbiology, Cell Therapy
Abigail Gaiser	Associate, QC Microbiology, Cell Therapy
Eseroma Puamau	Specialist, QC Microbiology, Cell Therapy
Meaghan McIntyre	Scientist, QC Microbiology, Cell Therapy
Robert Hewlett	Senior Manager, QC Analytical Technical Support, Cell Therapy
Camila De Los Santos Mora	QC Analytical Manager, A1 shift, Cell Therapy
Andy Gomez	Senior Specialist, QC Analytical, A2 shift, Cell Therapy
Jae Watts	Associate, QC Analytical, A2 shift, Cell Therapy
Christian Ignacio	Specialist, QC Analytical, A2 shift, Cell Therapy
Benjamin Lewis Tierney	Associate, QC Analytical, Cell Therapy
Marisa Maltais	Associate, QC Analytical, A2 shift, Cell Therapy
Cutlus Johnson	Associate, QC Analytical, A1 Shift, Cell Therapy

Alyssia Lopez	Associate, QC Analytical, A1 shift, Cell Therapy
Jai Agarwal	Associate, QC Analytical, A1 shift, Cell Therapy
Daniel Lee	Associate, QC Analytical, Cell Therapy
Adrienne Whitney	Associate, QC Analytical, B1 shift, Cell Therapy
Connie Estevez	Associate, QC Analytical, B1 Shift, Cell Therapy
Lizeth Hernandez	Specialist, QC Analytical, B1 shift, Cell Therapy
Sean Perry	Specialist, QC Analytical, Cell Therapy
Emily Sansoucy	Associate, QC Analytical B2 Shift, Cell Therapy
Peter Croci	Site Microbiologist, Cell Therapy
Shelley Hasenoehrl	Scientist, Site Microbiology, Cell Therapy
Jaclyn Blaisdell	Director, Cell Therapy Quality Assurance
Rajendra Prasad Konasani	Manager, Quality Engineering Cell Therapy
Ishita Dave	Principal Specialist, Quality Engineering Cell Therapy
Swasidh Kommi	Manager, Quality Engineering, Cell Therapy
Naveen Takkala	Manager, Quality Engineering Cell Therapy
Mohammed Gilani	Senior Manager, Field Quality Assurance Cell Therapy
George Annan	Senior Specialist, Shop Floor Quality Assurance Cell Therapy
Michael Caudill-Laughlin	Manager, Field Quality Assurance, Cell Therapy
Claudia Doravivanh	Senior Specialist, Shop Floor Quality Assurance Cell Therapy
Natassia Trettel	Specialist, Field Quality Assurance, Cell Therapy
Kishorkumar Patel	Manager, Field Quality Assurance, Cell Therapy
Russell Liu	Specialist, Shop Floor Quality Assurance, Cell Therapy, B2 Shift
Derrick Acheampong	Specialist, Shop Floor Quality Assurance, Cell Therapy, Overnight Shift
Domenic Marseglia	Senior Specialist, Field Quality Assurance, Cell Therapy
Jon Lynch	Specialist, Field Quality Assurance Cell Therapy, Overnight (6p-6a)
Kong Moua	Senior Specialist, Field Quality Assurance, Cell Therapy, Overnight
Jessica Fowler	Senior Manager, QA Laboratory Operations, Cell Therapy
Muzammil Kadawala	Senior Specialist, Quality Assurance Laboratory Operations, Cell Therapy
Bruce Dufresne	Senior Manager, Field Quality Assurance Cell Therapy
Gregory Ewing	Specialist, Warehouse Shop Floor Quality Assurance Cell Therapy, Night Shift
Nana Prempeh	Senior Specialist, Field Quality Assurance, Cell Therapy
Jecksan Santiago	Manager, Quality Assurance Operations Cell Therapy
Stephanie Uribe	Field Specialist, Quality Assurance Operations Cell Therapy
Mark W Connor	Senior Specialist, Shop Floor Quality Assurance, Cell Therapy

Ana Silvestre	Senior Specialist, Field Quality Assurance Cell Therapy
David Graham	Senior Specialist, Warehouse Field Quality Assurance, Cell Therapy
Yaw Koosono Ampem	Senior Specialist, Shop Floor Quality Assurance Cell Therapy, Overnight
Sahr S Kamanda	Specialist, Field Quality Assurance, Cell Therapy
Rita Carroll	Manager, Shop Floor Quality Assurance Cell Therapy
Matthew Leenhouts	Senior Specialist, Field Quality Assurance, Cell Therapy
William Orciuch	Specialist, Field Quality Assurance, Cell Therapy
Kim Bui	Senior Specialist, Warehouse Shop Floor Quality Assurance Cell Therapy
McKenzie Brennan	Specialist, Shop Floor Quality Assurance Cell Therapy
James Wolfe	Specialist, Warehouse Shop Floor Quality Assurance Cell Therapy, Night Shift
Zachary Ozker	Associate Director, Quality Assurance Investigations, Cell Therapy
Benjamin Mahon	Senior Manager, Quality System Data Analyst, Cell Therapy
Sushma Appala	Manager, Quality Assurance Investigations, Cell Therapy
Frantzy Cenatus	Senior Specialist, Quality Assurance Investigations, Cell Therapy
Kadie Ann Thompson	Senior Manager, Quality Assurance Investigations Cell Therapy
Ryan Manasian	Overnight Manager, Shop Floor Quality Assurance Cell Therapy
Dhruva Patel	Manager, Quality Assurance Investigations, Cell Therapy
Kristen Michelle Ritchotte	Manager, Quality Assurance Investigations, Cell Therapy
David Strong	Director, Cell Therapy Internal Manufacturing Quality Assurance
Heidi Davis	Executive Director Cell Therapy Global Quality Systems and Compliance
Jessica Ferris	Associate Director, Cell Therapy QA Disposition Business Process Owner
Jena Leblanc	Senior Manager, Cell Therapy Global Quality Disposition
Kimberly Dickinson	Principal Scientist, Bioassay, Global Product Quality, Cell Therapy
Mohiuddin Ovee	Associate Director, Analytical Services External Relationship Manager - Cell Therapy
Brianne Creamer	Manager, Cell Bank Planner
Sadie Vezina	Associate Scientist, Cell Culture, Bioprocess Technology, MS andT
Bhumika Sharma	Manager, Cell Culture MS&T
Balvinder S Vig	Executive Director, Strategy and Business Excellence
Arturs Rankis	Associate Director, Large Scale Cell Culture Manufacturing
Douglas Bennitt	Director, Cell Therapy Facilities and Engineering
Nathaniel Clements	Sr. Manager, Cell Therapy FUE & AIQ Qualification
Jeffrey Gardenour	Manager, Sr. Validation Engineer I, Cell Therapy FUE & AIQ Qualification
Christian Kusch	Senior Specialist, Validation Engineer II, Cell Therapy FUE & AIQ Qualification
Meghan Willett	Manager, Sr. Validation Engineer I, Cell Therapy FUE & AIQ Qualification

Sai Kiran Camsarapalli	Senior Manager, Operational Excellence
Brooke Ingram	Associate Director, Operational Excellence
Cathryn Shaw Reid	VP, Head of Cell Therapy Global Manufacturing
Barak I. Barnoon	Executive Director, Head of Manufacturing Engineering, Digital & Analytics - Cell Therapy Internal Manufacturing
Nikolai Makaranka	Director, Manufacturing Operations Analytics - Cell Therapy
Jill Carrillo	Executive Associate, Cell Therapy Global Manufacturing
Jiawei Gu	Senior Director, Cell Therapy Manufacturing Business Operations
Lisa Kay McClintock	Vice President, Site Leader, Cell Therapy Manufacturing
Michael Pulvirenti	Senior Manager, Cell Therapy Process Engineer
Anamika Singh	Senior Manager, Investigations, Cell Therapy
Kedar Shenoy	Manager, Investigations, Cell Therapy
Kymberlee Donatelli	Senior Specialist, Investigations, Cell Therapy
Loreal Lyback	Senior Specialist, Investigations, Cell Therapy
Roryk Brewer	Senior Specialist, Investigations, Cell Therapy
Kelly Saunders	Senior Manager, Investigations, Cell Therapy
Fathima Sameen	Manager, Cell Therapy Investigations
William Pecoroni	Manager, Investigations, Cell Therapy
Sophia Pearce	Senior Specialist, Investigations, Cell Therapy
Balakrishnan Ramasubramanian	Senior Specialist, Investigations, Cell Therapy
Zachary Neidich	Senior Specialist, Investigations, Cell Therapy
Giri Kumar Chandaka	Senior Manager, Investigations, Cell Therapy
Narorth Keung	Manager, Investigations, Cell Therapy
Sharup Barua	Senior Specialist, Investigations, Cell Therapy
Thomas Dumont	Senior Specialist, Investigations, Cell Therapy
Jason Lutcza	Senior Specialist, Investigations, Cell Therapy
Danielle E Harrison	Sr. Manager, Cell Therapy Process Engineer
Jeffrey Swartz	Associate Director, Cell Therapy Lifecycle Management Lead
Ruslan Laranjo	Manager, Process Engineer, Cell Therapy
Falguni Patel	Senior Manager, Cell Therapy Process Engineer
Ken Preedom	Associate Director, Strategy Lead, Cell Therapy
Vamshi Gangupomu	Director, Project Management Office, Cell Therapy
Melissa Hughes	Senior Manager, Senior Project Manager, Cell Therapy
Suguna Chunduri	Senior Manager, Senior Project Manager, Cell Therapy

Jamie Hubler	Senior Specialist, Portfolio Project Analyst, Cell Therapy
Michelle DiFrancesco	Manager, Project Manager, Cell Therapy
Jason Li	Manager, Project Manager, Cell Therapy
Shivani Patel Shah	Manager, Project Manager, Cell Therapy
Samara Audet	Senior Manager, Operational Excellence, Cell Therapy
Sherri Kha	Manager, Operational Excellence, Cell Therapy
Samantha Berreondo	Manager, Operational Excellence, Cell Therapy
Amir Ali Parsaee	Manager, Operational Excellence, Cell Therapy
Victor Lafa	Senior Manager, Value Stream Performance, Cell Therapy
Jessica Beyer	Senior Director, Cell Therapy Manufacturing
Brent Powers	Associate Director, Manufacturing Support Operations, Cell Therapy
Katrice Jalbert	Senior Manager, Manufacturing Operations Support, Cell Therapy
Rindara Mam	Training Specialist, Cell Therapy Manufacturing
Daniel Case	Training Specialist, Cell Therapy Manufacturing
Shaifali Agrawal	Manufacturing Training Manager, Cell Therapy Manufacturing
Maria Rosario Linares	Training Specialist, Cell Therapy Manufacturing
Antoine White	Senior Training Specialist, Cell Therapy Manufacturing
Kimberly Diggs	Training Manager, Cell Therapy Manufacturing
Valery Cody	Senior Training Specialist, Cell Therapy Manufacturing
John Obenchain	Senior Training Specialist, Cell Therapy Manufacturing
Allyson Gohel	Training Lead Specialist, Cell Therapy Manufacturing
Brian Monaghan	Senior Training Specialist, Cell Therapy Manufacturing
Jenine Shanks-Phillips	Manager, Compliance, Cell Therapy Manufacturing
Gabriella Kenny	Compliance Specialist II, Cell Therapy Manufacturing
Abena Kodua	Compliance Specialist II, Cell Therapy Manufacturing
Derek Trunfio	Documentation Manager, Cell Therapy Manufacturing
Christine Oppel	Documentation Specialist, Cell Therapy
Jillian Provost	Documentation Specialist, Cell Therapy
David Rubin	Director of Cell Therapy Manufacturing
Timothy Coy	Senior Manager, Scheduling, Cell Therapy
Joseph J Cimmino	Manager, Master Scheduler, Cell Therapy
Shawnne Biron	Production Scheduler, Cell Therapy
Ritika Prathapani	Senior Specialist, Production Scheduler, Cell Therapy
Rebecca Gallo	Specialist, Production Scheduler, Cell Therapy

Matthew Dennen	Manager, Manufacturing, Cell Therapy
Alex Sawicki	Senior Manufacturing Associate, Cell Therapy
Ezra Quartey	Manufacturing Associate, Cell Therapy Manufacturing
Niccolas LaScola	Lead Manufacturing Associate, Cell Therapy
Jeffrey Blanton	Manufacturing Associate, Cell Therapy
Joao Miranda	Manufacturing Associate, Cell Therapy
Craig Venezia	Manufacturing Associate II, Cell Therapy
Kelso Brown	Lead Manufacturing Associate, Cell Therapy
Kevin Michael Cullen	Associate Director, Manufacturing Operations, Cell Therapy
Stephen Lordan	Senior Manager, Manufacturing Cell Therapy Manufacturing
Prognanwita Barua	Manager, Manufacturing, Cell Therapy
Michael Curry	Manufacturing Associate II, Cell Therapy
Amanda Goguen	Lead Manufacturing Associate, Cell Therapy Manufacturing
John Huynh	Manufacturing Associate II, Cell Therapy
Brian Jackson	Manager, Manufacturing, Cell Therapy
Isaiah Figueroa	Senior Manufacturing Associate, Cell Therapy
Sara Braun	Lead Manufacturing Associate, Cell Therapy Manufacturing
Guetet Simeon	Senior Manufacturing Associate, Cell Therapy
Cory Fisher	Manager, Manufacturing, Cell Therapy
Brenda Mao	Manufacturing Associate, Cell Therapy
Erica English	Senior Manufacturing Associate, Cell Therapy
Ashley Caceres	Manufacturing Associate, Cell Therapy
Lauren Walter	Manufacturing Associate, Cell Therapy Manufacturing
SEAMUS SLATTERY	Manager, Cell Therapy Manufacturing
Glen Oetinger	Lead Manufacturing Associate, Cell Therapy Manufacturing
Heather Martin	Senior Manufacturing Associate, Cell Therapy
Ashley Baldwin	Manufacturing Associate, Cell Therapy
Martin Maguire	Manufacturing Associate, Cell Therapy
Michael Hayes	Manager, Manufacturing Cell Therapy Facility
Henry Boateng	Manufacturing Associate II, Cell Therapy
Mark Kling	Manufacturing Associate II, Cell Therapy
Eric Muse	Lead Manufacturing Associate, Cell Therapy Manufacturing
Victor Burgos	Manufacturing Associate, Cell Therapy
Jorge Rabelo	Senior Manufacturing Associate, Cell Therapy

Sokhom Loyn	Lead Manufacturing Associate, Cell Therapy
Robert Batchelder	Manager, Manufacturing, Cell Therapy
Helio Neno	Manufacturing Associate II, Cell Therapy
William Newlin	Manufacturing Associate, Cell Therapy
Kyle Perry	Manufacturing Associate, Cell Therapy
Anthony Brennan	Senior Manufacturing Associate, Cell Therapy
Kevin Tamayo	Manufacturing Associate, Cell Therapy
Connor OLoughlin	Lead Manufacturing Associate, Cell Therapy
Daniel Ackom	Manufacturing Associate, Cell Therapy
Stephen Demontigny	Manufacturing Associate II, Cell Therapy
Saraswoti Shrestha	Manufacturing Associate II, Cell Therapy
Fabiola Perez Gil Abin	Manager, Manufacturing, Cell Therapy
Eric Turner	Manufacturing Associate II, Cell Therapy
Andrew White	Senior Manufacturing Associate - Cell Therapy Manufacturing
Francis Konneh	Manufacturing Associate, Cell Therapy
Eric Feliciano	Manufacturing Associate II, Cell Therapy
Cecil Talbot	Manufacturing Associate, Cell Therapy
Kayla Felix	Manufacturing Associate, Cell Therapy
Mariko Lam	Manager, Manufacturing, Cell Therapy
Ryan Robertson	Senior Manufacturing Associate, Cell Therapy
Nysia Sok	Manufacturing Associate II, Cell Therapy
Kwaku Takyi	Manufacturing Associate, Cell Therapy
Patrick Ney	Lead Manufacturing Associate, Cell Therapy
Hadassah Viana	Manufacturing Associate II, Cell Therapy
Josue Caceres	Manufacturing Associate, Cell Therapy
Frederick Ashun	Manufacturing Associate II, Cell Therapy
Ramazan Dika	Senior Manufacturing Associate, Cell Therapy
Mary Cusack	Manager, Manufacturing, Cell Therapy
Lindsay D Duchnowski	Senior Manufacturing Associate, Cell Therapy
Shirin Foroutani	Manufacturing Associate II, Cell Therapy Manufacturing
Faith Wilson	Manufacturing Associate, Cell Therapy
Jenny Deng	Lead Manufacturing Associate, Cell Therapy
Christopher Holmes	Associate Director, Manufacturing Operations, Cell Therapy
Gary P Niles	Senior Manufacturing Manager, Cell Therapy Facility

Steven Camvan	Lead Manufacturing Associate, Cell Therapy
Timothy Norman Clark	Senior Manufacturing Associate, Cell Therapy
Frederick Wiafe	Manager, Manufacturing, Cell Therapy
Randy Keung	Manufacturing Associate II, Cell Therapy
Cindy Thumi	Manufacturing Associate II, Cell Therapy
William Johnson	Senior Manufacturing Associate, Cell Therapy
Garbai Grabo	Manufacturing Associate II, Cell Therapy
Jeffrey Blast	Manufacturing Associate, Cell Therapy
Jerryka Danis	Manufacturing Associate II, Cell Therapy
Arthur Mainor	Manufacturing Associate II, Cell Therapy
Michael Barinelli	Lead Manufacturing Associate, Cell Therapy
Daniel Charles	Manager, Manufacturing, Cell Therapy
James Taylor Trieu	Manufacturing Associate, Cell Therapy
Vignesh Chander	Senior Manufacturing Associate, Cell Therapy Manufacturing
Gregory Hill	Manufacturing Associate II, Cell Therapy
Erick Germano	Manufacturing Associate, Cell Therapy
Krupa Patel	Lead Manufacturing Associate, Cell Therapy
Bishoy Abdelmalek	Manufacturing Associate II, Cell Therapy
Manel Sylvarin	Manufacturing Associate, Cell Therapy
Jason Zhang	Manufacturing Associate, Cell Therapy
Matthew Leiskau	Senior Manufacturing Associate, Cell Therapy Manufacturing
Jordan Moultrie	Lead Manufacturing Associate, Cell Therapy
Alan Hicking	Manufacturing Associate II, Cell Therapy
Sarmad Khalid	Manufacturing Associate, Cell Therapy
Yendry Alejandro Arias Santos	Manufacturing Associate, Cell Therapy
Chastity Gutierrez	Manufacturing Associate, Cell Therapy
Ashley Hudson	Manufacturing Associate II, Cell Therapy
Chanda Bo	Manufacturing Associate, Cell Therapy
Kellie Porter	Manufacturing Associate, Cell Therapy
Kyle Custer	Manufacturing Associate II, Cell Therapy
Ryan Barry	Senior Manufacturing Associate, Cell Therapy
Michael Willett	Manufacturing Associate, Cell Therapy
Rhonda Greer	Senior Manager Manufacturing, Cell Therapy Manufacturing
Raween Mendis	Senior Manufacturing Associate, Cell Therapy

Henry Colebrook	Manufacturing Associate, Cell Therapy
Matthew Sordillo	Manager, Manufacturing, Cell Therapy
Colin Clark	Lead Manufacturing Associate, Cell Therapy
William Velazquez	Manufacturing Associate II, Cell Therapy
Shivani Patel	Manufacturing Associate II, Cell Therapy
Ashlee Connors	Manufacturing Associate, Cell Therapy
Michael Mason	Manufacturing Associate II, Cell Therapy
Sonitha Eng	Manufacturing Associate II, Cell Therapy
Patrick Sandjong	Manager, Cell Therapy Manufacturing
Jediah Duncan	Manufacturing Associate, Cell Therapy
Nary Som	Senior Manufacturing Associate, Cell Therapy
Derryck Walker	Lead Manufacturing Associate, Cell Therapy Manufacturing
David Duncan	Manufacturing Associate, Cell Therapy
Steve Bencosme	Manufacturing Associate, Cell Therapy
Bryce Eckley	Manager, Manufacturing Cell Therapy
Nydia Vargas	Lead Manufacturing Associate, Cell Therapy
Frederick Oppon	Manufacturing Associate, Cell Therapy
Lamthoun Rattanavong	Senior Manufacturing Associate, Cell Therapy Manufacturing
Courtney Cayford	Senior Manufacturing Associate, Cell Therapy
Chase Laventure	Senior Manufacturing Associate, Cell Therapy
Malai Ath	Lead Manufacturing Associate, Cell Therapy
Regina Beausoleil	Executive Assistant, Cell Therapy
Leah Newton	Senior Director, Supply Chain, Cell Therapy
Joe Clarke	Associate Director, Material Operations, Cell Therapy
Michael Muoho	Manager, Kitting & Delivery, Cell Therapy
Charles Asante	Material Handler II, Cell Therapy
Jose Velazquez	Material Handler, Cell Therapy
Daniel Martin Pherson	Senior Manager, Material Operations, Cell Therapy
Adam Freiband	Manager, Receiving and Warehousing, Cell Therapy
Russell Drew	Team Lead, Receiving and Warehousing, Cell Therapy
John Lopez	Material Handler, Cell Therapy
Sam Ineson	Material Handler III, Cell Therapy
Christopher Scanlon	Manager, Material Operations, Cell Therapy Warehouse
Ketny Obas	Material Handler, Cell Therapy

Barry Pietrantonio	Team Lead, Cell Therapy Receiving and Warehousing
Daniel Nhial	Material Handler, Cell Therapy
Jose Valladares	Material Handler II, Cell Therapy
Krzysztof Rudnicki	Senior Manager, Kitting and Delivery, Cell Therapy
Jordan Mattison	Material Handler II, Cell Therapy
Rudy Vasquez	Manager, Kitting & Delivery, Cell Therapy
Lais Pereira	Team Lead, Kitting & Delivery, Cell Therapy
Noelia Moreno Rodriguez	Material Handler II, Cell Therapy
Abou Bangoura	Material Handler II, Cell Therapy
Richard Kelly	Manager, Kitting & Delivery, Cell Therapy
Bora Chau	Material Handler, Cell Therapy
Brian Donahue	Material Handler, Cell Therapy
Jason Grasso	Material Handler II, Cell Therapy
Michelly Rodriguez	Team Lead, Kitting & Delivery, Cell Therapy
Alex Mackintosh Carver Jr	Team Lead, Kitting & Delivery, Cell Therapy
Christine Mueller	Senior Manager, Material Inventory - Cell Therapy
Bill Gleeson	Senior Specialist, Inventory, Cell Therapy
Charles Edwards	Associate Director, Supply Chain Product Services, Cell Therapy
Stacy Phillips	Manager, Packaging Operations - Cell Therapy
Nancy Fong	Packaging Operations Associate, Cell Therapy
William Mullen	Packaging Operations Associate, Cell Therapy
Bayo Salam	Senior Specialist, Logistics, Cell Therapy
Sindy Arenas Lopera	Cell Therapy Patient Planner
Lucas Winnett	Manager, Packaging Operations, Cell Therapy
Erika Hernandez	Packaging Operations Associate, Cell Therapy
Neal Worthington	Packaging Operations Associate, Cell Therapy
James Rondestvedt	Associate Director, Supply Chain Support, Cell Therapy
Eric Boateng	Senior Specialist, Supply Chain Compliance, Cell Therapy
Jose Bones Diaz	Manager, Master Data ERP, Cell Therapy
Leena Parab Daxikar	Senior Manager, ERP, Cell Therapy
Asma Djourdikh	Specialist, System Integration Analyst, Cell Therapy
Karen Ann Donahue	Manager, Supply Chain Compliance, Cell Therapy
Kenney Neergaard	Manager, Supply Chain Program Manager, Cell Therapy
Jamie DeJesus	Senior Specialist, Master Data, Site ERP, Cell Therapy

Michelle Hanley	Senior Specialist, Master Data, Site ERP, Cell Therapy
Fausto Jorge	Associate Director, Supply Chain Planning, Cell Therapy
Nisha J Bhagat	Senior Specialist, Material Planning - Cell Therapy
James G Cote	Manager, Material Planning, Cell Therapy
Biruk Sirmollo	Specialist, Material Planning, Cell Therapy
Lauren Bartolotti Busa	Associate Director, Culture and Engagement Lead, Cell Therapy
Henrik Andersen	SVP, Cell Therapy Development
Andrew Pomeroy	Associate Director, Supplier Relationship Manager, Cell Therapy External Clinical Manufacturing
Juan Wang	Senior Manager, Senior Principal Engineer Cell Therapy Process Validation
David Yinan Wang	Associate Director, Program Management, Strategy and Business Excellence
Virginia Corcoran	Associate Director, GPS PMO, Portfolio Excellence
David Gardner	Executive Director Supply Chain Digitization Excellence Master Data and Strategy
Umay Adile Saplakoglu	Vice President, Global Product Development & Supply Operational Excellence Divisional Deployment & Learning Lead, Strategy & Business Excellence
Brian Duran	Senior Director, CTO Operation Excellence
Shannon Nulty	Associate Director Cell Therapy Operational Excellence
Emily Johnson	Associate Director Cell Therapy, Operational Excellence
Victoria Carroll	Associate Director & Site Procurement Lead, Devens Cell-Therapy
Thomas Lewis	Associate Director, BIA GPS Cell Therapy Analytics
Vanessa Kitova	Manager, BIA GPS Cell Therapy Analytics

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THI
SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THI
SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number 001-01136

BRISTOL-MYERS SQUIBB COMPANY
(Exact name of registrant as specified in its charter)

Delaware	22
(State or other jurisdiction of incorporation or organization)	(I.R Iden

430 E. 29th Street, 14FL, New York, NY 10016
(Address of principal executive offices) (Zip Code)
(212) 546-4200
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of e
Common Stock, $0.10 Par Value	BMY	N
1.000% Notes due 2025	BMY25	N
1.750% Notes due 2035	BMY35	N
Celgene Contingent Value Rights	CELG RT	N

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchan shorter period that the registrant was required to file such reports), and (2) has been subject to the filing requirements for the past 90 days. Ye

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursua during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller repo "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Em

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complyi provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

APPLICABLE ONLY TO CORPORATE ISSUERS:

At April 20, 2023, there were 2,100,847,138 shares outstanding of the Registrant's $0.10 par value c

BRISTOL-MYERS SQUIBB COMPANY
INDEX TO FORM 10-Q
March 31, 2023

PART I—FINANCIAL INFORMATION

Item 1.
Financial Statements:
Consolidated Statements of Earnings and Comprehensive Income
Consolidated Balance Sheets
Consolidated Statements of Cash Flows
Notes to Consolidated Financial Statements

Item 2.
Management's Discussion and Analysis of Financial Condition and Results of Operations

Item 3.
Quantitative and Qualitative Disclosure About Market Risk

Item 4.
Controls and Procedures

PART II—OTHER INFORMATION

Item 1.
Legal Proceedings

Item 1A.
Risk Factors

Item 2.
Unregistered Sales of Equity Securities and Use of Proceeds

Item 6.
Exhibits

Summary of Abbreviated Terms
Signatures

* Indicates brand names of products which are trademarks not owned by BMS. Specific trademark ownership information is included in the Exhibit Index at the end of th

PART I—FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

BRISTOL-MYERS SQUIBB COMPANY
CONSOLIDATED STATEMENTS OF EARNINGS
Dollars in millions, except per share data
(UNAUDITED)

EARNINGS	
Net product sales	
Alliance and other revenues	
Total Revenues	
Cost of products sold[a]	
Marketing, selling and administrative	
Research and development	
Acquired IPRD	
Amortization of acquired intangible assets	
Other (income)/expense, net	
Total Expenses	
Earnings before income taxes	
Provision for income taxes	
Net earnings	
Noncontrolling interest	
Net earnings attributable to BMS	
Earnings per common share:	
Basic	
Diluted	

(a) Excludes amortization of acquired intangible assets.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
Dollars in millions
(UNAUDITED)

COMPREHENSIVE INCOME	
Net earnings	$
Other comprehensive income, net of taxes and reclassifications to earnings:	
Derivatives qualifying as cash flow hedges	
Pension and postretirement benefits	
Marketable debt securities	
Foreign currency translation	
Total Other comprehensive (loss)/income	
Comprehensive income	
Comprehensive income attributable to noncontrolling interest	
Comprehensive income attributable to BMS	$

The accompanying notes are an integral part of these consolidated financial statemer

BRISTOL-MYERS SQUIBB COMPANY
CONSOLIDATED BALANCE SHEETS
Dollars in millions
(UNAUDITED)

ASSETS
Current assets:
- Cash and cash equivalents
- Marketable debt securities
- Receivables
- Inventories
- Other current assets
- Total Current assets

Property, plant and equipment
Goodwill
Other intangible assets
Deferred income taxes
Other non-current assets
Total Assets

LIABILITIES
Current liabilities:
- Short-term debt obligations
- Accounts payable
- Other current liabilities
- Total Current liabilities

Deferred income taxes
Long-term debt
Other non-current liabilities
Total Liabilities

Commitments and Contingencies

EQUITY
BMS Shareholders' equity:
- Preferred stock
- Common stock
- Capital in excess of par value of stock
- Accumulated other comprehensive loss
- Retained earnings
- Less cost of treasury stock
- Total BMS Shareholders' equity

Noncontrolling interest
Total Equity
Total Liabilities and Equity

The accompanying notes are an integral part of these consolidated financial statemer

BRISTOL-MYERS SQUIBB COMPANY
CONSOLIDATED STATEMENTS OF CASH FLOWS
Dollars in millions
(UNAUDITED)

Cash Flows From Operating Activities:	
Net earnings	$
Adjustments to reconcile net earnings to net cash provided by operating activities:	
Depreciation and amortization, net	
Deferred income taxes	
Stock-based compensation	
Impairment charges	
Divestiture gains and royalties	
Acquired IPRD	
Equity investment losses	
Other adjustments	
Changes in operating assets and liabilities:	
Receivables	
Inventories	
Accounts payable	
Rebates and discounts	
Income taxes payable	
Other	
Net cash provided by operating activities	
Cash Flows From Investing Activities:	
Sale and maturities of marketable debt securities	
Purchase of marketable debt securities	
Proceeds from sales of equity investment securities	
Capital expenditures	
Divestiture and other proceeds	
Acquisition and other payments, net of cash acquired	
Net cash (used in)/provided by investing activities	
Cash Flows From Financing Activities:	
Short-term debt obligations, net	
Issuance of long-term debt	
Repayment of long-term debt	
Repurchase of common stock	
Dividends	
Stock option proceeds and other, net	
Net cash used in financing activities	
Effect of exchange rates on cash, cash equivalents and restricted cash	
Decrease in cash, cash equivalents and restricted cash	
Cash, cash equivalents and restricted cash at beginning of period	
Cash, cash equivalents and restricted cash at end of period	$

The accompanying notes are an integral part of these consolidated financial statemer

Note 1. BASIS OF PRESENTATION AND RECENTLY ISSUED ACCOUNTING STANDARDS

Basis of Consolidation

Bristol-Myers Squibb Company ("BMS", "we", "our", "us" or "the Company") prepared these unaudited consolidated financial stater GAAP for interim reporting. Under those rules, certain footnotes and other financial information that are normally required for annual Company is responsible for the consolidated financial statements included in this Quarterly Report on Form 10-Q, which include all adju position of the Company as of March 31, 2023 and December 31, 2022, the results of operations and cash flows for the three mont balances and transactions have been eliminated. These consolidated financial statements and the related footnotes should be read i statements of the Company for the year ended December 31, 2022 included in the 2022 Form 10-K. Refer to the Summary of Abbreviate Q for terms used throughout the document.

Business Segment Information

BMS operates in a single segment engaged in the discovery, development, licensing, manufacturing, marketing, distribution and sale serious diseases. A global research and development organization and supply chain organization are responsible for the discovery, develo commercial organizations market, distribute and sell the products. The business is also supported by global corporate staff functions. Executive Officer ("CEO"), as the chief operating decision maker, manages and allocates resources at the global corporate level. Managi enables the CEO to assess both the overall level of resources available and how to best deploy these resources across functions, the research and development projects in line with our overarching long-term corporate-wide strategic goals, rather than on a product or fr consistent with the financial information regularly reviewed by the CEO for purposes of evaluating performance, allocating resources, s forecasting future periods. For further information on product and regional revenue, see "—Note 2. Revenue".

Use of Estimates and Judgments

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Accordingly, the results and trends in these unaudited of full year operating results. The preparation of financial statements requires the use of management estimates, judgments and assum used in determining accounting for acquisitions; impairments of intangible assets; charge-backs, cash discounts, sales rebates, returns a taxes. Actual results may differ from estimates.

Reclassifications

Certain reclassifications were made to conform the prior period consolidated financial statements to the current period presentation.

Recently Adopted Accounting Standards

Fair Value Measurements

In June 2022, the FASB issued amended guidance on measuring the fair value of an equity security subject to contractual restrictions tl clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security a The guidance also clarifies that an entity cannot, as a separate unit of account, recognize and measure a contractual sale restriction. The a securities subject to contractual sale restrictions: the fair value of equity securities subject to contractual sale restrictions reflected in the restriction(s); and the circumstances that could cause a lapse in the restriction(s). The amended guidance is effective January 1, 2024 c guidance was adopted on January 1, 2023 and the adoption did not have an impact on our consolidated financial statements.

Business Combinations

In October 2021, the FASB issued amended guidance on accounting for contract assets and contract liabilities from contracts with intended to address inconsistency related to recognition of an acquired contract liability and payment terms and their effect on subsequer should account for the related revenue contracts in accordance with existing revenue recognition guidance generally by assessing how th financial statements. The guidance was adopted on January 1, 2023 and the adoption did not have an impact on our consolidated financia

Note 2. REVENUE

The following table summarizes the disaggregation of revenue by nature:

Dollars in millions	
Net product sales	$
Alliance revenues	
Other revenues	
Total Revenues	$

The following table summarizes GTN adjustments:

Dollars in millions	
Gross product sales	$
GTN adjustments [a]	
Charge-backs and cash discounts	
Medicaid and Medicare rebates	
Other rebates, returns, discounts and adjustments	
Total GTN adjustments	
Net product sales	$

(a) Includes adjustments for provisions for product sales made in prior periods resulting from changes in estimates of $87 million and $74 million for the three months en

The following table summarizes the disaggregation of revenue by product and region:

Dollars in millions	
In-Line Products	
Eliquis	$
Opdivo	
Pomalyst/Imnovid	
Orencia	
Sprycel	
Yervoy	
Mature and other products	
Total In-Line Products	
New Product Portfolio	
Reblozyl	
Abecma	
Opdualag	
Zeposia	
Breyanzi	
Onureg	
Inrebic	
Camzyos	
Sotyktu	
Total New Product Portfolio	
Total In-Line Products and New Product Portfolio	
Recent LOE Products[a]	
Revlimid	
Abraxane	
Total Recent LOE Products	
Total revenues	$
United States	$
International	
Other[b]	
Total revenues	$

(a) Recent LOE Products include products with significant decline in revenue from the prior reporting period as a result of a loss of exclusivity.
(b) Other revenues include royalties and alliance-related revenues for products not sold by BMS's regional commercial organizations.

Revenue recognized from performance obligations satisfied in prior periods was $166 million and $147 million for the three months er primarily of royalties for out-licensing arrangements and revised estimates for GTN adjustments related to prior period sales.

Note 3. ALLIANCES

BMS enters into collaboration arrangements with third parties for the development and commercialization of certain products. Althoug parties are active participants in the operating activities of the collaboration and exposed to significant risks and rewards depending on these collaborations as alliances and its partners as alliance partners.

Selected financial information pertaining to alliances was as follows, including net product sales when BMS is the principal in the third- Expenses summarized below do not include all amounts attributed to the activities for the products in the alliance, but only the p amortization if the payments were deferred or capitalized.

Dollars in millions	
Revenues from alliances	
Net product sales	$
Alliance revenues	
Total alliance revenues	$
Payments to/(from) alliance partners	
Cost of products sold	$
Marketing, selling and administrative	
Research and development	
Other (income)/expense, net	

Dollars in millions	M
Selected alliance balance sheet information	
Receivables – from alliance partners	$
Accounts payable – to alliance partners	
Deferred income – from alliances[a]	

upfront and milestone payments.

The nature, purpose, significant rights and obligations of the parties and specific accounting policy elections for each of the Company's
K.

Note 4. DIVESTITURES, LICENSING AND OTHER ARRANGEMENTS

Divestitures

The following table summarizes the financial impact of divestitures including royalties, which are included in Other (income)/expense, n
divestitures were not material in all periods presented (excluding divestiture gains or losses).

	Three Months Ended March 31,				
	Net Proceeds		Divestiture (Gains)/Losses		
Dollars in millions	2023	2022	2023	2022	
Diabetes business [a]	$ 216	$ 172	$ —	$ —	$
Mature products and other	4	225	—	(211)	
Total	$ 220	$ 397	$ —	$ (211)	$

(a) Net proceeds for diabetes business relates to net proceeds from royalties received subsequent to the sale of the diabetes business.

Mature Products and Other

During the first quarter of 2022, product rights to several mature products were sold to Cheplapharm, resulting in cash proceeds of $221 1

Licensing and Other Arrangements

The following table summarizes the financial impact of *Keytruda** royalties, *Tecentriq** royalties, upfront licensing fees and milest approval, which are included in Other (income)/expense, net.

Dollars in millions	
*Keytruda** royalties	$
*Tecentriq** royalties	
Contingent milestone income	
Amortization of deferred income	
Other royalties and licensing income	
Total	$

Immatics

During the first quarter of 2022, BMS obtained a global exclusive license to Immatics' TCR bispecific IMA401 program. which is being BMS and Immatics collaborate on the development and BMS will be responsible for the commercialization of IMA401 worldwide, ir funding and manufacturing. Immatics has the option to co-fund U.S. development in exchange for enhanced U.S. royalty payments anc included an upfront payment of $150 million which was expensed to Acquired IPRD in the first quarter of 2022. Immatics is eligible tc based milestones of up to $770 million as well as royalties on global net sales.

Dragonfly

During the first quarter of 2022, a Phase I development milestone for interleukin-12 ("IL-12") was achieved resulting in a $175 millio The parties also amended the terms of three future milestones by requiring the achievement of certain criteria by specified dates u development of IL-12.

During the first quarter of 2023, BMS notified Dragonfly that it was terminating the global exclusive license that relates to Dragon Dragonfly effective April 18, 2023.

Other

Nimbus Change of Control Income

During the first quarter of 2022, BMS and Nimbus Therapeutics entered into a settlement resolving all legal claims and business inter $40 million of income included in Other (income)/expense. The settlement also provides for BMS to receive additional amounts for c based milestones and 10% of any change in control proceeds received by Nimbus Therapeutics related to its TYK2 inhibitor. In Febru Therapeutics' TYK2 inhibitor for approximately $4.0 billion in upfront proceeds plus contingent sales-based milestones aggregating u related to the change of control provision is included in Other (income)/expense during the first quarter of 2023 and is expected to be rec

Note 5. OTHER (INCOME)/EXPENSE, NET

Dollars in millions	
Interest expense (Note 10)	$
Royalty and licensing income (Note 4)	
Royalty income - divestiture (Note 4)	
Equity investment losses (Note 9)	
Integration expenses (Note 6)	
Loss on debt redemption (Note 10)	
Divestiture gains (Note 4)	
Litigation and other settlements [a]	
Investment income	
Provision for restructuring (Note 6)	
Other	
Other (income)/expense, net	$

(a) Includes $400 million of income recorded in connection with Nimbus' TYK2 program change of control provision for the three months ended March 31, 2023. Refe further information.

Note 6. RESTRUCTURING

Celgene Acquisition Plan

As part of the Celgene Acquisition Plan, the Company expects to incur charges of approximately $3.5 billion, including cash outlays approximately $3.1 billion have been recognized to date including integration planning and execution expenses, employee termination b contract termination costs and other shutdown costs associated with site exits. The remaining charges are primarily related to IT systen 2024.

Other Restructuring

Restructuring and integration plans were initiated to realize expected cost synergies resulting from cost savings and avoidance from the acquisition in 2020. Charges of approximately $250 million are expected to be incurred through the end of 2023 and consist of in termination benefit costs and other costs. Cumulative charges of approximately $180 million have been recognized for these actions to activities occurred resulting in employee termination costs of $61 million, which are primarily attributed to changes in our operating mod

The following provides the charges related to restructuring initiatives by type of cost:

Dollars in millions	
Celgene Acquisition Plan	$
Other Restructuring	
Total charges	$
Employee termination costs	$
Other termination costs	
Provision for restructuring	
Integration expenses	
Accelerated depreciation	
Total charges	$
Cost of products sold	$
Marketing, selling and administrative	
Other (income)/expense, net	
Total charges	$

The following summarizes the charges and spending related to restructuring plan activities:

Dollars in millions	
Beginning balance	
Provision for restructuring[a]	
Foreign currency translation and other	
Payments	
Ending balance	

(a) Includes a reduction of the liability resulting from changes in estimates of $3 million and $9 million for the three months ended March 31, 2023 and 2022, respectively

Note 7. INCOME TAXES

Dollars in millions	Th 20
Earnings before income taxes	$
Provision for income taxes	
Effective tax rate	

Income taxes in interim periods are determined based on the estimated annual effective tax rates and the tax impact of discrete items th effective tax rate is primarily due to jurisdictional earnings mix resulting from amortization of acquired intangible assets, equity invest releases of income tax reserves of $89 million related to the resolution of Celgene's 2009-2011 IRS audits, partially offset by the impact a previously creditable excise tax. Additional changes to the effective tax rate may occur in future periods due to various reasons, includi reserves and revised interpretations or changes to the relevant tax code. Income tax payments were $149 million and $255 million f respectively.

BMS is currently under examination by a number of tax authorities that proposed or are considering proposing material adjustments to tax credits and the deductibility of certain expenses. As previously disclosed, BMS received several notices of proposed adjustments fror for the 2008 to 2012 tax years. BMS disagrees with the IRS's positions and continues to work cooperatively with the IRS to resolve thes IRS administrative appeals process to resolve these matters. Timing of the final resolution of these complex matters is uncertain and financial statements.

It is reasonably possible that the amount of unrecognized tax benefits as of March 31, 2023 could decrease in the range of approximately a result of the settlement of certain tax audits and other events. The expected change in unrecognized tax benefits may result in the pay taxes and/or recognition of tax benefits.

It is reasonably possible that new issues will be raised by tax authorities that may increase unrecognized tax benefits, however, an estim time. BMS believes that it has adequately provided for all open tax years by jurisdiction.

Note 8. EARNINGS PER SHARE

Dollars in millions, except per share data	
Net earnings attributable to BMS	$
Weighted-average common shares outstanding – basic	
Incremental shares attributable to share-based compensation plans	
Weighted-average common shares outstanding – diluted	
Earnings per common share	
Basic	$
Diluted	

The total number of potential shares of common stock excluded from the diluted earnings per common share computation because o months ended March 31, 2023 and 2022, respectively.

Note 9. FINANCIAL INSTRUMENTS AND FAIR VALUE MEASUREMENTS

Financial assets and liabilities measured at fair value on a recurring basis are summarized below:

	March 31, 2023			
Dollars in millions	Level 1	Level 2	Level 3	Level 1
Cash and cash equivalents				
Money market and other securities	$ —	$ 7,737	$ —	$ —
Marketable debt securities				
Certificates of deposit	—	201	—	—
Commercial paper	—	73	—	—
Derivative assets	—	255	—	—
Equity investments	293	614	—	424
Derivative liabilities	—	207	—	—
Contingent consideration liability				
Contingent value rights	6	—	—	5
Other acquisition related contingent consideration	—	—	18	—

As further described in "Item 8. Financial Statements and Supplementary Data—Note 9. Financial Instruments and Fair Value Me Company's fair value estimates use inputs that are either (1) quoted prices for identical assets or liabilities in active markets (Level 1 inpu in active markets or for identical or similar assets or liabilities in markets that are not active (Level 2 inputs); or (3) unobservable input is adjusted for characteristics specific to the security and is not adjusted for contractual sale restrictions. Equity investments subject March 31, 2023 and December 31, 2022.

Marketable Debt Securities

The following table summarizes marketable debt securities:

	March 31, 2023				Decemb	
		Gross Unrealized				Gross
Dollars in millions	Amortized Cost	Gains	Losses	Fair Value	Amortized Cost	Gains
Certificates of deposit	$ 201	$ —	$ —	$ 201	$ 32	$ —
Commercial paper	73	—	—	73	98	—
Total marketable debt securities[(a)]	$ 274	$ —	$ —	$ 274	$ 130	$ —

(a) All marketable debt securities mature within one year as of March 31, 2023, and December 31, 2022.

Equity Investments

The following summarizes the carrying amount of equity investments:

Dollars in millions	M
Equity investments with readily determinable fair values	$
Equity investments without readily determinable fair values	
Limited partnerships and other equity method investments	
Total equity investments	$

The following summarizes the activity related to equity investments. Changes in fair value of equity investments are included in Other (i

Dollars in millions	
Equity investments with readily determinable fair values	
Net loss recognized	$
Net gain recognized on investments sold	
Net unrealized loss recognized on investments still held	
Equity investments without readily determinable fair values	
Upward adjustments	
Impairments and downward adjustments	
Equity in net loss of affiliates	
Total Equity investment losses	$

Cumulative upwards adjustments and cumulative impairments and downward adjustments based on observable price changes in equity i held as of March 31, 2023 were $186 million and $61 million, respectively.

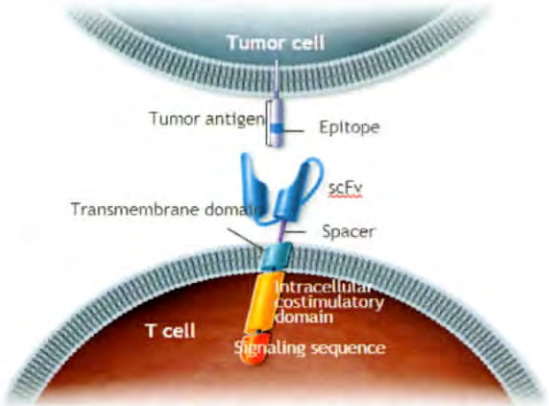
Qualifying Hedges and Non-Qualifying Derivatives

Cash Flow Hedges

BMS enters into foreign currency forward and purchased local currency put option contracts (foreign exchange contracts) to hedge cert other foreign currency transactions. The objective of these foreign exchange contracts is to reduce variability caused by changes in foreig of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese yen. The fair values of these positions) or liabilities (loss positions) in the consolidated balance sheet. Changes in fair value for these foreign exchange contracts, w recorded in Accumulated other comprehensive loss ("AOCL") and reclassified to net earnings when the hedged item affects earnings (2023, assuming market rates remain constant through contract maturities, we expect to reclassify pre-tax gains of $156 million into cost of AOCL during the next 12 months. The notional amount of outstanding foreign currency exchange contracts was primarily $4.9 billion contracts as of March 31, 2023.

Indication and Production Description

JCAR017 is a CD19-directed genetically modified autologous T cell immunotherapy intended for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.



- JCAR017 is administered as a defined composition of CAR-positive viable T cells (consisting of CD8 and CD4 components)
- JCAR017 is a cell suspension for infusion
- A single dose of JCAR017 contains 50 to 110 x 10^6 CAR-positive viable T cells, consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components, with each component supplied separately in one or more single-dose vials.
- The infusion volume is calculated based on the concentration cryopreserved drug product CAR-positive viable T cells. The volume may differ for each component infused.

NDC: 73153-900-01

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

MAURA T. HEALEY
Governor

KIMBERLEY DRISCOLL
Lieutenant Governor

KATHLEEN E. WALSH
Secretary

Robert Goldstein, Ph.D
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

NEW MANUFACTURER/DISTRIBUTOR

FILE OF: Bristol-Meyers Squibb
38 Jackson Road
Devens, MA 01434

INSPECTORS: Sandra McMahon, Senior Inspector and Kissie Morales, Licensing Inspector

DATE: July 26, 2023

SUBJECT: Request for Inspection

1. On July 26, 2023, Senior Inspector Sandra McMahon and Licensing Inspector Kissie Morales from the Drug Control Program went to the above facility to conduct an inspection for a Massachusetts Controlled Substances Registration (MCSR) Manufacturer/Distributor application requesting schedule VI. We introduced ourselves to Joe Clarke, Associate Director for Material Operations and Brittiny Lempicki, Quality Compliance Manager, explained the reason for the visit and obtained permission to inspect.

2. The facility is a large campus located in a gated area on Devens. Visitors are required to stop at a gatehouse to obtain a badge for entry upon showing identification. Once through the gate, there is a main building with the reception area where the escorts meet the visitors after being signed in. We were escorted to the Cell Therapy Facility Building #310 on campus. The facility operates 24 hours/day, 365 days/year. The company manufactures and distributes nationally only one schedule VI drug for infusion at this site. The finished product is specific to a particular patient and sent to infusion sites on request only.

3. The raw materials are received to the supply chain team in the warehouse that is located on the ground floor of the building. Upon receipt, each delivery is assigned a unique batch number and then put into general storage for QA inspection and release to the manufacturing area. Upon release, materials go to the "kitting area"

that is a smaller version of the warehouse so the product is easier to manage for the manufacturing. FDA has conducted the GMP inspection and sent a letter of approval. Once manufacturing is complete, product is stored in freezers/refrigerators in a designated area until packed for shipping. Shipments are placed in a cryoport in a specialized vehicle; all shipments must be in cryogenic units for maintaining product

4. The outer perimeter of the buildings have cameras as well as all corridors within the building. The facility has a security protocol that is strictly adhered to. Recordkeeping is maintained digitally and backup is stored in the cloud. There is a "Global Market Team" for all shipping orders. Any product that is unused, requiring waste or rejected are destroyed on site.

5. This registration will be valid for one year, must be renewed annually, and is non-transferable. For any change of name, location, or status, please notify the Drug Control Program in writing. The facility must also notify the Drug Control Program in the event of a loss or theft of a controlled substance at 617-973-0929.

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: McKesson Medical-Surgical Inc.

Physical Address: 3056 Tradeport Drive

City: Orlando State: FL Zip: 32824

Mailing Address (if different from physical address): Attn: Facility Manager/Licensing 3056 Tradeport Drive

City: Orlando State: FL Zip: 32824

Telephone: 904.534.4831 Website: www.mckesson.com

Name of Designated Representative (DR): Jeffrey LaVelle

Licensing Company Email: McKessonLicensing@McKesson. DR Email: Jeffrey.LaVelle@McKesson.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

see attached

Original Signature (electronic, copies or stamps not accepted)

5/16/23
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: This facility is not yet operational

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Virginia

Parent Company (if any): McKesson Medical Surgical Holdings Inc. (ultimate owner McKesson Corporation publicly traded

Corporation Name: McKesson Medical-Surgical Inc.

Mailing Address: McKesson Licensing Team c/o Deborah Bliss 6555 N State Highway 161 I

City: Irving State: TX Zip: 75039

Telephone: 904.332.4179 Email: Elaine.Stutman@McKesson.com

Contact Person Name: Elaine Stutman

Date of SEC Registration: 7.7.1994 | SEC Registration Number: 2417015 | Stock Exchange Symbol: MCK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

McKesson Medical-Surgical Inc.

Facility Name

Saralisa Brau

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/14/23

Date

Board Use Only	Date Received: 6/29/23	Amount:

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its wholly owned subsidiaries (hereinafter "McKesson") delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 100 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. ***The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions. This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines.***

In January 2017, **McKesson Corporation** entered into an agreement (the "DEA Settlement") with the DEA and DOJ to settle all potential administrative and civil claims stemming from investigation into McKesson's practices for identifying and reporting suspicious orders of controlled substances, beginning in 2009. Under the settlement McKesson agreed to pay $150 million and to implement remedial measures related to its controlled substances monitoring program. In addition, the following distribution centers' DEA registrations were or will be suspended for the following specified products and time periods: Aurora, Colorado - all controlled substances from January 17, 2017 to January 17, 2020; Livonia, Michigan - all controlled substances from January 17, 2017 to January 17, 2019; Washington Court House, Ohio - all controlled substances for the two-year period following completion of the Livonia suspension, from February 17, 2019 to February 17, 2021; and Lakeland, Florida - hydromorphone products from January 17, 2017 to January 17, 2018. The terms of the suspensions of the Livonia, Washington Court House, and Lakeland facilities permit those distribution centers to continue shipping controlled substances to customers that purchase products under McKesson's contract with the Department of Veterans Affairs.

In March 2017, in response to the DEA Settlement, the New York State Department of Health, Bureau of Narcotic Enforcement, suspended the Class 2A (Out-of-State) controlled substance license for **McKesson Corporation**'s Livonia, Michigan distribution center. The permit was suspended until January 1, 2019, consistent with the suspension timeframes of the DEA Settlement. No other suspensions or fines were issued, and the New York action aligned with the suspension periods and expectations agreed to in the DEA Settlement.

In June 2017, in response to the DEA Settlement, the Idaho Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson Corporation** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Idaho controlled

substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Idaho controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions or fines were issued, and the Idaho action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In November 2017, in response to the DEA Settlement, the Louisiana Board of Pharmacy suspended the Controlled Substance Registrations of **McKesson Corporation** distribution centers in Washington Court House, Ohio and the Livonia, Michigan. The Livonia Louisiana controlled substance registration was suspended for two years, effective 6/17/17 to 1/17/19. The Washington Court House Louisiana controlled substance registration is suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to reimburse the Louisiana Board $250.00 for administrative costs No other suspensions or fines were issued, and the Louisiana action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

In December 2017, in response to the DEA Settlement, the New Hampshire Board of Pharmacy suspended the right of **McKesson Corporation**'s distribution centers in Washington Court House, Ohio and Livonia, Michigan to distribute controlled substances. The Livonia distribution center's ability to distribute controlled substance was suspended, effective 12/12/17 to 1/17/19. The Washington Court House distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. McKesson also agreed to pay an administrative fine of $2,000.00. No other suspensions of fines were issued, and the New Hampshire action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On March 14, 2018, in response to the DEA Settlement, the Iowa Board of Pharmacy voted to issue Controlled Substance Act registrations for two of **McKesson Corporation**'s distribution centers. The Board issued the registrations pursuant to Controlled Substances Act Registration by Consent Agreements (the "Agreements"). The Agreements are applicable only to the registrations and do not impose discipline upon the distribution center's wholesale permits. The general terms of the Agreements are summarized below:

- Livonia, Michigan - the facility's Iowa controlled substance registration was issued but was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and

- Washington Court House, Ohio - the facility's Iowa controlled substance registration was issued but is restricted and the facility will be prohibited from distributing controlled substances into the state from 1/18/19 to 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On March 20, 2018, in response to the DEA Settlement, the Maryland State Board of Pharmacy suspended the right of **McKesson Corporation**'s distribution center in Washington Court House, Ohio to distribute controlled substances. The distribution center's ability to distribute controlled substance will be suspended for two years, effective 1/18/19 to 1/18/21. No other suspensions of fines were issued, and the Maryland action aligns with the suspension periods and expectations agreed to in the DEA Settlement.

On April 9, 2018, in response to the DEA Settlement, **McKesson Corporation** entered into stipulations with the Utah Board of Pharmacy. The stipulations apply to the McKesson distribution centers located in Washington Court House, Ohio and Aurora, Colorado. The Washington Court House facility's right to distribute controlled substances into Utah has been suspended effective 1/18/2019 to 1/18/2021 and the Aurora facility's right to distribute controlled substances into Utah has been suspended from 4/9/2018 to 1/17/2020. The Utah Board of Pharmacy's action mirrors the suspension and exceptions agreed to in McKesson's settlement with the DEA Settlement.

In 2018, May **McKesson Corporation** was fined by the California Board of Pharmacy related to the fact that its Memphis, TN distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now and has been since December 1, 2017, fully licensed. McKesson paid $1,000 fine. The fine is related to a non-disciplinary action.

On May 31, 2018, in response to the DEA Settlement, **McKesson Corporation** entered into a consent agreement with the Oregon Board of Pharmacy (the "Oregon Consent"). The Oregon Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The Washington Court House facility's right to distribute controlled substances into Oregon has been suspended effective 1/18/2019 to 1/18/2021. The suspension period imposed by Oregon aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On November 7, 2018, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Denver, Colorado distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of $1,150 was imposed and paid November 29, 2018. The Board released McKesson Medical-Surgical Inc. from the terms and conditions of the December 6, 2018, Stipulation and Final Agency Order and restored the Registration to unencumbered status.

On December 17, 2018, in response to the DEA Settlement, **McKesson Corporation** entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On January 14, 2019, **McKesson Corporation** entered into a settlement for a payment of $10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

On February 27, 2019, in response to the DEA Settlement, **McKesson Corporation** entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On March 1, 2019, the Ohio Board of Pharmacy sent a Notice of Opportunity for Hearing to the **McKesson Medical-Surgical Inc.** distribution center in Urbancrest, OH, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. The allegations relate to an investigation that McKesson Medical-Surgical Inc. shipped dangerous drugs to an unlicensed site in September 2017. A monetary penalty of $4,500 was imposed and paid on March 27, 2019.

On May 10, 2019, in response to the DEA Settlement, **McKesson Corporation** entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by New Mexico aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 21, 2019, in response to the DEA Settlement, **McKesson Corporation** entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio and Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars ($15,000).

On June 10, 2019, in response to the DEA Settlement, **McKesson Corporation** entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

On June 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reproval with **McKesson Corporation** (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to both the Washington Court House, Ohio and Livonia, MI distribution centers. Subject to the terms of the settlement, McKesson was issued a public letter of Reproval, agreed to pay $4,000 in investigative fees.

On August 29, 2019, **McKesson Corporation** received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("McKesson St. Louis").

On August 29, 2019, **McKesson Corporation** entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("**McKesson Chicagoland**"). The terms of the settlement included a fine in the amount of $1,150.00.

On January 7, 2020, **McKesson Corporation** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products that had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and butalbital products that continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019 (the "2020 Clear Lake Consent").

On January 14, 2020, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Arizona State Board of Pharmacy, regarding its Tempe, AZ distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,000 was imposed and paid on January 14, 2020.

On May 29, 2020, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Roseville, CA distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of $1,150 was imposed and paid on July 1, 2020.

On April 20, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,125 was imposed and paid on April 20, 2021.

On May 05, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Maine Board of Pharmacy, regarding its Roseville, CA distribution center, in relation to the late reporting of a disciplinary action that was imposed by the Colorado Board of Pharmacy, for failure to report a change of designated representative within the required timeframe. A $500 civil penalty/fine was paid on 5/7/2021.

On May 22, 2021, in response to the DEA Settlement, **McKesson Corporation** entered into a final agreement with the Illinois Department of Financial and Professional Regulation. The Illinois Consent Order applies to the McKesson distribution centers located in Aurora, Colorado, Livonia, Michigan and Washington Court House, Ohio.

- Aurora, Colorado - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2020 except for various exceptions that mirror exceptions in the DEA settlement;

- Livonia, Michigan - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and

- Washington Court House, Ohio - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On May 27, 2021, **McKesson Corporation** entered into a consent agreement with the Maine Board of Pharmacy regarding its Aurora, IL distribution center failing to report the Colorado disciplinary action to the Maine Board of Pharmacy within 10 days as required. The Colorado disciplinary action is now reported to the Maine Board of Pharmacy. The terms of the consent agreement included a fine in the amount of $500.00.

On June 6, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on June 8, 2021.

On June 15, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $3000.00 was imposed and paid on June 15, 2021.

On June 23, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $125 was imposed and paid on June 23, 2021.

On October 1, 2021, **McKesson Corporation** ("McKesson") entered into a non-disciplinary agreement with the Connecticut Department of Consumer Protection, regarding its Memphis, TN distribution center. The agreement resolves allegations that, from January 2015 – January 2021, McKesson sold controlled substances to a practitioner that did not have an active Connecticut Controlled Substances Certificate of Registration. McKesson made no admission of liability and there were no findings of any violation of law. A monetary penalty of $4,500 was imposed.

On October 14, 2021, in response to the DEA Settlement, **McKesson Corporation** entered into a Settlement Agreement with the Ohio Board of Pharmacy (the "WCH Ohio Settlement"). The WCH Ohio Settlement applies to the McKesson distribution center located in Washington Court House, Ohio. The Ohio Settlement also resolved allegations of suspicious order reporting violations related to sales occurring between 2011 and 2017. Under the terms of terms of the WCH Ohio Settlement, there were no findings of any violation of law and McKesson made no admissions to the same. McKesson was subject to a reprimand and a fine of twenty-thousand dollars ($20,000).

On December 20, 2021, **McKesson Corporation** entered into a Consent Order with the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation (the "IDFPR") based on reciprocal state action from the 2020 Clear Lake Consent. The Illinois Consent applied to McKesson's Clear Lake, IA distribution center. Under the terms of the Illinois Consent Order, the facility was subject to a public reprimand by the IDFPR.

On January 18, 2022, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center,

for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on January 18, 2022.

On January 20, 2022, **McKesson Medical-Surgical Inc.** was fined by the California Board of Pharmacy related to the fact that its Middletown, PA distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now fully licensed. McKesson Medical-Surgical Inc. paid $700 fine. The fine is related to a non-disciplinary action.

February 15, 2022, **McKesson Corporation** entered into a Settlement Agreement with the United States Department of Justice, the United States Attorney's Office for the Western District of Tennessee, and the Drug Enforcement Administration resolving allegations of recordkeeping and reporting deficiencies at one of its packaging facilities located in Memphis, Tennessee, known as McKesson **RxPak**. McKesson RxPak ceased all operations on March 4, 2020 and is no longer in business. There are no admissions of liability or wrongdoing under the terms of the Settlement Agreement.

On March 24, 2022, **McKesson Corporation** and the California Board of Pharmacy (the "Board") entered into a settlement agreement which resolved allegations against McKesson relating to the sale of controlled substances in 2017 and 2018 to an outpatient hospital pharmacy that the pharmacy discovered were being stolen by a pharmacy employee. Pursuant to the settlement agreement, the Board publicly reproved McKesson's Santa Fe Springs distribution center permit, and McKesson agreed to pay the board's costs related to the investigation and enforcement of the matter. As set forth in the settlement agreement, McKesson denies any allegation that it violated California laws regarding the distribution of controlled substances and there are no findings of any violation of state or federal laws.

On May 20, 2022, **McKesson Medical Surgical, Inc.**'s Urbancrest, Ohio facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On July 19, 2022, **McKesson Medical Surgical, Inc.**'s Urbancrest, Ohio facility entered into a settlement agreement with the Alabama Board of Pharmacy. The Alabama discipline was in response to discipline the facility received from the Ohio Board of Pharmacy in 2021 McKesson paid a $3,000 fine under the Alabama settlement.

On September 16, 2022, **McKesson Medical-Surgical Inc.'s** Leetsdale, PA facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On October 28, 2022, **McKesson Corporation**'s Aurora, IL facility received a non-disciplinary confidential letter of concern from the Colorado State Board of Pharmacy in relation

to the late reporting of the 2021 Maine Board of Pharmacy discipline. No formal action or penalty was imposed.

On December 20, 2022, **McKesson Medical-Surgical Inc.**'s Roseville, CA facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Compliant from November 2022. The Administrative Complaint is a result of alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On December 20, 2022, **McKesson Corporation**'s Aurora, IL facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Compliant from September 2022. The Administrative Complaint is a result of alleged failure comply with certain licensing requirements required to maintain a license in violation of Rule 680-X-2.23(g)(3). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On December 20, 2022, **McKesson Medical-Surgical Inc.**'s Manteno, IL facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Compliant from September 2022. The Administrative Complaint is a result of alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation of Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

McKesson Medical-Surgical Inc. located at 3056 Tradeport Drive, Orlando, FL 32824 is a wholesale distributor of prescription drugs, devices, over the counter medications and medical supplies and equipment to the primary care and extended care markets.

The facility is approximately 483,000 square feet. The entire facility is temperature controlled and utilizes the Vaisala Continuous Monitoring System to monitor temperature and humidity on a 24/7 basis. The security system, which is monitored by ADT, is a Honeywell Security system that is access controlled and has motion, sound, glass break and smoke detectors, as well as security cameras on the interior and exterior of the building.

McKesson Medical-Surgical
8741 Landmark Road
Richmond, VA 23228

www.mckesson.com


Ownership
McKesson Corporation
Federal ID 94-3207296
6535 N. State Highway 161
Irving, TX 75039
McKesson Medical-Surgical Top Holdings Inc.
Federal ID 59-2280364
6651 Gate Parkway
Jacksonville, FL 32216
McKesson Medical-Surgical Holdings Inc.
Federal ID 13-3734754
9954 Mayland Drive Suite 4000
Richmond, VA 23233
McKesson Medical-Surgical Inc.
Federal ID 94-2640465
9954 Mayland Drive, Suite 4000
Richmond, VA 23233
McKesson Medical-Surgical Inc.
Federal ID 94-2640465
3056 Tradeport Drive
Orlando, FL 32824

Title	Name	Address	Phone
President; Director	Stanton J. McComb	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	804-553-2311
VP & Treasurer; Director	Willard Station	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	804-264-7552
Corporate Secretary; Director	Saralisa Charlotte Brau	6535 North State Highway 161 Irving, TX, 75039	202-904-7031

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That McKesson Medical-Surgical Inc. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on February 27, 1980;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

January 20, 2023

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 2023012018259962

Ron DeSantis, Governor

Melanie S. Griffin, Secretary

Florida dbpr

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS

THE Prescription Drug Wholesale Distributor HEREIN HAS REGISTERED UNDER THE PROVISIONS OF CHAPTER 499, FLORIDA STATUTES

MCKESSON MEDICAL-SURGICAL INC.

3056 TRADEPORT DRIVE
ORLANDO FL 32824

LICENSE NUMBER: 2220308

EXPIRATION DATE: JUNE 30, 2025

Always verify licenses online at MyFloridaLicense.com

Do not alter this document in any form.

This is your license. It is unlawful for anyone other than the licensee to use this document.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/29/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH RISK & INSURANCE SERVICES
FOUR EMBARCADERO CENTER, SUITE 1100
CALIFORNIA LICENSE NO. 0437153
SAN FRANCISCO, CA 94111

CONTACT NAME:
PHONE (A/C, No, Ext):
FAX (A/C, No):
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Old Republic Insurance Company	24147
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
MCKESSON CORPORATION AND
ALL ITS SUBSIDIARIES
6555 STATE HIGHWAY 161
IRVING, TX 75039

COVERAGES **CERTIFICATE NUMBER:** SEA-003837349-09 **REVISION NUMBER:** 21

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY 317743	07/01/2023	07/01/2025	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
	X CONTRACTUAL LIABILITY						MED EXP (Any one person)	$ 10,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$ 1,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						GENERAL AGGREGATE	$ 2,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$ 2,000,000
								$
A	AUTOMOBILE LIABILITY			MWTB 317742	07/01/2023	07/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$ 2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS			SELF INSURED FOR			BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY			PHYSICAL DAMAGE			PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$
	DED [ ] RETENTION $							$
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC 313826-23	07/01/2023	07/01/2024	X PER STATUTE [ ] OTH-ER	
A	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N: N	N / A		MWXS-313828-23 (OH, WA)	07/01/2023	07/01/2024	E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			Subject to a self-insured retention per policy terms and conditions.			E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

McKesson Corporation
6555 State Hwy 161
Irving, TX 75039

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh Risk & Insurance Services

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/MDEG/Affiliate(s) Information

Name of MDEG McKesson Medical-Surgical Inc. MDEG License # (if applicable) _____

Physical Address 3056 Tradeport Drive

City Orlando State FL Zip 32824

Mailing Address (if different from physical address) 3056 Tradeport Drive Attn: Facility Manager/Licensing

City Orlando State FL Zip 32824

Telephone 407-563-1050 Website www.mckesson.com

Licensing Company Email Elaine.Stutman@McKesson.com or McKessonLicensing@McKesson.com

Section 2: Personal Information

First Jeffrey Middle Allen Last LaVelle

Alias(es, nicknames, name changes, etc.) Jeff

Date of Birth [redacted] SSN or ITIN _____ Sex ☒ M ☐ F ☐ X

Mailing Address 3056 Tradeport Drive

City Orlando State FL Zip 32824

Telephone [redacted] Email Jeffrey.LaVelle@McKesson.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Child Support Information (NRS 425.520, 425.540)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
See attached resume			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years, beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/21 - 5/2023	[redacted] Fox Run Road	Buckner	KY	40010
5/2023-Present	[redacted] Harbour Village Blvd #4205	Ponce Inlet	FL	32127
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has at least 1,500 hours of verifiable work experience relating to the products provided by the medical practice (e.g., medical products salesman). Beginning with the most current, list your hours of employment related to the above. (Use the space)

Business Name		From - To (MM/YY – MM/YY)	
McKesson Medical-Surgical Inc.		6/2010 - 5/2023	
Business Address	**City**	**State**	**Zip**
5150 Interchange Way Ste B	Louisville	KY	40229
Phone	**Title**	**Number of Employed Hours**	
	Director of Operations	13 years+	
Description of Duties			
Oversee daily operations, see attached			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		x
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		x

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/16/23
Date

I, Jeffrey LaVelle, certify that as the MDEG Administrator for McKesson Medical-Surgical Inc.,

that I (initial that you have read and meet the following requirements):

1. JL Have a high school diploma or its equivalent;
2. JL Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JL Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JL Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey LaVelle
Print Name (First, Last)

Jeffrey LaVelle
Original Signature (electronic, copies or stamps not accepted)

5/16/23
Date

Board Use Only	Date Received:

Jeffrey A. LaVelle

[redacted] Harbour Village Blvd, Unit 4205 • Ponce Inlet, FL 32127 • [redacted]

Cultural business leader recognized for analyzing potential or existing gaps in performance to plan and quality driven performance metrics. Proven leadership along with combined experience within a corporate and field operations setting. A skilled approach for identifying talent, executing a self-controlled approach, and optimizing the company's strategic initiatives. By embracing my team, inclusion and respecting the need of our customers my mindset centers on loyalty, building trust and crushing strategic initiatives.

INTEGRITY • DETERMINED • SOCIALIBILITY • SELF-CONFIDENT

SUMMARY OF QUALIFICATIONS

- A diverse people leader with more than 10 years' experience overseeing facility operations, process improvement, organizational development, and regulatory competencies.
- Proven business management acumen influencing strategic planning, resource allocation, innovative implementation, and operational efficiencies.
- Demonstrated workforce planning and group facilitation success up to seventy-five full time employees while directing distribution, transportation, and administrative managers.
- Ethical business leader able to build and maintain integrity-based relationships with customers, suppliers, employees, and executive leadership.
- Trustworthy decision-maker who recognizes the value of employee engagement.

CAREER ACHIEVEMENTS

LEADERSHIP

- Managed overall direction, coordination and fulfillment of daily operations including profit & loss, annual planning, employee engagement, facilities management, safety, security, and employee centered programs.
- Successfully led and integrated programs designed to improve and sustain order quality, performance metrics, inventory integrity and cost-to-serve reductions.
- Create and implemented corporate compliance programs related to prescription drug supply chain, DSCSA, medical distribution policy manuals and implementation of standard operating procedures.
- Consistent team focus on customer centered programs designed to increase order accuracy, system error reduction and 99% order accuracy.
- Effectively implemented JD Edwards ERP Warehouse Management System.
- Effectively implemented JDA Labor Management System by introducing engineered standards, iWin incentives while recognizing overtime reduction of 65% and 25% FTE reduction.

OPERATIONS MANAGEMENT

- Supply chain excellence while achieving all State, Federal and third-party regulatory entities.
- NABP - Verified Accredited Wholesale Distributor (VAWD) certified distribution center.
- Recognized Lean Event annual savings exceeding $150k by implementing route optimization initiatives covering a multistate B2C model.
- Recognized 17% improvement YoY, achieving 76% EOS and 85% MQS scores through cultural initiatives, effective action plan execution and employee driven programs.
- Reduced DPMO by 45% by leading regional programs for managers responsible for inventory integrity, system processes, quality through idea sharing, analytics and process improvement initiatives.

- Coordinated with marketing, procurement, global sourcing while influencing supplier strategy across multiple divisions for Physician Office business with responsibility for $132 million portfolio with targeted goals of $3.8 million in net buy-side contribution achieving 103% of plan for supplier financial performance.
- Played key strategy role in supplier performance incentive negotiations with focus on $1.4 million in cash discounts, $1.25 million in incentive growth programs, and $775k purchase price variance.

PROFESSIONAL EXPERIENCE

McKesson Medical Surgical, Orlando FL – Continuous Improvement Leader	May 2023 - Current
McKesson Medical Surgical, Louisville KY – Distribution Center Leader	May 2010 – April 2023
PSS World Medical, Jacksonville FL – Director, Regulatory Affairs	December 2008 – May 2010
PSS World Medical, Jacksonville FL – Director, Supplier Management	December 2006 – Dec. 2008
Physician Sales & Service, Orlando FL - Operations Leader	December 2000 – Dec. 2006

EDUCATION

UNIVERSITY OF LOUISVILLE

- Bachelor of Science, Organizational Leadership and Learning — March 2013 - May 2016

SELECTED PROFESSIONAL DEVELOPMENT & RECOGNITION

- Six Sigma Green Belt Certification, FY23
- Eagle Award Recipient – Executive appointed acknowledgment awarded annually to top performers for leadership and financial performance
- Operations Round Table – Executive nominated team designated for top performers to develop, challenge, and implement key operational initiatives (12 years)
- American Management Association Negotiating to Win
- Lean Office, Center for Career Development
- Emotional Intelligence for Leadership, Center for Career Development
- Certified State Representative (CDR) State of Florida – Prescription drug wholesale distributor designee
- Operations Excellence Inspection performance – 100% for FY21 & 97% FY23

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended March 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to_____
Commission File Number: 1-13252



McKESSON CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**94-3207296**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

6555 State Hwy 161,
Irving, TX 75039
(Address of principal executive offices. including zip code)
(972) 446-4800
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	*(Trading Symbol)*	*(Name of each exchange on which registered)*
Common stock, $0.01 par value	MCK	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, September 30, 2022, was approximately $48.2 billion.

Number of shares of common stock outstanding on April 28, 2023: 135,602,262

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its calendar year 2023 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

McKESSON CORPORATION

TABLE OF CONTENTS

Item		Page
	PART I	
1.	Business	3
1A.	Risk Factors	14
1B.	Unresolved Staff Comments	25
2.	Properties	25
3.	Legal Proceedings	25
4.	Mine Safety Disclosures	25
	Information about our Executive Officers	26
	PART II	
5.	Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	27
6.	Reserved	29
7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	30
7A.	Quantitative and Qualitative Disclosures About Market Risk	58
8.	Financial Statements and Supplementary Data	59
9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	134
9A.	Controls and Procedures	134
9B.	Other Information	134
9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	134
	PART III	
10.	Directors, Executive Officers, and Corporate Governance	134
11.	Executive Compensation	135
12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	135
13.	Certain Relationships and Related Transactions, and Director Independence	137
14.	Principal Accountant Fees and Services	137
	PART IV	
15.	Exhibits and Financial Statement Schedule	138
16.	Form 10-K Summary	143
	Signatures	144

McKESSON CORPORATION

PART I

Item 1. Business.

INDEX TO BUSINESS

Section	Page
General	3
Business Segments	4
U.S. Pharmaceutical	4
Prescription Technology Solutions	7
Medical-Surgical Solutions	7
International	7
Restructuring, Business Combinations, Investments, and Divestitures	8
Competition	8
Patents, Trademarks, Copyrights, and Licenses	9
Human Capital	9
Government Regulation	11
Other Information about the Business	13
Forward-Looking Statements	14

General

McKesson Corporation ("McKesson," the "Company," or "we," and other similar pronouns), which traces its business roots to 1833, is a diversified healthcare services leader dedicated to advancing health outcomes for patients everywhere. Our teams partner with biopharma companies, care providers, pharmacies, manufacturers, governments, and others to deliver insights, products, and services to help make quality care more accessible and affordable.

The Company's fiscal year begins on April 1 and ends on March 31. Unless otherwise noted, all references in this document to a particular year refers to the Company's fiscal year. The Company was incorporated on July 7, 1994 in the State of Delaware.

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), are available free of charge on the Company's website (www.mckesson.com under the "Investors — Financials — SEC Filings" caption) as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission ("SEC" or the "Commission"). The content on any website referred to in this Annual Report on Form 10-K ("Annual Report") is not incorporated by reference into this report, unless expressly noted otherwise. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The address of the website is www.sec.gov.

McKESSON CORPORATION

Business Segments

The Company operates its business in four reportable segments: U.S. Pharmaceutical, Prescription Technology Solutions ("RxTS"), Medical-Surgical Solutions, and International.

Our U.S. Pharmaceutical segment distributes branded, generic, specialty, biosimilar and over-the-counter ("OTC") pharmaceutical drugs, and other healthcare-related products in the United States ("U.S."). This segment provides practice management, technology, clinical support, and business solutions to community-based oncology and other specialty practices. In addition, the segment sells financial, operational, and clinical solutions to pharmacies (retail, hospital, alternate sites) and provides consulting, outsourcing, technological, and other services.

Our Prescription Technology Solutions segment helps solve medication access, affordability, and adherence challenges for patients by working across healthcare to connect patients, pharmacies, providers, pharmacy benefit managers, health plans, and biopharma companies. RxTS serves our biopharma and life sciences partners, delivering innovative solutions that help people get the medicine they need to live healthier lives. RxTS also offers prescription price transparency, benefit insight, dispensing support services, third-party logistics, and wholesale distribution support designed to benefit stakeholders.

Our Medical-Surgical Solutions segment provides medical-surgical supply distribution, logistics, and other services to healthcare providers, including physician offices, surgery centers, nursing homes, hospital reference labs, and home health care agencies. We offer more than 285,000 national brand medical-surgical products as well as McKesson's own line of high-quality products through a network of distribution centers in the U.S.

Our International segment provides distribution and services to wholesale, institutional, and retail customers in Europe and Canada where we own, partner, or franchise with retail pharmacies, and support better, safer patient care by delivering vital medicines, supplies, and information technology solutions.

U.S. Pharmaceutical Segment:

Our U.S. Pharmaceutical segment provides distribution and logistics services for branded, generic, specialty, biosimilar, and OTC pharmaceutical drugs along with other healthcare-related products to customers. This business provides solutions and services to pharmacies, hospitals, oncology and other specialty practices, pharmaceutical manufacturers, biopharma partners, physicians, payers, and patients throughout the U.S. We also source generic pharmaceutical drugs through our ClarusONE Sourcing Services LLP joint venture with Walmart Inc. ("ClarusONE").

Our U.S. Pharmaceutical segment operates and serves customers through a network of 29 distribution centers in the U.S., including two strategic redistribution centers. We invest in technology and other systems at all of our distribution centers to enhance safety, reliability, and product availability. For example, we offer McKesson Connect℠, an internet-based ordering system that provides item look-up and real-time inventory availability as well as ordering, purchasing, third-party reconciliation, and account management functionality. We make extensive use of technology as an enabler to ensure customers have the right products at the right time in the right place.

To maximize distribution efficiency and effectiveness, we follow the Six Sigma methodology, which is an analytical approach that emphasizes setting high-quality objectives, collecting data, and analyzing results to a fine degree in order to improve processes, reduce costs, and enhance service accuracy and safety. We provide solutions to our customers including supply management technology, world-class marketing programs, managed care, repackaging products, and services to help them meet their business and quality goals. We continue to implement information systems to help achieve greater consistency and accuracy both internally and for our customers.

We have four primary customer pharmaceutical distribution channels: (i) retail national accounts, which include national and regional retail chains, food and drug combinations, mail order pharmacies, and mass merchandisers, (ii) community pharmacies and health (formerly described as independent, small, and medium chain retail pharmacies), (iii) institutional healthcare providers such as hospitals, health systems, integrated delivery networks, and long-term care providers, and (iv) oncology, biopharma, and other specialty partners.

Retail National Accounts: We provide business solutions that help our retail national account customers increase revenues and profitability. Solutions include:

- Central Fill℠ – Prescription refill service that enables pharmacies to more quickly refill prescriptions remotely, more accurately, and at a lower cost, while reducing inventory levels and improving customer service.
- Strategic Redistribution Centers – Two facilities totaling over 740,000 square feet that offer access to inventory for single source warehouse purchasing, including pharmaceuticals and biologics. These distribution centers also provide the foundation for a two-tiered distribution network that supports best-in-class direct store delivery.
- McKesson SynerGx® – Generic pharmaceutical purchasing program and inventory management that helps pharmacies maximize their cost savings with a broad selection of generic drugs, competitive pricing, and one-stop shopping
- Inventory Management – An integrated solution comprised of forecasting software and automated replenishment technologies that reduce inventory-carrying costs.
- ExpressRx Track™ – Pharmacy automation solution featuring state-of-the-art robotics, upgraded imaging, and expanded vial capabilities, and industry-leading speed and accuracy in a small footprint.

Community Pharmacy and Health: We strengthen the overall health of community pharmacies and elevate the role they play in people's lives. We accomplish this by providing supply chain excellence, pharmacy and patient solutions, as well as supporting independent pharmacies through industry and legislative advocacy. Our pharmacy and patient solutions include:

- Health Mart® – A national network of approximately 4,700 independently-owned pharmacies and one of the industry's most comprehensive pharmacy franchise programs. Health Mart provides franchisees support for operational excellence, managed care contracting, marketing, a private label line of products, merchandising solutions, and clinical programs to enhance patient care.
- Health Mart Atlas® – Comprehensive managed care and reconciliation assistance services that help community pharmacies save time, access competitive reimbursement rates, and improve cash flow.
- McKesson Reimbursement Advantage℠ ("MRA") – MRA is one of the industry's most comprehensive reimbursement optimization packages, comprising financial services (automated claim resubmission), analytic services, and customer care.
- McKesson OneStop Generics® – Generic pharmaceutical purchasing program that helps pharmacies maximize their cost savings with a broad selection of generic drugs, competitive pricing, and one-stop shopping.
- Pinpoint Community Solutions – McKesson's perpetual inventory management system targeted to independent pharmacy owners with five or fewer stores. The solution provides customers the opportunity to improve cash flow and increase efficiency with inventory visibility to help maximize operational performance.
- FrontEdge™ – Strategic planning, merchandising, and price maintenance program that helps community pharmacies maximize store profitability.
- McKesson RxOwnership Program – A confidential, no-fee resource for pharmacists and pharmacy owners interested in buying, starting, or selling an independent pharmacy, regardless of their pharmacy affiliation.

Institutional Healthcare Providers: At McKesson, we are relentless in our pursuit of opportunities to achieve operational efficiency, reduce waste, and improve the financial performance of our customers so they can achieve more of their goals today and into the future. Solutions include:

- RxO Advisory Services – A suite of supply chain management, pharmacy optimization, and 340B program advisory services driven by data and analytics.
- McKesson Plasma and Biologics – Specialty and plasma drug distributor that leads in market exclusive drug access; partner to health systems customers in navigating the complexities of limited distribution drug; and optimization of McKesson Distribution benefits.

- Outpatient and Specialty Pharmacy – A portfolio of services and solutions customized to each customer's business and clinical strategy.
- Contracting and Contract/Purchasing Optimization – Solutions across generics, specialty, branded products, biosimilars, and 340B products, for inpatient and outpatient settings.
- Supply Assurance – Solutions and strategies to enhance product availability and proactively manage inventory of critical items.
- Patient Assistance Solutions – Technologies and services that enable health systems and providers to better financially support their patients and community benefit programs.

The U.S. Pharmaceutical segment also offers solutions which enable its customers to drive greater efficiencies in their day to day operations, effectively managing their inventories and complying with complex government regulations. Solutions include McKesson Pharmacy Systems, MacroHelix, and Supply Logix, all of which provide innovative software technology and services that support retail pharmacies and hospitals.

Oncology, Biopharma, and Other Specialty Partners:

The U.S. Pharmaceutical segment provides a range of solutions to oncology and other specialty practices and offers community specialists (oncologists, rheumatologists, ophthalmologists, urologists, neurologists, and other specialists) an extensive set of customizable solutions and services designed to strengthen core practice operations, enhance value-based care delivery, and expand their service offering to patients. Community-based physicians in this business have broad flexibility and discretion to select the products and commitment levels that best meet their practice needs. Services in provider solutions include specialty drug distribution, group purchasing organizations ("GPO") like Onmark®, technology solutions, practice consulting services, and vaccine distribution, including our exclusive distributor relationship with the Centers for Disease Control and Prevention's ("CDC") Vaccines for Children program. Additionally, to support the U.S. efforts to fight the pandemic caused by the SARS-CoV-2 coronavirus ("COVID-19"), this segment has been distributing certain COVID-19 vaccines since December 2020 at the direction of the U.S. government.

This business provides a variety of solutions, including practice operations, healthcare information technology, revenue cycle management and managed care contracting solutions, evidence-based guidelines, and quality measurements to support The U.S. Oncology Network ("USON"), one of the nation's largest networks of physician-led, integrated, community-based oncology practices dedicated to advancing high-quality, evidence-based cancer care. In October 2022, McKesson completed a transaction with HCA Healthcare, Inc. ("HCA") to form an oncology research business, combining McKesson's U.S. Oncology Research ("USOR") and HCA's Sarah Cannon Research Institute ("SCRI"), which is one of the world's leading oncology research organizations, to enhance clinical trial access and availability across the country.

This segment includes Ontada®, McKesson's oncology technology and insights business providing software to support the clinical, financial, and operational needs of our oncology practice customers. Ontada also partners with oncology providers and biopharma partners to perform real-world evidence studies, retrospective research, and to provide clinical data insights, advisory solutions and education opportunities.

When we discuss specialty products or services, we consider the following factors: diseases requiring complex treatment regimens such as cancer and rheumatoid arthritis; plasma and biologics products; ongoing clinical monitoring requirements, high-cost, special handling, storage, and delivery requirements and, in some cases, exclusive distribution arrangements. Our use of the term "specialty" may not be comparable to that used by other industry participants, including our competitors.

Prescription Technology Solutions Segment:

Our Prescription Technology Solutions segment works across healthcare to connect patients, pharmacies, providers, pharmacy benefit managers, health plans, and biopharma companies to deliver medication access, affordability, and adherence solutions that support patients from first prescription fill to ongoing therapy, regardless of their insurance coverage. RxTS has connections with most electronic health record systems, over 50,000 pharmacies, approximately 900,000 providers, most pharmacy benefit managers and health plans, and has supported over 650 biopharma brands representing most therapeutic areas. Through its industry connections and ability to navigate the healthcare ecosystems, RxTS offers innovative solutions created to benefit healthcare stakeholders. Its comprehensive solution suites span across the entire patient journey, including medication access and affordability, prescription decision support, prescription price transparency, benefit insight and dispensing support services, as well as third-party logistics and wholesale distribution support, to help increase speed to therapy, reduce prescription abandonment, and support improved health outcomes for the patient. In the past year, RxTS helped patients save more than $8 billion on brand and specialty medications, helped to prevent an estimated 9.9 million prescriptions from being abandoned due to affordability challenges, and helped patients access their medicine more than 78 million times.

Medical-Surgical Solutions Segment:

Our Medical-Surgical Solutions segment delivers medical-supply distribution, logistics, biomedical maintenance, and other services to healthcare providers across the alternate-site spectrum. Our more than 275,000 customers include physician offices, surgery centers, post-acute care facilities, hospital reference labs, and home health agencies. We partner with manufacturers and channel partners to support our key target end-markets, including primary care, extended care, government, and other markets. We distribute medical-surgical supplies (such as gloves, needles, syringes, and wound care products), infusion pumps, laboratory equipment, and pharmaceuticals. Through a network of distribution centers in the U.S., we offer more than 285,000 products from national brand manufacturers and McKesson's own brand of high-quality products. Through the right mix of products and services, we help improve efficiencies, profitability, and compliance. We also never lose focus on helping customers improve patient and business outcomes. We develop customized plans to address the product, operational, and clinical support needs of our customers, including inventory management, reducing administrative burdens, and training and educating clinical staff. We deliver for our customers, so they can deliver and care for their patients. Additionally, under contracts with the U.S. Department of Health and Human Services ("HHS") and Pfizer, Inc., McKesson's Medical-Surgical business leverages its expertise to manage the assembly, storage, and distribution of supply kits needed to administer COVID-19 vaccines, as well as some of the sourcing of those supplies. The kits are produced and distributed at the direction of HHS to support the administration of all COVID-19 vaccines approved in the U.S.

International Segment:

Our International segment provides distribution and services to wholesale, institutional, and retail customers in Europe and Canada where we own, partner, or franchise with retail pharmacies. Our operations in Canada also support better, safer patient care by delivering vital medicines, supplies, and information technology solutions to customers, and through several retail health and wellness brands, across Canada.

In July 2021, we announced our intention to exit our businesses in Europe. On January 31, 2022, we completed the sale of our Austrian business to Quadrifolia Management GmbH. On April 6, 2022, we completed the sale of our retail and distribution businesses in the United Kingdom ("U.K. disposal group") to Aurelius Elephant Limited. On October 31, 2022, we completed the sale of certain of our businesses in the European Union ("E.U.") located in France, Italy, Ireland, Portugal, Belgium, and Slovenia, our German headquarters and wound-care business, part of a shared services center in Lithuania, and our ownership stake in a joint venture in the Netherlands ("E.U. disposal group") to the PHOENIX Group. In executing our strategy to exit Europe, we continue to evaluate suitable exit alternatives for our remaining retail and distribution businesses in Norway. Refer to Financial Note 2, "Business Acquisitions and Divestitures," to the consolidated financial statements included in this Annual Report for additional information on our European divestiture activities.

Prior to the European divestiture activities described above, we operated through two businesses in Europe: Pharmaceutical Distribution and Retail Pharmacy. Our European Pharmaceutical Distribution business delivered pharmaceutical and other healthcare-related products to pharmacies across Europe. This business functioned as a vital link, using technology-enabled management systems at our regional wholesale branches to connect manufacturers to retail pharmacies, supplying medicines and other products sold in pharmacies.

Our European Retail Pharmacy business served patients and consumers in European countries directly through our own pharmacies and participant pharmacies operating under brand partnership arrangements. This business provided customers with traditional prescription pharmaceuticals, non-prescription products, and medical services, as well as e-commerce operating under the Lloyds pharmacy branding in Belgium, Ireland, and Italy up until the sale of the E.U. disposal group. In addition, we partnered with independent pharmacies under local banner programs.

McKesson Canada is one of the largest pharmaceutical wholesale and retail distributors in Canada. The wholesale business delivers products to retail pharmacies, hospitals, long-term care centers, clinics and institutions in Canada through a national network of distribution centers and provides logistics and distribution services for manufacturers.

Beyond wholesale pharmaceutical logistics and distribution, McKesson Canada provides automation and technology solutions to its retail and hospital customers. Additionally, McKesson Canada provides comprehensive specialty health services to Canadians, including a national network of specialty pharmacies, personalized patient care and support programs, and INVIVA, Canada's first and largest accredited network of private infusion clinics. McKesson Canada also owns and operates PDCI, Canada's leading market access consultancy, supporting manufacturers as they introduce new products into the Canadian market.

The Canada retail business includes approximately 2,700 banner pharmacies under the IDA®, Guardian®, The Medicine Shoppe®, Remedy'sRx®, Proxim®, and Uniprix® banners, and approximately 400 owned pharmacies under the Rexall™ brand where we provide patients with greater choice and access, integrated pharmacy care and industry-leading service levels. McKesson Canada also owns and operates Well.ca™, a leading Canadian online health and wellness retailer.

Restructuring, Business Combinations, Investments, and Divestitures

We have undertaken additional strategic initiatives in recent years designed to increase operational efficiencies, focus on our core healthcare businesses, execute on our business strategy, and enhance our competitive position. These initiatives are detailed in Financial Note 2, "Business Acquisitions and Divestitures," and Financial Note 3, "Restructuring, Impairment, and Related Charges, Net," to the consolidated financial statements included in this Annual Report.

Competition

We operate in highly competitive environments in North America and Europe. In recent years, the healthcare industry has been subject to increasing consolidation. In the pharmaceutical distribution environment in which our U.S. Pharmaceutical and International segments operate, we face strong competition from international, national, regional, and local full-line, short-line, and specialty distributors, service merchandisers, self-warehousing chain drug stores, manufacturers engaged in direct distribution, third-party logistics companies, and large payer organizations. We consider our largest competitors in distribution, wholesaling, and logistics to be AmerisourceBergen Corporation and Cardinal Health, Inc. Our retail businesses, which primarily operate in our International segment, face competition from various global, national, regional, and local retailers, including chain and independent pharmacies.

Our RxTS business experiences substantial competition from many companies, including other biopharma services companies, software services firms, consulting firms, shared service vendors, and internet-based companies with technology applicable to the healthcare industry. Competition in this business varies in size from large to small companies, in geographical coverage, and in scope and breadth of products and services offered.

Our Medical-Surgical Solutions segment provides medical-surgical supply distribution, logistics, and other services to healthcare providers, including physician offices, surgery centers, nursing homes, hospital reference labs, home health care agencies, and other alternative sites with competition from a wide range of national and regional medical supply and equipment distributors throughout the U.S.

In addition, we compete with other service providers and healthcare manufacturers, as well as other potential customers of our businesses, which may from time to time decide to develop, for their own internal needs, supply management capabilities that might otherwise be provided by our businesses. We believe that our scale and diversity of product and service offerings are our primary competitive advantages. In all areas, key competitive factors include price, quality of service, breadth of product lines, innovation and, in some cases, convenience to the customer.

Patents, Trademarks, Copyrights, and Licenses

McKesson and its subsidiaries hold patents, copyrights, trademarks, and trade secrets related to McKesson products and services. We pursue patent protection for our innovations and obtain copyright protection for our original works of authorship, when such protection is advantageous. Through these efforts, we have developed a portfolio of patents and copyrights in the U.S. and worldwide. In addition, we have registered or applied to register certain trademarks and service marks in the U.S. and in foreign countries.

We believe that, in the aggregate, McKesson's confidential information, patents, copyrights, trademarks, and intellectual property licenses are important to its operations and market position, but we do not consider any of our businesses to be dependent upon any one patent, copyright, trademark, or trade secret, or any family or families of the same. We cannot guarantee that our intellectual property portfolio will be sufficient to deter misappropriation, theft, or misuse of our technology, nor that we can successfully enjoin infringers. We periodically receive notices alleging that our products or services infringe on third-party patents and other intellectual property rights. These claims may result in McKesson entering settlement agreements, paying damages, discontinuing use or sale of accused products, or ceasing other activities. While the outcome of any litigation or dispute is inherently uncertain, we do not believe that the resolution of any of these infringement notices would have a material adverse impact on our results of operations.

We hold inbound licenses for certain intellectual property that is used internally, and in some cases, utilized in McKesson's products or services. While in the future it may be necessary to seek or renew licenses relating to various aspects of our products and services, we believe, based upon past experience and industry practice, such licenses generally can be obtained on commercially reasonable terms. We believe our operations as well as our products and services are not materially dependent on any single license or other agreement with any third party.

Human Capital

Our vision for a healthier world begins with our employees, who bring our mission to life every day. We deliver programs that focus on improving employee health and wellness, creating opportunities for growth and development, and providing an inclusive workplace where our employees can reach their full potential. At March 31, 2023, we had approximately 51,000 employees worldwide, including 6,000 part-time employees. We had approximately 35,000 employees in the U.S., 13,000 employees in Canada, and 3,000 employees in Europe. Our employees in Europe primarily relate to our remaining operations in Norway. Our headcount at March 31, 2023 decreased compared to the same prior year period due to the completed divestitures of the E.U. disposal group and U.K. disposal group during fiscal 2023. Approximately 26,000 former employees were associated with these divestitures. Refer to Financial Note 2, "Business Acquisitions and Divestitures," to the consolidated financial statements included in this Annual Report for additional information on our European divestiture activities. We also supplement our work force with contractors and/or consultants for certain business projects, processes, and/or operations as demand requires, including for programs such as the COVID-19 vaccine distribution and related ancillary supply kit programs.

Diversity, Equity, and Inclusion ("DEI"): We are committed to making the principles of DEI integral to everything we do because we believe building a healthier future is everyone's business. We build successful teams by recruiting, developing, and retaining diverse talent and we recognize our culture of inclusion and belonging as an important element that drives long-term shareholder value. We offer various ongoing learning opportunities, such as our company-wide inclusion curriculum, to recognize, value, and leverage the diversity of our workforce, enhance the inclusiveness of our culture, and candidly discuss DEI topics. We also offer our employees the opportunity to join employee resource groups ("ERGs"), which are voluntary, employee-led, company-sponsored groups that focus on making a difference among our employees in North America. ERGs can help employees make authentic connections, showcase leadership skills, and create a positive impact. Our ERGs make our community even stronger by connecting people of all backgrounds and experiences and enabling them to feel that they are a part of something greater. Our 11 ERGs provide community and insights into the perspectives and experiences across different ethnicities, genders, generations, disability or military/veteran status, as well as members and allies of the LGBTQIA+ community. We hold regular town hall meetings where employees can ask questions of executives and make their voices heard.

At March 31, 2023, women and people of color represented the following:

Metric [1]	McKesson Overall	McKesson Leadership [2]
Women	62 %	42 %
People of Color [3] [4]	47 %	26 %

(1) The data for our metrics is derived from our voluntary self-identification process as of March 31, 2023 and therefore represents our best estimate at this time.

(2) Represents our leadership at the vice president level and above.

(3) Represents U.S. employees only because the data for Canada and Europe is not available.

(4) People of Color includes the following self-identification categories: American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander, or Two or More Races.

Culture and Leadership: What sets McKesson apart as an exceptional place is our people. Our employees understand that together, unified by our global I²CARE and ILEAD principles, we fulfill our mission of improving care in every setting. Our I²CARE values (Integrity, Inclusion, Customer-First, Accountability, Respect, Excellence) are foundational to all that we do, and who we are as a company. ILEAD (Inspire, Leverage, Execute, Advance, Develop) is our common definition of and shared commitment to leadership. By embracing this commitment, we bring out the best in ourselves and position McKesson to continue to drive better health – for our company, our customers, and the patients they serve – for years to come. We promote leadership behaviors through culture initiatives that offer practical tips on how to debate, decide, and commit, be open and candid, and maintain an enterprise-first mindset when navigating conversations affecting operations within and across our business segments. These values and behaviors help make McKesson unique.

Investment in Employees: To support employee growth and development, we provide regular feedback and training, and work to create and maintain an inclusive environment where everyone can bring their authentic self to work and know they are appreciated, with their perspectives heard and considered. Through training, we encourage leaders to embrace diverse perspectives and lead inclusively. Employee development programs include training, coaching, and 360-degree assessments, which can support the careers of future leaders and their teams. We offer financial assistance programs for higher education opportunities that support employees' career growth at the company.

To provide compensation that is focused on attracting and retaining talent with the skills and experience necessary for a specific role, our compensation program is built on a set of quantifiable factors defined by our guiding principles of internal equity, market competitiveness, and pay for performance. We operate in several countries and our benefits vary accordingly. Our compensation philosophy is rooted in a commitment to our people by offering a fair and transparent program that regularly assesses the competitive job market based on geography and cost of labor. We use external resources to provide competitive benchmarking analyses against other companies and set pay ranges around the median of the competitive market. As part of our commitment to pay transparency, during fiscal 2023, we enhanced the insight and visibility of our employee compensation. The majority of our employees in North America can view the competitive base pay range for their roles as well as for new internal and external job postings. Also, the pay range for new external job postings is included on McKesson's website (www.mckesson.com under the "Careers" caption).

We offer health and wellness benefits to advance the physical, mental, and social well-being of our people, savings programs to help prepare them for retirement, and flexible work arrangements, among other offerings, when possible. We seek employee feedback through annual and mid-year employee opinion surveys, which assesses our employees' levels of engagement, commitment, and overall satisfaction using industry benchmarks, and then design action plans to improve those metrics. We seek feedback on our people leaders through our annual manager quality survey, which is an opportunity for employees to help their managers grow professionally and build valuable leadership skills that create a positive, productive, and inclusive workplace at McKesson.

As broader U.S. labor markets continue to be challenging and evolving, we continue our dedication to recruiting and retaining qualified employees across the organization. In fiscal 2022, we made investments in our talent acquisition team by adding recruiters, systems, and process improvements to strengthen our ability to attract employees and reduce the lead time to fill open positions as well as updating and enhancing the benefits, rewards, and experiences we offer to our employees, making McKesson a great place to work. This is known as our "Employee Value Proposition" ("EVP"). Our EVP reflects what makes McKesson unique and which is demonstrated through the care we show to our employees and communities, the meaning we find in our work, and the sense of belonging we build across the organization. We continued to make investments in fiscal 2023 to retain our top talent, including providing long-term incentive awards for certain job markets and job classes.

During the first quarter of fiscal 2022, we approved changes to our real estate strategy to increase efficiencies and support flexibility for our employees, as discussed in Financial Note 3, "Restructuring, Impairment, and Related Charges, Net," to the consolidated financial statements included in this Annual Report. Our North American future of work approach is based on the following for certain employees: purposeful collaboration, flexibility, co-location, and leader-driven connections. We embraced a hybrid work model and certain of our employees have been coming together in person to collaborate with a purpose. While we remain committed to working flexibly, collaboration will continue to be a cornerstone of our philosophy. We believe that collaboration is critically important to staying connected and maintaining our culture.

Health and Safety: Our security and safety departments employ systems designed to continually monitor our facilities and work environment to help identify and prevent or mitigate potential risks. This includes having procedures in place and investing in equipment for both physical and electronic security. We routinely assess facilities to closely monitor adherence to established security and safety standards. If we identify a vulnerability, it is documented, and the facility prepares an action plan. Our employees receive specialized training related to their role, work setting, and equipment used in their work environment. As our processes evolve, we update relevant safety training modules, which may include new employee training programs.

In response to the COVID-19 pandemic, our priority has been, and continues to be, protecting the health and safety of our employees, customers, patients, and communities while also safeguarding the healthcare supply chain. We offer medical benefits covering COVID-19 related visits, testing (including over-the-counter tests), treatment and vaccines, telehealth options, and paid time off ("PTO"). We also have COVID-19 protocols in place, which have been designed, and updated as necessary, to be consistent with federal, state, and local laws and with customer requirements for our U.S. and Canada employees.

Government Regulation

We operate in many highly regulated industries and are subject to oversight by various federal, state, and local governmental entities in the U.S. and elsewhere. We incur significant expense and make large capital expenditures and investments to enable us to comply with regulations and guidance promulgated by governmental entities. See "Risk Factors" in Item 1A of Part I below for information regarding material risks associated with our compliance with governmental regulations.

Controlled Substances: We are subject to the operating and security standards of the U.S. Drug Enforcement Administration ("DEA"), the U.S. Food and Drug Administration ("FDA"), HHS, the Centers for Medicare & Medicaid Services ("CMS"), various state boards of pharmacy, state health departments, and comparable agencies in the U.S. and other countries. Certain of our businesses may be required to register for permits and/or licenses with government agencies, depending upon the type of operations and location of product development, manufacture, distribution, and sale. For example, we are required to hold valid DEA and state-level registrations and licenses, meet various security and operating standards, and comply with the Controlled Substances Act and its accompanying regulations governing the sale, marketing, packaging, holding, distribution, and disposal of controlled substances. We maintain extensive controlled substance monitoring and reporting programs at considerable expense in order to help us meet those standards.

Government Contracts: Our contracts with government entities typically are subject to procurement laws that include socio-economic, employment practices, environmental protection, recordkeeping and accounting, and other requirements. These statutory and regulatory requirements complicate our business and increase our compliance burden. We are subject to audits, investigations, and oversight proceedings about our compliance with contractual and legal requirements.

Federal, state, and local governmental entities in the U.S. and elsewhere continue to strengthen their position and scrutiny of practices that may indicate fraud, waste, and abuse affecting government healthcare programs such as Medicare and Medicaid. Our relationships with pharmaceutical and medical surgical product manufacturers, healthcare providers, and other companies and individuals, as well as our provision of products and services to government entities, subject our business to statutes, regulations, and government guidance that are intended to prevent fraud and abuse. Among other things, those laws: (1) prohibit persons from soliciting, offering, receiving, or paying any remuneration in order to induce the referral of an individual for, or to induce the ordering or purchasing of, items or services that are in any way paid for by Medicare, Medicaid, or other government-sponsored healthcare programs; (2) impose many restrictions upon referring physicians and providers of designated health services under Medicare and Medicaid programs; and (3) prohibit the knowing submission of a false or fraudulent claim for payment to, and knowing retention of an overpayment by, a federal healthcare program such as Medicare and Medicaid. Many of these laws are vague or indefinite and are often subject to varied and evolving interpretations by courts, regulators, and enforcing agencies and, as such, may be interpreted or applied by a prosecutorial, regulatory, or judicial authority in a manner that could require us to make changes in our operations at added expense.

Healthcare Regulation: In the U.S., the Patient Protection and Affordable Care Act ("ACA") significantly expanded health insurance coverage to uninsured Americans and changed the way healthcare is financed by both governmental and private payers. The implementation of the Inflation Reduction Act of 2022 ("IR Act") is anticipated to change benefit design and how Medicare pays for drugs, which are all intended to reduce the price of drugs. Three central features of the IR Act would authorize the government to negotiate drug prices for certain Parts B and D drugs over time, establish an inflation rebate program, and cap patient cost sharing under Medicare.

Provincial governments in Canada that provide partial funding for the purchase of pharmaceuticals and independently regulate the sale and reimbursement of drugs have sought to reduce the costs of publicly funded health programs. For example, provincial governments have taken steps to reduce consumer prices for generic pharmaceuticals and, in some provinces, change professional allowances paid to pharmacists by generic drug manufacturers.

McKesson continues to advocate for policies that would improve drug cost transparency under a patient's drug plan to better inform prescribing decisions, and also address access to care, affordability, and treatment regimen adherence, all designed to improve clinical outcomes and reduce the health spending burden.

Additionally, there have been increasing efforts by governments to regulate the pharmaceutical drug supply chain in order to prevent the introduction of counterfeit, stolen, contaminated, or otherwise harmful drugs into the pharmaceutical distribution system, otherwise known as pedigree tracking. For example, the U.S. Drug Quality and Security Act of 2013 ("DQSA") requires us to participate in a federal prescription drug track and trace system that preempts state drug pedigree requirements, and the U.S. Food and Drug Administration Amendments Act of 2007 requires the FDA to establish standards and identify and validate effective technologies, such as track and trace or authentication technologies, to secure the pharmaceutical supply chain against counterfeit drugs. The Drug Supply Chain Security Act requires standardized, unit-level traceability of pharmaceutical products along the entire drug supply chain, with a goal of end-to-end unit-level traceability by November 27, 2023. Pedigree tracking laws such as these increase our compliance burden and our pharmaceutical distribution costs.

Data Security and Privacy: We are subject to many privacy and data protection laws that change frequently and have requirements that vary from jurisdiction to jurisdiction. Our efforts to comply with these laws complicates our operations and adds to our costs. For example, under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") we must maintain administrative, physical, and technological safeguards to protect individually identifiable health information and ensure the confidentiality, integrity, and availability of electronic protected health information. We are subject to significant compliance obligations under privacy laws such as the General Data Protection Regulation ("GDPR") in the European Union, the Personal Information Protection and Electronic Documents Act ("PIPEDA") in Canada, and an expanding list of comprehensive state privacy laws in the United States. Some privacy laws prohibit the transfer of personal information to certain other jurisdictions or otherwise limit our use of data. Many of these laws also require us to provide access or other data rights (modification, deletion, portability, etc.) to consumers' and patients' individual personal data records within specified periods of time. Laws such as the federal Cyber Incident Reporting for Critical Infrastructure Act of 2022 may require us to provide notifications of significant data privacy breaches or cybersecurity incidents before our investigations are complete. We are subject to privacy and data protection compliance audits or investigations by various government agencies.

Environmental Regulation: We are subject to many environmental and hazardous materials regulations, including those relating to radiation-emitting equipment operated at U.S. Oncology Network practices. Additionally, our operations are subject to regulations under various federal, state, local and foreign laws concerning the environment, including laws addressing the discharge of pollutants into the air and water, the management and disposal of hazardous substances and wastes, and the cleanup of contaminated sites.

We sold our chemical distribution operations in 1987 and retained responsibility for certain environmental obligations. Agreements with the U.S. Environmental Protection Agency and certain states may require environmental assessments and cleanups at several closed sites. These matters are described further in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements included in this Annual Report.

Climate Change Regulation: Governments in the U.S. and abroad are considering new or expanded laws to address climate change. Such laws may require reductions of greenhouse gas ("GHG") emissions, mandates that companies implement processes to monitor and disclose climate-related matters, additional taxes or offset charges on specified energy sources, and other requirements. Compliance with climate-related laws may be further complicated by disparate regulatory approaches in various jurisdictions. New or expanded climate-related laws could impose costs on us, including capital expenditures to develop data gathering and reporting systems and additional GHG reduction measures. Until the timing and extent of climate-related laws are clarified, we cannot predict their potential effect on our capital expenditures, results of operations, or competitive position.

Other Information about the Business

Customers: During fiscal 2023, sales to our ten largest customers, including group purchasing organizations ("GPOs") accounted for approximately 68% of our total consolidated revenues. Sales to our largest customer, CVS Health Corporation ("CVS"), accounted for approximately 27% of our total consolidated revenues in fiscal 2023. In fiscal 2023, we extended our pharmaceutical distribution partnership with CVS to June 2027. Our ten largest customers comprised approximately 42%, and CVS was approximately 21%, of our total trade accounts receivable at March 31, 2023. We also have agreements with GPOs, each of which functions as a purchasing agent on behalf of member hospitals, pharmacies, and other healthcare providers, as well as with government entities and agencies. The accounts receivable balances are with individual members of the GPOs, and therefore no significant concentration of credit risk exists. Substantially all of these revenues and accounts receivable are included in our U.S. Pharmaceutical segment.

Suppliers: We obtain pharmaceutical and other products from manufacturers, none of which accounted for more than our largest supplier at 12% of our total purchases in fiscal 2023. The loss of a supplier could adversely affect our business if alternate sources of supply are unavailable. We believe that our relationships with our suppliers are generally sound. The ten largest suppliers in fiscal 2023 accounted for approximately 70% of our total purchases.

Some of our distribution arrangements with manufacturers provide us consideration based on a percentage of our purchases. In addition, we have certain distribution arrangements with pharmaceutical manufacturers that include an inflation-based consideration component whereby we benefit when the manufacturers increase their prices as we sell our existing inventory at the new higher prices. For these manufacturers, a reduction in the frequency and magnitude of price increases, as well as restrictions in the amount of inventory available to us, could have an adverse impact on our gross profit margin.

Research and Development: Research and development expenses were $89 million, $70 million, and $74 million for the years ended March 31, 2023, 2022, and 2021, respectively.

Financial Information About Foreign and Domestic Operations: Certain financial information relating to foreign and domestic operations is discussed in Financial Note 20, "Segments of Business," to the consolidated financial statements included in this Annual Report as well as in "Foreign Operations" in Item 7 of Part II of this Annual Report. See "Risk Factors" in Item 1A of Part I below for information regarding risks associated with our foreign operations.

Forward-Looking Statements

This Annual Report, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of Part II of this report and the "Risk Factors" in Item 1A of Part I of this report, contains forward-looking statements within the meaning of section 27A of the Securities Act of 1933 ("Securities Act") and section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by their use of terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "projects," "plans," "estimates," "targets," or the negative of these words or other comparable terminology. The discussion of financial trends, strategy, plans, assumptions, or intentions may also include forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated, or implied. Although it is not possible to predict or identify all such risks and uncertainties, they include, but are not limited to, the factors discussed in Item 1A of Part I of this report under "Risk Factors" and in our publicly available SEC filings and press releases. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date such statements were first made. Except to the extent required by federal securities laws, we undertake no obligation to publicly release the result of any revisions to any forward-looking statements to reflect events or circumstances after the date the statements are made, or to reflect the occurrence of unanticipated events.

Item 1A. Risk Factors.

INDEX TO RISK FACTORS

Section	Page
Litigation and Regulatory Risks	14
Company and Operational Risks	16
Industry and Economic Risks	21
General Risks	24

The discussion below identifies certain representative risks that might cause our actual business results to materially differ from our estimates. It is not practical to identify or describe all risks and uncertainties that might materially impact our business operations, reputation, financial position, or results of operations. Our business could be materially affected by risks that we have not yet identified or that we currently consider to be immaterial. This is not a complete statement of all potential risks and uncertainties.

Litigation and Regulatory Risks

We experience costly and disruptive legal disputes.

We are routinely named as a defendant in litigation or regulatory proceedings and other legal disputes, which may include asserted class action litigation, such as those described in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements included in this Annual Report. Regulatory proceedings involve allegations such as false claims, healthcare fraud and abuse, and antitrust violations. Civil litigation proceedings involve commercial, employment, environmental, intellectual property, tort, and other claims. Despite valid defenses that we assert, legal disputes are often costly, time-consuming, distracting to management, and disruptive to normal business operations. The uncertainty and expense associated with unresolved legal disputes might harm our business and reputation even if the matter ultimately is favorably resolved. The outcome of legal disputes is difficult to predict, and outcomes may occur that we believe are not justified by the evidence or existing law. Outcomes include monetary damages, penalties and fines, and injunctive or other relief that requires us to change our business operations and incur significant expense. Accordingly, legal disputes might have a materially adverse impact on our reputation, our business operations, and our financial position or results of operations.

We might experience losses not covered by insurance or indemnification.

Our business exposes us to risks that are inherent in the distribution, manufacturing, dispensing, and administration of pharmaceuticals and medical-surgical supplies, the provision of ancillary services, the conduct of our payer businesses, and the provision of products that assist clinical decision-making and relate to patient medical histories and treatment plans. For example, pharmacy operations are exposed to risks such as improper filling of prescriptions, mislabeling of prescriptions, inadequacy of warnings, unintentional distribution of counterfeit drugs, and expiration of drugs. Although we seek to maintain adequate insurance coverage, such as property insurance for inventory and professional and general liability insurance, coverages on acceptable terms might be unavailable, or coverages might not cover our losses. We generally seek to limit our contractual exposure, but limitations of liability or indemnity provisions in our contracts may not be enforceable or adequately protect us from liability. Uninsured losses might have a materially adverse impact on our business operations and our financial position or results of operations.

We experience costly legal disputes, government actions, and adverse publicity regarding our role in distributing controlled substances such as opioids.

The Company is a defendant in many litigation matters alleging claims related to the distribution of controlled substances (opioids), as described in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements in this Annual Report. We are sometimes named as a defendant in similar, new cases. The plaintiffs in those cases include governmental entities (such as states, provinces, counties, and municipalities) as well as businesses, groups, and individuals. The cases allege violations of controlled substance laws and other laws, and they make common law claims such as negligence and public nuisance. Many of these cases raise novel theories of liability and can have unexpected outcomes that we believe are not justified by evidence or existing law. Legal proceedings such as these often involve significant expense, management time and distraction, and risk of loss that can be difficult to predict or quantify. It is not uncommon for claims to be resolved over many years. Outcomes include monetary damages, penalties and fines, and injunctive or other relief that requires us to change our business operations and incur significant expense. Although the Company has valid defenses and is vigorously defending itself, some proceedings have been and others may be resolved by negotiated outcome. For example, we are also subject to consent decrees issued by state courts that govern our distribution of controlled substances. Not all proceedings, however, are resolved by settlement. Our reputation has been and may continue to be impacted by publicity regarding opioids litigation and related allegations. An adverse outcome of any such legal proceedings might have a materially adverse impact on our business operations and our financial position or results of operations.

We might experience increased costs to distribute controlled substances such as opioids.

Legislative, regulatory, or industry measures related to the distribution of controlled substances such as prescription opioids could affect our business in ways that we may not be able to predict. For example, some states have passed legislation that could require us to pay taxes or assessments on the distribution of opioid medications in those states and other states have considered similar legislation. Liabilities for taxes or assessments or other costs of compliance under any such laws might have a materially adverse impact on our reputation, our business operations, and our financial position or results of operations.

We are subject to extensive, complex, and challenging healthcare, environmental, and other laws.

As described in "Government Regulation" in Item 1 of Part I above, our industry is highly regulated, and further regulation of our distribution businesses and technology products and services could impose increased costs, negatively impact our profit margins and the profit margins of our customers, delay the introduction or implementation of our new products, or otherwise negatively impact our business and expose the Company to litigation and regulatory investigations. We incur cleanup costs under environmental laws and may incur additional costs under environmental laws. Additionally, we are subject to various routine and ad hoc inspections by government agencies to determine compliance with various statutes and regulations. Any noncompliance by us with applicable laws or the failure to maintain, renew, or obtain necessary permits and licenses could lead to enforcement actions or litigation and might have a materially adverse impact on our business operations and our financial position or results of operations.

Employee List

Name
Ball, Chris Duane
Persaud, Mike
Santana, Elis
Feliciano, Elvis
Fernandez, Carlos Enrique
Perez-Mestraitua, Fidel L
Perez, Claribet
Persaud, Inderjeet
Derousie, Brooks S
Mathis, Will
Velez, Carmelo
Betancourt, John
Garrett, Jarvis L.
Vidro, Jose M.
Harper, Dennis H.
Santiago, Hector
Velazquez Jr, Angel L
Oquendo, Ramon
Allen, Ricardo A.
Rummell, Gregory J
Crawford, Victor R.
Amador, Pedro J.R
VanPoppel, John
Grullon, Esmanuel
Hoang, An Q
Barnes, Daniel
Plaza, Jonathan
Buria, David
Quinones, Alvin L
Concepcion, Agustin
Scholl, Daniel P
Howell, Kevin N
LaVelle, Jeffrey A
Napoles, Angel R
Griffith, Linda
Coleman, jeremiah
Espinales, Diana I
Romano, Joan Catherine
Nygaard, Jeff M
Marrero, Jacoba
Rogovin, Barry
Stringer, Cynthia A
Washington, Barbara J
Dupont, Terry L
Stewart, Jason

Kinander, Marc D
Shields, John W
Livesey, Scott Thomas
Fisher, William B
Sejdic, Kemal
Jones, Drayton Lanardo
DeSouza, Bernadette
Hursey, Brian
Diosomito, James
Silva, Mirtha
Hursey, Victoria
Cintron, Jose
Candelaria, Jose Angel
Orsini, Manuel J
Cox, Rob
Quinones, Ruben C
Olivier, Stephen
Salsburg, Randall L
Buchhold, Albert T
Meadows, Michael P
Roush, Nathan K
Vibbert, Peter
Mercado, Bruno
Gibbs, Andrew M
Alvarez, David
Douangboupha, Phiprasong

Clark, Tony G
Tejada, Roberto
Hixon, Zach
Valladares, Luis
Valladares, Severo
Reese-Jasmin, Ronica
Arose, Michael
Arvelo, Alexis
Plaza, Brunilda
Dwyre, John
Colon, Ruben
Perez, Carlos
Santos, Marta M.
Fernandez Reyes, Ivan
Prince, Shawn D
Figueroa-Cordero, Miguel Angel
Del Valle, Ana Maria
Cotto, Ramon Anibal
Saylor, Roosevelt Andre

Marquez, Jose Manuel
Etienne, Sony
Wilson, Erick
Hollenbeck, Michael
Martin Pineda, Jose Alejandro
Mont, Anthony James
Martinez, Raisha
Ross, Christopher Levon
Texeira, Laizette M
Buell, Tyler Joseph
Flowers, Cameron Austin
Minnis, Sean C.
Juarez, Marco Tulio
Williams, Jason Scott
Rodrigues, David Pina
Suarez, Katelyn Marie
White, Cheryl A
Hunter, Steven C.
Perez, Miguel
Perez, Omar
Bernardez, Javier J. J
Landin, Marcos
Fields, Fortune
Rosado, Freddie
Dorvilus, Bachann
McKenzie, Wayne Noel
Hyppolite, Johnny
Cantave, Kadette
Marquez, Juan
Paul, Alex
Bridgnauth, Leonard
Shannon, Levi
Robles, Nestor Irving
Rosa Rivera, William
Jones, Lee Leon
Candelaria, Pedro
Charles, Celo
Baez, Francisco
Hamilton, Craig Andrew
Williams, Trab D
Perez, Charles
Fulmore, Rod
Harvey, Bill M
Crumity, Rickey Lawrence

Wilson, Luke

Crabbe, Mark A
Smith, David G
Polk, Moe L
Montgomery, Viv
Vargas Rivera, Cid Marie
Perez, Andres A
Gomez, Ralphy
Recny, Steven Michael
Hutchison, Nick J.
Shoemaker, Jeremy
Vazquez, Ronald Alberto
Class-Rivera, Neftali
Llorente, Yanier
Davis, Larry
Motilal, Samlal
Deleon, Daniel A
King, Deangelo
Chapman, Clayton B
Alicea, Jerry
Scott, Angela M
Bastidas, Angel Manuel
Melendez, Joel
Beltran, Orlando
Castro Silva, Jorge L
Gonzalez-Santaella, William

Rivera, Orlando A.
Soto, Luis F.
Mandolang, Felix M.
Bell, Roy A.
Jones, Jack A.
Cimino, Jose Cono
Cardenas, Javier
Colina, Jefferson
Aponte, Francisco
Collazo Mendez, Hector Luis
Ledezma, Sorennys
Kadet, Geureline
Daniello, Gennaro
Perez, Angelica
Rodriguez, Zoraima
Luciano, Gustavo
Del Valle Rivera, Keyla
Wilkerson, Verdia
Salas, Dayana
Dailey, Daria

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02958	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Amatheon Animal Health, LLC

Physical Address: 1301 NW 84th Ave. Suite 101A

City: Miami State: FL Zip: 33126

Mailing Address (if different from physical address): **same as above**

City: State: Zip:

Telephone: 800-399-8387 Website: www.amatheon.com

Name of Designated Representative (DR): Alfonso Robleto

Licensing Company Email: customerserviceteam@amatheon.com DR Email: alfonsorobleto@amatheon.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
■ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: AmerisourceBergen
Address: 1 West First Avenue City: Conshohocken State: PA Zip: 19428

Name: Hikma
Address: 200 Connell Drive, 4th Floor City: Berkeley Heights State: NJ Zip: 0792

Name: Pfizer
Address: 66 Hudson Boulevard East City: New York State: NY Zip: 10001

Name: Top Rx
Address: 2950 Brother Boulevard City: Bartlett State: TN Zip: 38133

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida
Parent Company (if any): N/A
Corporation/Organization Name: Amatheon Animal Health, LLC
Mailing Address: 1301 NW 84th Ave., Suite 101A
City: Miami State: FL Zip: 33126
Telephone: 800-399-8387 Email: chrisyankana@amatheon.com
Contact Person Name: Christopher Yankana

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 3: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 3: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 3)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Amatheon Animal Health, LLC

Facility Name

Christopher Yankana

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

08/11/2023

Date

Board Use Only	Date Received: _____	Amount: 1000-CK - 100000 7241

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

*see attached disciplinary documents and explanation

Original Signature (electronic, copies or stamps not accepted)

08/11/2023

Date

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

Case No.: 2019-035120

v.

LIFELINE PHARMACEUTICALS, LLC,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (hereinafter, "this agreement") as disposition of the alleged violations described in the Notice of Violation in case number 2019-035120 (hereinafter, "the allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereinafter, "the Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. Lifeline Pharmaceuticals, LLC (hereinafter, "Respondent") is permitted as an out-of-state prescription drug wholesale distributor by the Department, having been issued permit number 23:2522.

2. Respondent's address of record is 5800 Gulf Tech Drive, Ocean Springs, Mississippi 39564.

3. Respondent was issued a Notice of Violation on August 12, 2019, alleging that it

committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent, by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent admits that the allegations, if proven, would constitute violations of Chapter 499, Florida Statutes.

SETTLEMENT TERMS

6. Respondent agrees to immediately cease any practices that are in violation of Chapter 499, Florida Statutes.

7. Respondent agrees to pay a settlement amount of Seven Thousand Nine Hundred Fifty Dollars ($7,950). **Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047, Attention: Tammy Shaw, Senior Legal Assistant.** Respondent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Respondent are absolute conditions precedent to the Department's execution of this agreement.

8. Respondent affirms that the violations alleged in the Notice of Violation letter issued in case number 2019-035120 have been corrected.

9. The acceptance of this agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes and Rule 61N-1.024, Florida Administrative Code.

STANDARD PROVISIONS

10. It is expressly understood that a violation of the terms of this agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

11. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. **The final order shall operate to close case number 2019-035120. The final order shall be the final disposition in this proceeding and shall constitute final agency action with respect thereto.**

12. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this agreement and the final order in which this agreement is incorporated, provided the final order does not conflict with this agreement.

13. Respondent waives the right to seek any attorney's fees or costs from the Department in connection with this proceeding.

14. This agreement may be executed in any number of counterparts including, without limitation, telecopies and facsimile transmission copies, all of which together shall constitute a single document.

15. The parties agree that this agreement represents a fair, appropriate, and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

16. The terms and provisions of this agreement are severable and, if any term or provision is declared or deemed void, invalid, illegal, or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

17. It is expressly understood that this agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts

this agreement and adopts it in a final order.

18. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals and, as duly designated representatives, to fully bind such principals.

LIFELINE PHARMACEUTICALS, LLC,	FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION DIVISION OF DRUGS, DEVICES, AND COSMETICS,
By:	By:
Name: RICK NIELSEN	Name: WALTER COPELAND
Title: PRESIDENT/CEO	Title: DIVISION DIRECTOR
Date: 09/02/2019	Date: 09.17.2019

Prepared by:

Kathryn E. Price
DDC Chief Attorney

FILED 1580
Department of Business and Professional Regulation
Senior Deputy Agency Clerk
CLERK Brandon Nichols
Date 9/20/2019
File # 2019-08151

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

v. **Case No.: 2019-035120**

LIFELINE PHARMACEUTICALS, LLC,

Respondent.
_____/

FINAL ORDER

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (Department), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Lifeline Pharmaceuticals, LLC and the Department, attached hereto and incorporated by reference. This Final Order resolves alleged violations of Section 499.005(4), Florida Statutes (2015-2019), through a violation of Section 499.012(16), Florida Statutes (2015), and 499.012(15), Florida Statutes (2016-2019), by failing to notify the Department of the departure of its certified designated representative ("CDR"), and failing to name a new CDR within ten days; Section 499.005(19), Florida Statutes (2014-2019), by making false or fraudulent statements to the Department; and Section 499.005(4), Florida Statutes (2014-2019), through a violation of Section 499.012(16), Florida Statutes (2014-2015), and Section 499.012(15), Florida Statutes (2016-2019), by continuing business operations without reporting a valid CDR to the Department.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department of Business & Professional Regulation as indicated on this Final Order.

DONE and ORDERED this 17th day of September, 2019 in Tallahassee, Florida.

HALSEY BESHEARS, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____
Walter Copeland
Division Director
Drugs, Devices, and Cosmetics

Prepared by:

Kathryn E. Price
DDC Chief Attorney

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the Notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by regular United States mail to: Martin Dix, Esquire, at Akerman, LLP, 106 E. College Avenue, Suite 1200, Tallahassee, Florida 32301 this 20th day of September, 2019.

By: Brandon M. Nichols
Agency Clerk's Office

Amatheon Animal Health, LLC
MI Discipline Narrative

On October 13, 2021, Michigan Department of Licensing and Regulatory Affairs (LARA) fined Amatheon for failure to timely report a change of location and facility manager change within the 30 days required by LARA. Amatheon subsequently timely paid the fine, which fully adjudicated and resolved the matter with LARA. To be clear, the fine was levied against the lapsed, inactive license at the previous location. Prior to the fine being issued, Michigan had already issued an unencumbered nonresident wholesale distributor license for the new location on October 28, 2020, which remains active and in good standing.

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

AMATHEON ANIMAL HEALTH, LLC
License No. 53-06-006059,

File No. 53-20-001834

Respondent.

CONSENT ORDER

On November 10, 2020, the Department of Licensing and Regulatory Affairs executed an Administrative Complaint charging Respondent with violating the Public Health Code, MCL 333.1101 *et seq.*

The parties have stipulated that the Michigan Board of Pharmacy's Disciplinary Subcommittee (DSC) may enter this Consent Order and Stipulation. The DSC has reviewed this Consent Order and Stipulation and agrees that resolution of the Complaint best serves the public interest.

Therefore, IT IS FOUND that the facts alleged in the Complaint are true and constitute violations of MCL 333.17748(4) and MCL 333.17768(1) for both counts alleged in the Complaint.

Accordingly, IT IS ORDERED that for the cited violations of the Public Health Code:

Respondent is FINED $1,000.00 to be paid to the State of Michigan within 90 days of the effective date of this Order. Respondent shall **direct payment** to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Compliance Section, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and shall clearly display **File Number 53-20-001834**.

If Respondent violates any provision of this Order, the DSC may take disciplinary action pursuant to Mich Admin Code, R 338.1632 and MCL 333.16221(h).

This Order shall be effective thirty (30) days from the date signed by the Board, as set forth below.

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

Dated: _____

STIPULATION

1. Respondent does not contest the allegations of fact and law in the Complaint. Respondent understands that, by pleading no contest, Respondent does not admit the truth of the allegations but agrees the Disciplinary Subcommittee of the Michigan Board of Pharmacy may treat the allegations as true for the resolution of the Complaint and may enter an order finding Respondent violated MCL 333.17748(4) and MCL 333.17768(1) for both counts alleged in the Complaint.

2. Respondent understands and intends that by signing this Stipulation, Respondent is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act, MCL 24.201 *et seq*, to require the Department to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent is waving the right to appear with an attorney and such witnesses as Respondent may desire to present a defense to the charges.

3. This matter is a public record required to be published and made available to the public pursuant to the Michigan Freedom of Information Act, MCL 15.231 *et seq.*, and this action will be reported to the National Practitioner Data Bank and any other entity as required by state or federal law.

4. This Order is approved as to form and substance by Respondent and the Department and may be entered as the final order of the DSC in this matter.

5. Factors taken into consideration in the formation of this Order are:

   a. Respondent requested a settlement and explained the extenuating circumstances of a prolonged litigation resulting in Respondent company being split away from its parent company and there were many personnel changes during the process.

b. Respondent's owners admitted to failing to notify the Department of its change in location and its change in facility manager and stated the actions were unintentional and in no way were fraudulent.

c. Respondent's owners believe the failure to notify the Department only occurred due to the extenuating circumstances of litigation and subsequent personnel changes and do not foresee this oversight happening again. Moreover, to prevent any further unintentional failure on Respondent's part, Respondent implemented an entirely new operating procedure with internal safeguards that make non-compliance an impossibility in the future.

6. A Department representative may discuss this matter with the DSC and recommend acceptance of the resolution set forth in this Order.

7. This proposal is conditioned upon acceptance by the DSC. Respondent and the Department expressly reserve the right to further proceedings without prejudice should the Order be rejected.

AGREED TO BY:

_____

Forrest Pasanski, Director
Enforcement Division
Bureau of Professional Licensing

Dated: _____

AGREED TO BY:

_____

Amatheon Animal Health, LLC.
Respondent

By: CHRISTOPHER JANKANA

Its: CHIEF FINANCIAL OFFICER

Dated: 07-06-2021

AGREED TO BY:

_____

I. Eric Nordan (P82500)
Attorney for Respondent

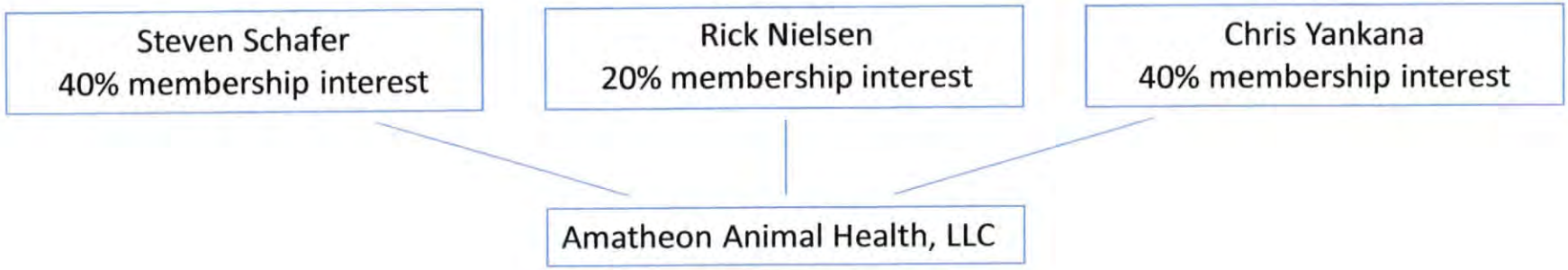
Dated: _____

Pc/jp

Amatheon Animal Health, LLC

Ownership Organizational Chart

As of July 14, 2023



Amatheon Animal Health, LLC

Ownership Organizational Chart

Prior to July 14, 2023 transaction



Name	Title	Business Address	Percent of Ownership
Christopher Yankana	Owner, CFO	1301 NW 84TH AVE, SUITE 101A Miami, FL 33126	40%
Steven R, Schafer	Owner, CEO	1301 NW 84TH AVE, SUITE 101A Miami, FL 33126	40%
Rick Nielsen	Owner, CCO	1301 NW 84TH AVE, SUITE 101A Miami, FL 33126	20%

State of Florida
Department of State

I certify from the records of this office that AMATHEON ANIMAL HEALTH, LLC is a limited liability company organized under the laws of the State of Florida, filed on March 24, 2016.

The document number of this limited liability company is L16000059701.

I further certify that said limited liability company has paid all fees due this office through December 31, 2022, that its most recent annual report was filed on January 31, 2022, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the First day of February, 2023

Secretary of State

Tracking Number: 6607151506CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS
2601 BLAIR STONE ROAD
TALLAHASSEE FL 32399-1047

(850) 487-1395

AMATHEON ANIMAL HEALTH, LLC
AMATHEON PHARMACEUTICALS
1301 NW 84TH AVE.
SUITE 101A
MIAMI FL 33126

Congratulations! With this license you become one of the nearly one million Floridians licensed by the Department of Business and Professional Regulation. Our professionals and businesses range from architects to yacht brokers, from boxers to barbeque restaurants, and they keep Florida's economy strong.

Every day we work to improve the way we do business in order to serve you better. For information about our services, please log onto **www.myfloridalicense.com**. There you can find more information about our divisions and the regulations that impact you, subscribe to department newsletters and learn more about the Department's initiatives.

Our mission at the Department is: License Efficiently, Regulate Fairly. We constantly strive to serve you better so that you can serve your customers. Thank you for doing business in Florida, and congratulations on your new license!

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

2220277 ISSUED: 04/18/2022

RX DRUG WHOLESALE DISTRIBUTOR
AMATHEON ANIMAL HEALTH, LLC
AMATHEON PHARMACEUTICALS

HAS REGISTERED under the provisions of Ch.499 FS.
Expiration date : APR 30, 2024 L2204180000145

DETACH HERE

RON DESANTIS, GOVERNOR

MELANIE S. GRIFFIN, SECRETARY

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
FLORIDA DRUGS, DEVICES AND COSMETICS

LICENSE NUMBER	
2220277	

The PRESCRIPTION DRUG WHOLESALE DISTRIBUTOR
Named below HAS REGISTERED
Under the provisions of Chapter 499 FS.
Expiration date: APR 30, 2024

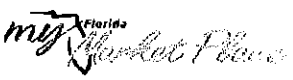
AMATHEON ANIMAL HEALTH, LLC
AMATHEON PHARMACEUTICALS
1301 NW 84TH AVE.
SUITE 101A
MIAMI FL 33126

ISSUED: 04/18/2022 DISPLAY AS REQUIRED BY LAW SEQ # L2204180000145



The Department of Management Services' Office of Supplier Diversity "serves those who serve Florida."

The Office of Supplier Diversity provides resources designed to improve business and economic opportunities for Florida's woman-, veteran- and minority-owned businesses. Learn more about becoming a certified business enterprise at ***dms.myflorida.com/osd*** or call 850-487-0915.



To find out about State of Florida tools supporting statewide centralized procurement activities which have streamlined interactions between vendors and state government entities, please contact or visit the Department of Management Services' MyFloridaMarketPlace at: ***https://vendor.myfloridamarketplace.com***

AC# 3094485

SIGNATURE

(For the protection of our professional license holders, this license contains hidden security features to prevent counterfeiting. Unauthorized reproduction is strictly prohibited and will be prosecuted to the fullest extent of the law)

The Department of Business and Professional Regulation (DBPR), issues licenses for many licensed businesses and practitioners in the State of Florida.

DBPR is changing the way you interact with state government. Many of DBPR's services are available online at www.MyFloridaLicense.com. We encourage you to utilize these services to make address changes, licensing changes or to renew your license.

Name changes require legal documentation verifying the name change, which must be mailed to the DBPR. An original, a certified copy or a duplicate copy of an original or certified copy of a document that shows the legal name change will be accepted, unless the DBPR has a question about the authenticity of the document.

If applicable, the DBPR will send a renewal notice to your last known address or email address of record. If you have not received your renewal notice, please call our Customer Contact Center at 850.487.1395 or online at www.MyFloridaLicense.com/contactus.

Please refer to your profession's governing statutes and Administrative codes for further information regarding renewals. These may be accessed from our website.

AC# 3094485

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0593219	06-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	06-16-2023

AMATHEON ANIMAL HEALTH
1301 NW 84TH AVE STE 101A
MIAMI, FL 33126

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0593219	06-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	06-16-2023

AMATHEON ANIMAL HEALTH
1301 NW 84TH AVE STE 101A
MIAMI, FL 33126

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0593219	06-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	06-16-2023

AMATHEON ANIMAL HEALTH
1301 NW 84TH AVE STE 101A
MIAMI, FL 33126

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

NABP ACCREDITED

DRUG DISTRIBUTOR

Amatheon Animal Health, LLC dba
Amatheon Pharmaceuticals

located at

1301 NW 84th Ave, Ste 101A, Miami, FL 33126

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/07/2023 to 04/06/2026
Period of Accreditation

1596

SureTec

INVOICE

Insource (Acrisure, LLC dba)
9500 South Dadeland Boulevard, 4th Floor
Miami, FL 33156

Agency Code 910101

Applicant	AMATHEON PHARMACEUTICALS
Effective Date	August 1, 2023
Expiration Date	July 31, 2024
Obligee	Nevada State Board of Pharmacy
Bond Description	Pharmaceutical Wholesale Distributor
Bond Number	3459861

Bond Amount	$100,000.00
Premium	$750.00

SureTec Insurance Company
2103 CityWest Boulevard, Suite 1300
Houston, TX 77042

Should you have any questions concerning this invoice, please call (888) 344-3362

Bond premium is due 45 days from the end of the month in which the bond or endorsement executed.

Thank you for your business. We appreciate it!

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Amatheon Animal Health, LLC

Pharmacy/Wholesaler License # (if applicable): WH02958

Physical Address: 1301 NW 84th Avenue, Suite 101A

City: Miami State: FL Zip: 33126

Mailing Address (if different from physical address): **same as above**

City: State: Zip:

Telephone: 800-399-8387 Website: www.amatheon.com

Licensing Company Email: customerserviceteam@amatheon.com

Section 2: Personal Information

First: Alfonso Middle: Last: Robleto

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Southwest 102nd Lane

City: Miami State: FL Zip: 33186

Telephone: [redacted] Email: alfonsorobleto@amatheon.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Florida International University		2007- 2011	
Address	**City**	**State**	**Zip**
11200 SW 8th St	Miami	FL	33199
Diploma/Degree obtained, if any			
Minor Degree, History, Criminal Justice/Bachelors of Science, Criminal Justice/Bachelors of Science, Political Science			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020 - 2023	[redacted] Southwest 102nd Lane	Miami	FL	33186
2001-2020	[redacted] SW 68 Terrace	Miami	FL	33193
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Amatheon Animal Health LLC			08/2017-Present	
Business Address		**City**	**State**	**Zip**
1301 NW 84th Avenue, Suite 101A		Miami	FL	33126
Phone	**Title**		**Number of Employed Hours**	
800-399-8387	Director of Business Intelligence & Purchasing		12,480	
Description of Duties				
Contract negotiations ;National Accounts Catalog Management including Coupa;Manages Supplier relations including product sourcing/allocations and negotiating extended credit;Custom report building;Manages rolling inventory				

Business Name			From - To (MM/YY – MM/YY)	
Full resume attached for reference				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

8/11/23
Date

I, Alfonso Robleto, **certify that as the designated representative for**

Amatheon Animal Health LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AR I am at least 21 years of age;
3. AR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Alfonso Robleto
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/11/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alfonso Robleto

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/11/23

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami-Dade

I, Alfonso Robleto, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/11/23

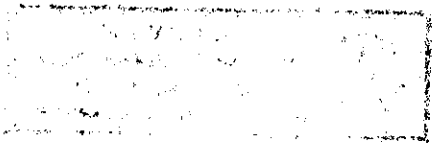
Date

Subscribed and Sworn to before me this 11 day of August.

Notary Public Signature

YARA SAATHOFF
MY COMMISSION # HH 129219
EXPIRES: May 12, 2025
Bonded Thru Notary Public Underwriters

(Seal)



Alfonso A. Robleto

E-mail: [redacted]

PROFESSIONAL EXPERIENCE

Amatheon Pharmaceuticals – Miami, Florida August 2017 to present
Purchasing Manager

- Successful contract negotiations resulting in additional profit totaling 500k
- National Accounts Catalog Management including Coupa Implementation.
- Manages Supplier relations including product sourcing/allocations and negotiating extended credit terms.
- Aggressively negotiates product pricing amongst all major manufacturing entities.
- Manages $1.3 million in rolling inventory through 40+ suppliers/manufacturers.
- Manages product pricing – ensures maximum profit through knowledge of manufacturer pipeline, product launches, and competitive data
- Custom report building
- Successful contract negotiations resulting in additional profit totaling 500k
- Negotiated contract pricing with couriers (UPS/FedEx)

Amatheon Pharmaceuticals – Miami, Florida April 2014 to July 2017
Purchasing Clerk

- Issues Purchase orders based on Min/Max reports, reconciles product receipt with AP/ AR
- Forecast monthly inventory purchases.
- Physical Inventory Management including supplier shortages/ customer shortages and overages.
- Cost discrepancy reconciliation
- Manages Product stability studies for extended item excursions.
- Negotiated terms, pricing and deliveries for warehouse materials and supplies.

Amatheon Pharmaceuticals – Miami, Florida December 2012 to March 2014
Warehouse team member

- Leads 5-member team, directs warehouse workflow in a fast-paced, dynamic environment
- Key staff member – expertly manages $500,000 inventory, anticipating and immediately mitigating issues
- Ensures timely processing of shipments through enhanced managerial skills
- Provides rapid improvement recommendations through efficiency and budget allocations data analysis
- Reduced shipping costs 12% totaling 120k using innovative inventory management techniques

Bimini Shipping, LLC – Miami, Florida August 2011 to December 2012
Shipping Agent

- Executed documentation to import/export ships with U.S. Coast Guard Notice of Arrival/Departure System
- Ensured crew and cargo manifests for entry, clearance forms submitted/coordinated to federal agencies

EDUCATION

- Bachelors of Science, Political Science, Florida International University, 2011, Miami, Florida
- Bachelors of Science, Criminal Justice, Florida International University, 2011, Miami, Florida
- Minor Degree, History, Criminal Justice, Florida International University, 2011, Miami, Florida

CERTIFICATIONS

- Florida Certified Designated Representative- Florida Department of Business and Professional Regulation

SKILLS

- Bilingual – fluent in both Spanish and English
- Proficient using Flexible Business Systems, Excel, Crystal reports, Microsoft Dynamics Great Plains

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Amatheon Animal Health, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH02958

Physical Address: 1301 NW 84th Ave., Suite 101A

City: Miami State: FL Zip: 33126

Mailing Address (if different from physical address): ** same as above**

City: State: Zip:

Telephone: 800-399-8387 Website: www.amatheon.com

Licensing Company Email: customerserviceteam@amatheon.com

Section 2: Personal Information

First: Christopher Middle: Last: Yankana

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] SW 61 CT

City: Miami State: FL Zip: 33156

Telephone: [redacted] Email: chrisyankana@amatheon.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St. John's University		9/85- 12/89	
Address	**City**	**State**	**Zip**
81-98 170th St	Jamaica	NY	11432
Diploma/Degree obtained, if any			
Masters of Business Administration – Finance/ Masters of Business Administration – Public Accounting			

School Name		From - To (MM/YY – MM/YY)	
University of Miami		8/82 – 5/85	
Address	**City**	**State**	**Zip**
1320 S Dixie Hw	Coral Gables	FL	33146
Diploma/Degree obtained, if any			
Bachelors of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
St. Stanislaus College			
Address	**City**	**State**	**Zip**
Georgetown Guyana			
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1997 -Present	[redacted] SW 61 CT	Miami	FL	33156
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Amatheon Animal Health, LLC			2017-Present	
Business Address		**City**	**State**	**Zip**
1301 NW 84th Ave., Suite 101A		Miami	FL	33126
Phone	**Title**			
800-399-8387	CFO			
Description of Duties				
Responsible for all financial, compliance, and logistical functions within operation				

Business Name			From - To (MM/YY – MM/YY)	
Tri-Source Pharma, LLC			2002-2017	
Business Address		**City**	**State**	**Zip**
80 SW 8th St Suite 2660		Miami	FL	33130
Phone	**Title**			
(844) 696-4667	CFO/Strategy Officer/Founder			
Description of Duties				
Established and implemented company wide goals and policies, and managed all aspects of financial, operational and marketing/sales activities including distribution functions				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

please see attached disciplinary attachment

Original Signature (electronic, copies or stamps not accepted)

08/11/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Yankana
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/11/2023
Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami-Dade

I, Christopher Yankana, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/11/2023
Date

Subscribed and Sworn to before me this 11 day of August.

Notary Public Signature

YARA SAATHOFF
MY COMMISSION # HH 129219
EXPIRES: May 12, 2025
Bonded Thru Notary Public Underwriters

(Seal)



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler/Dispensing Site Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Amatheon Animal Health, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH02958

Physical Address: 1301 NW 84th Ave., Suite 101A

City: Miami State: FL Zip: 33126

Mailing Address (if different from physical address): **same as above**

City: State: Zip:

Telephone: 800-399-8387 Website: www.amatheon.com

Licensing Company Email: customerserviceteam@amatheon.com

Section 2: Personal Information

First: Steven Middle: Last: Schafer

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Purdy Ave., [redacted]

City: Miami Beach State: FL Zip: 33139

Telephone: [redacted] Email: steveschafer@amatheon.com

Are you a citizen of the United States? ■ Yes ☐ No

	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

School Name			From - To (MM/YY – MM/YY)
University of Florida			1986-1990
Address	**City**	**State**	**Zip**
201 Criser Hall PO Box 114000	Gainesville	FL	32611
Diploma/Degree obtained, if any			
Bachelors of Science Advertising, Minor in Psychology			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2001- Present	[redacted] Purdy Avenue, Apt [redacted]	Miami Beach	FL	33139
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

[redacted]

Business Name		From - To (MM/YY – MM/YY)
Amatheon Animal Health LLC		2002- Present
Business Address	**City**	**State** / **Zip**
1301 NW 84th Ave., Suite 101A	Miami	FL / 33126
Phone	**Title**	
800-399-8387	Founder/CEO	
Description of Duties		
Developing key performance metrics and dashboards that help the sales organization focus on performance drivers; building high performance, cohesive and customer focused solutions		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section II: Arrests, Convictions, Litigation, Settlements	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

please see attached discipline documents

Original Signature (electronic, copies or stamps not accepted)

02/11/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Steven Schafer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/11/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami-Dade

I, Steven Schafer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/11/2023

Date

Subscribed and Sworn to before me this 11 day of August.

Notary Public Signature

YARA SAATHOFF
MY COMMISSION # HH 129219
EXPIRES: May 12, 2025
Bonded Thru Notary Public Underwriters

(Seal)



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Amatheon Animal Health, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH02958

Physical Address: 1301 NW 84th Avenue, Suite 101A

City: Miami State: FL Zip: 33126

Mailing Address (if different from physical address): ** Same as above**

City: State: Zip:

Telephone: 800-399-8387 Website: www.amatheon.com

Licensing Company Email: customerservicesteam@amatheon.com

Section 2: Personal Information

First: Rick Middle: Last: Nielsen

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Miami View Drive

City: North Bay Village State: FL Zip: 33141

Telephone: [redacted] Email: Ricknielsen@amatheon.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pennsylvania State University		1989-1993	
Address	**City**	**State**	**Zip**
128 Outreach Building	University Park	PA	16802
Diploma/Degree obtained, if any			
Bachelor of Science, Minor Marketing/Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Country Day		1975-1989	
Address	**City**	**State**	**Zip**
6199 Concordia	Kingshill, St Croix	U.S. Virgin Islands	00820
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2015- Present	[redacted] Miami View Drive	North Bay Village	FL	33141
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Amatheon Animal Health LLC			2019- Present
Business Address	**City**	**State**	**Zip**
1301 NW 84th Avenue, Suite 101A			33126
Phone	**Title**		
800-399-8387	CCO		

Description of Duties

Overseeing compliance within the organization, and ensuring compliance with laws, regulatory requirements, policies, and procedures.

Business Name			From - To (MM/YY – MM/YY)
Lifeline Pharmaceuticals			2006-Present
Business Address	**City**	**State**	**Zip**
1301 NW 84th Ave #101	Doral	FL	33126
Phone	**Title**		
(877) 430-6337	President, CEO & Certified Designated Representative		

Description of Duties

Sales training and Management, Management of daily operations including all pharmaceutical distribution centers; positioned company as unique value added service, doubled sales growth from 2006-2010

Business Name			From - To (MM/YY – MM/YY)
Full resume attached for reference			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
NA				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached discipline records

Original Signature (electronic, copies or stamps not accepted)

08/10/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rick Nielsen

Print Name (First, Last)

Original Signature (~~electronic, copies~~ or stamps not accepted)

08/10/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami-Dade

I, RICK NIELSEN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/11/23

Date

Subscribed and Sworn to before me this 11 day of August.

Notary Public Signature

Edwin L. Rodriguez
Comm.#HH111226
Expires: March 29, 2025
Bonded Thru Aaron Notary

(Seal)



Rick S. Nielsen

[redacted] West Drive [redacted] N. Bay Village, FL 33141

[redacted]

Professional Experience

Lifeline Pharmaceuticals **Miami, FL** **2006-Present**
Prescription Drug Wholesaler
President, CEO & Certified Designated Representative

- Sales Training and Management
- Management of daily operations including all pharmaceutical distribution centers
- Positioned company as unique value added service, doubled Sales growth from 2006-2010
- Maintained 18% annual growth rate since 2010

Worldwide Medical Supplies & Pharmaceuticals **Florida City, FL** **2004-2006**
Prescription Drug Wholesaler
VP of Sales & Certified Designated Representative

- Managed Sales and Regulatory Affairs
- Inventory management for Prescription Drugs and medical supplies.
- Licensed by the Florida Department of Health as a Designated Representative. The license means that I have passed the state exam and have had 2 years' experience in managing pharmaceutical distribution centers.

Health Coalition Inc **Coral Gables, FL** **2000-2004**
Prescription Drug Wholesaler
Account Manager

- Increased my Sales territory by implementing client inventory system via telephone and visiting ALF's, Physician Offices and Pharmacies
- Managed Inventory by received, stocking and shipping Prescription Drugs
- Monitored distribution of prescription drugs.
- Promoted to Sales Manager. Implemented Sales and Product Training

Education

Pennsylvania State University **University Park, PA 1989-1993**
Bachelors of Science and Minor Marketing and Business Administration

Country Day **St. Croix, VI** **1975-1989**

amatheon
ANIMAL HEALTH

1301 NW 84th Ave
Suite 101A, Miami, FL 33126
AMATHEON.COM
800.399.VETS

Employee List

David Yankana
Carlos Alvarez
David Gonzalez
David Castellanos
George Taylor
Daniel Beltron
Kelvin Mobley
Andrew Gonzalez
Raymundo Cruz
Ruben Ramirez
Rigoberto Luna
Steven Gonzalez
Teresa Quesada
Kacey Rodriguez
Edwin Rodriguez
Justin Smith
Myriela Tundidor
Yara Saathoff
Alfonso Robleto
Chris Yankana
Zucel Nunez
Rick Nielsen

4MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: CVS TN DISTRIBUTION, LLC

Physical Address: 10017 KINGSTON PIKE

City: KNOXVILLE State: TN Zip: 37922

Mailing Address (if different from physical address): LICENSING DEPT MC#1160

City: WOONSOCKET State: RI Zip: 02895

Telephone: 401-770-5149 Website: _____

Name of Designated Representative (DR): CHRISTOPHER W. PARK

Licensing Company Email: Eufemia.Bryden@cvshealth.com DR Email: Christopher.Park@cvshealth.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: SUN PHARMACEUTICAL INDUSTRIES, INC
Address: 1 COMMERCE DRIVE STE B City: CRANBURY State: NJ Zip: 08512

Name: AMNEAL PHARMACEUTICALS
Address: 115 CARROLL KNICELY DRIVE City: GLASGOW State: KY Zip: 42141

Name: HIKMA PHARMACEUTICALS USA, INC
Address: 200 CONNELL DRIVE City: BERKELY HEIGHTS State: NJ Zip: 07922

Name: MYLAN PHARMACEUTICALS, INC.
Address: 781 CHESTNUT RIDGE City: MORGANTOWN State: WV Zip: 26505

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: TN
Parent Company (if any): CVS PHARMACY, INC
Corporation/Organization Name: CVS TN DISTRIBUTION, LLC
Mailing Address: LICENSING DEPT MC#1160, ONE CVS DRIVE
City: WOONSOCKET State: RI Zip: 02895
Telephone: 401-770-5149 Email: Eufemia.Bryden@cvshealth.com
Contact Person Name: EUFEMIA T. BRYDEN

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

CVS TN DISTRIBUTION, LLC

Facility Name

KIMBERLEY M. DESOUSA-ASSISTANT SECRETARY

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8/31/23

Date

Board Use Only	Date Received: 9/6/23	Amount: 1000 - CK - 51191880 ✓

NABP

CVS TN Distribution, LLC

Primary DBA: N/A
Application ID: 4736909
e-Profile ID: 10322
Address: 10017 Kingston Pike, , Knoxville, Tennessee, 37922
Program Type: Drug Distributor Accreditation
Application Status: In Review

Verified 9/8/23

Corporate Ownership of CVS TN Distribution, L.L.C., d/b/a CVS/pharmacy #884
10017 Kingston Pike, Knoxville, TN 37922

CVS Health Corporation
A Delaware Corporation
FEIN 05-0494040
One CVS Drive, Woonsocket, RI 02896
Officers and Directors
Farah, Roger N., Director and Chairman of the Board, Aguirre, Fernando, Director
Balser, Jeffrey R., Director, Brown, II, C. David, Director, DeCoudreaux, Alecia A., Director
DeParle, Nancy-Ann M., Director, Finucane, Anne M., Director
Ludwig, Edward J., Director, Lynch, Karen S., Director, Millon, Jean-Pierre, Director
Schapiro, Mary L., Director
Lynch, Karen S., President and CEO
Chaguturu, Sreekanth K., EVP and Chief Medical Officer
Falkowski, David A., EVP and Chief Compliance Officer
Finke, Daniel P., EVP and President, Health Care Benefits
Guertin, Shawn, EVP and Chief Financial Officer
Havanec, Laurie P., EVP and Chief People Officer
Ostafin, Violetta, EVP and Chief Strategy Officer
Joyner, J. David, EVP and President, CVS Caremark
Khichi, Samrat S., EVP, Chief Policy Officer and General Counsel
Mandadi, Tilak, EVP and Chief Data, Digital and Technology Officer
Peluso, Michelle, EVP, Chief Customer Officer and Co-President, CVS Pharmacy
Shah, Prem, EVP, Chief Pharmacy Officer and Co-President, CVS Pharmacy
Clark, James D., SVP, Controller and Chief Accounting Officer
Cowhey, Thomas F., SVP, Capital Markets
DeNale, Carol A., SVP and Treasurer
McGrath, Laurence, F., SVP, Business Development and Investor Relations
Slate, Shari M., SVP and Chief Diversity, Equity and Inclusion Officer
McIntosh, Colleen M., SVP, Corporate Secretary, Chief Governance Officer and Asst. General Counsel
Moffatt, Thomas S., Vice President, Asst. Corporate Secretary and Sr. Legal Counsel
Zhang, Yimin, Vice President, Tax

100%

CVS Pharmacy, Inc.
A Rhode Island Corporation
FEIN 05-0340626
One CVS Drive, Woonsocket, RI 02895
Officers and Directors
DeNale, Carol A., Director, Moffatt, Thomas S., Director
DeNale, Carol A., President/Treasurer, Moffatt, Thomas S., Vice President/Secretary
Beaulieu, Sheelagh M., Assistant Treasurer, Cole, Joshua C., Assistant Treasurer
DeSousa, Kimberley M., Assistant Secretary, Smith, Joshua J., Assistant Secretary
St Angelo, Melanie K., Assistant Secretary

100%

CVS TN Distribution, L.L.C.
A Tennessee Limited Liability Company
FEIN 06-1630381
One CVS Drive, Woonsocket, RI 02895
Officers
Moffatt, Thomas S., President, DeNale, Carol A., Sr. Vice President/Treasurer,
St Angelo, Melanie K., Secretary, Cole, Joshua C., Assistant Treasurer

Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

WOLTERS KLUWER
K
118 W EDWARDS STE 200
S, IL 62704

August 29, 2023

Request Type: Certificate of Existence/Authorization
Request #: 0544963

Issuance Date: 08/29/2023
Copies Requested: 1

Document Receipt

Receipt # : 008335256 Filing Fee: $20.00

Payment-Credit Card - State Payment Center - CC #: 3857223674 $20.00

Regarding: **CVS TN DISTRIBUTION, L.L.C.**
Filing Type: Limited Liability Company - Domestic
Formation/Qualification Date: 08/16/2001
Status: Active
Duration Term: Perpetual
Business County:

Control # : 412766
Date Formed: 08/16/2001
Formation Locale: TENNESSEE
Inactive Date:

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

CVS TN DISTRIBUTION, L.L.C.

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 062555214



30821

TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH RELATED BOARDS

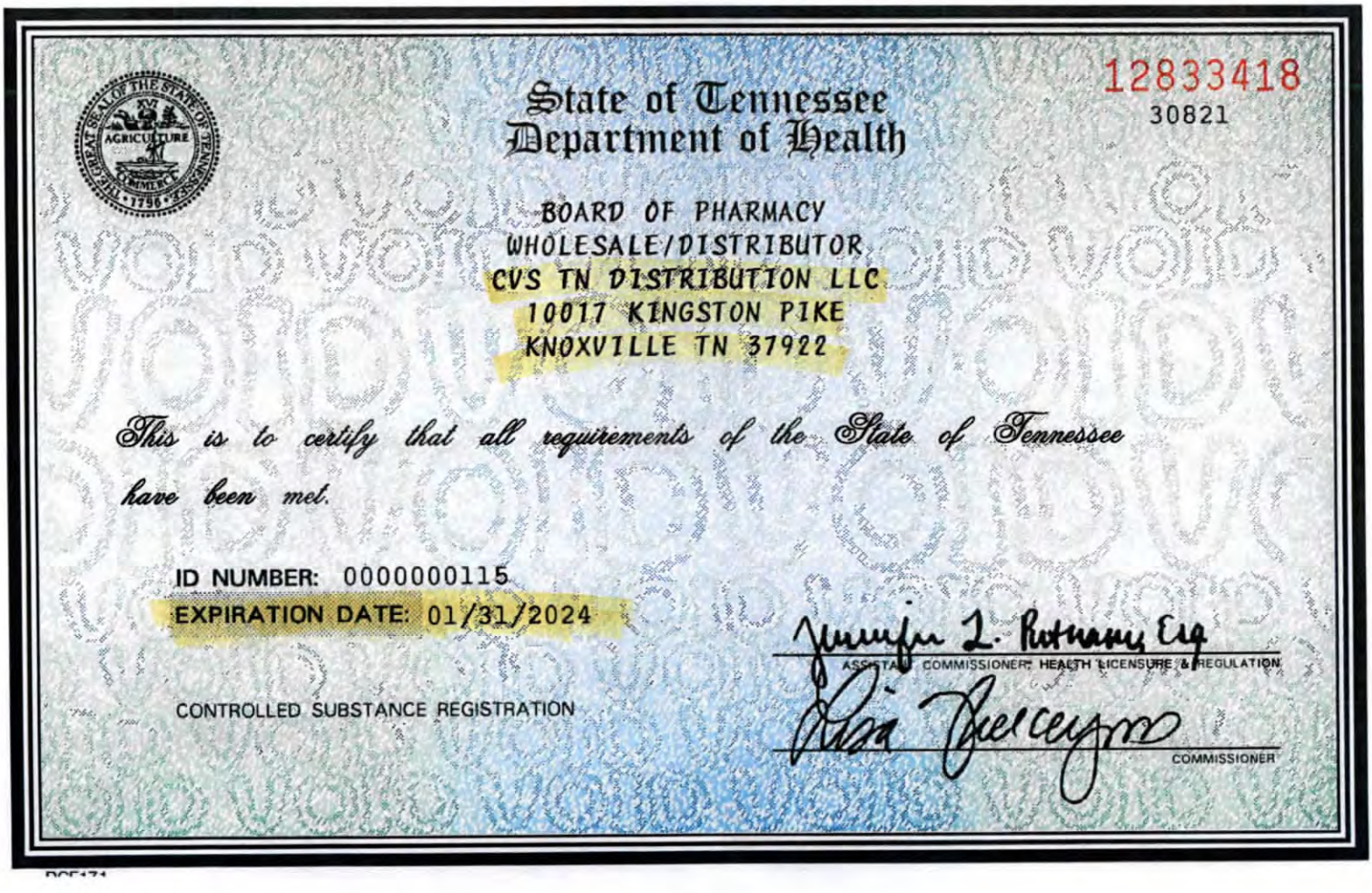
ID NUMBER: 0000000115
EXPIRATION DATE: 01/31/2024

This is to certify that all requirements of the State of Tennessee have been met.

PHARMACY BOARD
WHOLESALE/DISTRIBUTOR
CVS TN DISTRIBUTION LLC

COMMISSIONER OF HEALTH

MIA BRYDEN
CVS TN DISTRIBUTION LLC
ONE CVS DRIVE
LICENSING DEPT
WOONSOCKET RI 02895



12833418
30821

State of Tennessee
Department of Health

BOARD OF PHARMACY
WHOLESALE/DISTRIBUTOR
CVS TN DISTRIBUTION LLC
10017 KINGSTON PIKE
KNOXVILLE TN 37922

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000000115
EXPIRATION DATE: 01/31/2024

CONTROLLED SUBSTANCE REGISTRATION

Jennifer L. Rotnam, Esq
ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
PR0205559	04-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-14-2023

CVS TN DISTRIBUTION, LLC
10017 KINGSTON PIKE
KNOXVILLE, TN 37922

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
PR0205559	04-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-14-2023

CVS TN DISTRIBUTION, LLC
10017 KINGSTON PIKE
KNOXVILLE, TN 37922

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
PR0205559	04-30-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-14-2023

CVS TN DISTRIBUTION, LLC
10017 KINGSTON PIKE
KNOXVILLE, TN 37922

CONTROLLED SUBSTANCE/REGULATED CHEMICAL REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Bryden, Eufemia T

From: Sheila Bush (Support) <pharmacy.health@tn.gov>
Sent: Tuesday, September 05, 2023 4:30 PM
To: Bryden, Eufemia T
Subject: [State of Tennessee] Re: [EXTERNAL] re: LICENSE VERIFICATION for an Out of State WHolesaler application

****** External Email - Use Caution ******

##- Please type your reply above this line -##

Your request (1150976) has been updated. To add additional comments, reply to this email.

Sheila Bush (State of Tennessee)
Sep 5, 2023, 15:29 CDT

Hi,
We will process your request.
Thanks

TN Department of Health

Sheila W Bush |Administrative Director
Tennessee Board of Pharmacy
665 Mainstream Dr
Nashville, TN 37243
tn.gov/health
Connect with TDH on Facebook or Twitter @TNDeptofHealth!

Our Mission - To protect, promote and improve the health and prosperity of people in Tennessee.

Bryden, Eufemia T
Aug 31, 2023, 16:39 CDT

Good afternoon, CVS TN Distribution, LLC is applying for an Out of State Wholesaler license in the state of NV and the board needs this license verification completed. Please process accordingly. Thank you.

Attachment(s)
NV BOP LICENSE VERIFICATION_0001.pdf

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: CVS TN DISTRIBUTION, LLC

Address: 10017 KINGSTON PIKE

City: KNOXVILLE State: TN Zip: 37922

I hereby authorize the TN BOARD OF PHARMACY to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires

Has this license been encumbered in any way? ☐ Yes ☐ No	Type of Encumbrance: (if any) ☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☐ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☐ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☐ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☐ Yes ☐ No

Signature of State Official	Title	State	Date	State Seal

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 015215857

Application/License No. _____

CVS TN Distribution, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 10017 Kingston Pike, Knoxville, TN 37922 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02176 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 29, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 29th day of August, 20 23.

CVS TN Distribution, LLC
APPLICANT/PRINCIPAL

Authorized Representative

Liberty Mutual Insurance Company
SURETY COMPANY

Surety Company's Representative

April D. Perez, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Jessica Iannotta

Witness Annette Audinot

Countersigned by:

n/a
Nevada Resident Agent

Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, April D. Perez

all of the city of Morristown, state of New Jersey each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 29th day of August, 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

Financial Statement – December 31, 2022

Assets

Cash and Bank Deposits	$3,908,755,039
*Bonds — U.S Government	3,451,999,931
*Other Bonds	18,862,255,155
*Stocks	19,372,953,698
Real Estate	190,092,373
Agents' Balances or Uncollected Premiums	7,929,876,358
Accrued Interest and Rents	166,740,412
Other Admitted Assets	15,968,062,977
Total Admitted Assets	**$69,850,735,943**

Liabilities

Unearned Premiums		$10,133,358,204
Reserve for Claims and Claims Expense		27,953,643,316
Funds Held Under Reinsurance Treaties		368,610,620
Reserve for Dividends to Policyholders		1,379,296
Additional Statutory Reserve		197,278,000
Reserve for Commissions, Taxes and Other Liabilities		9,206,000,954
Total		**$47,860,270,390**
Special Surplus Funds	$195,696,103	
Capital Stock	10,000,075	
Paid in Surplus	13,324,803,036	
Unassigned Surplus	8,459,966,339	
Surplus to Policyholders		**21,990,465,553**
Total Liabilities and Surplus		**$69,850,735,943**

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the state of Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2022, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March 2023.

T A Mikolajewski

Assistant Secretary

CVSHealth

Melanie K. St Angelo
Senior Manager, Corporate Services

One CVS Drive
Woonsocket, RI 02895

p 401-770-3565
f 401-652-0941

melanie.luker@cvshealth.com

September 5, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy
#206
Reno NV 89521

Re: CVS TN Distribution, L.L.C.

To Whom It May Concern:

This letter is in response to your request for a personal history record application to be included with the Wholesaler application for CVS TN Distribution, L.L.C., a TN limited liability company (the "Company").

Please be advised that the Company has a single-member owner, CVS Pharmacy, Inc., a Rhode Island corporation, owning 100% of the membership interests in the Company.

CVS TN Distribution, L.L.C.

By: Melanie K. St Angelo
Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler CVS TN DISTRIBUTION, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 10017 KINGSTON PIKE

City KNOXVILLE State TN Zip 37922

Mailing Address (if different from physical address) LICENSING DEPT MC#1160 ONE CVS DRIVE

City WOONSOCKET State RI Zip 02895

Telephone 401-770-5149 Website _____

Licensing Company Email Eufemia.Bryden@cvshealth.com

Section 2: Personal Information

First CHRISTOPHER Middle WAYNE Last PARK

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 10017 KINGSTON PIKE

City KNOXVILLE State TN Zip 37922

Telephone [redacted] Email Christopher.Park@cvshealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)		
TUSCULUM COLLEGE	06/11-05/13		
Address	City	State	Zip
60 SHILOH RD.	TUSCULUM	TN	37745
Diploma/Degree obtained, if any			
BS BUS MGMT CONCENTRATION HUMAN RESOURCES			

School Name	From - To (MM/YY – MM/YY)		
UNIVERSITY OF TN	1982 - 1987		
Address	City	State	Zip
Diploma/Degree obtained, if any			
NO DEGREE			

School Name	From - To (MM/YY – MM/YY)		
LENOIR CITY HIGH SCHOOL	1982		
Address	City	State	Zip
1485 OLD HWY 95	LENOIR	TN	37771
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name	From - To (MM/YY – MM/YY)		
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name	From - To (MM/YY – MM/YY		
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/19-CURRENT	[redacted] HICKORY CREEK	LENOIR	TN	37771
07/05-06/19	[redacted] HIRST CIRCLE	LENOIR	TN	37772
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
CVS TN DISTRIBUTION, LLC			1997-CURRENT	
Business Address		City	State	Zip
10017 KINGSTON PIKE		KNOXVILLE	TN	37921
Phone	Title		Number of Employed Hours	
865-231-9933	SR. MANAGER, DC OPERATIONS		66,593	
Description of Duties				
SEE ATTACHED				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, CHRISTOPHER W. PARK, **certify that as the designated representative for**

CVS TN DISTRIBUTION, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CP I am at least 21 years of age;
3. CP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

CHRISTOPHER PARK
Print Name (First, Last)

Christopher Park
Original Signature (electronic, copies or stamps not accepted)

9-01-23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

CHRISTOPHER W. PARK

Print Name (First, Last)

Christopher Park

Original Signature (electronic, copies or stamps not accepted)

9-1-23

Date

Please have this section completed in the presence of a Notary Public.

State of TN, ss. County of KNOX

I, Christopher PARK, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Christopher Park

Original Signature

9-1-23

Date

Subscribed and Sworn to before me this 1st day of September.

Giovanni Gonzalez

Notary Public Signature

GIOVANNI GONZALEZ
STATE OF TENNESSEE NOTARY PUBLIC
KNOX COUNTY

(Seal)

Chris Park
[redacted]Hickory Creek
Lenoir City, TN
[redacted]

Objective

To obtain a position with a great company which offers me the opportunity for both personal and professional growth. To work in a challenging and rewarding environment where I can use my experience and knowledge.

Experience

1997-Present CVS Caremark Knoxville, TN

Senior Operations Manager

- Plan, organize, schedule, forecast, and coordinate work in order to meet production schedules and operational goals.
- Review/analyze production, quality, and other operational reports, initiating changes, as needed, to ensure a high level of service to store operations.
- Ensure all compliance related items operate within regulated requirements including all DEA, FDA, Dept. of Agriculture regulations.
- Develop and implement plans, procedures, programs, and strategies to enhance performance, service level, and cost-per-piece.
- Prepare departmental budget and control expenditures against approved budget.
- Develop an accountable supervisory staff with an emphasis on teambuilding, communication, performance accountability, and positive employee relations management.
- Promote and reinforce safety and security awareness and compliance and regulatory adherence among the supervisory staff and hourly employee groups
- Ensure maximum utilization of manpower and equipment.
- Oversee all Inventory related aspects of the distribution center including front store product and pharmaceuticals
- Use data from IT systems to evaluate performance and quality and to plan improvements
- Allocate and manage staff resources according to changing needs
- Prepared departmental budget and control expenditures against approved budget

1994-1997 CVS Knoxville,TN

Inventory Control Supervisor

- Planned, organized, scheduled, forecasted, and coordinated work in order to meet production schedules and operational goals.
- Reviewed/analyzed production, quality, and other operational reports, initiated changes, as needed, to ensure a high level of service to store operations.
- Developed and implemented plans, procedures, programs, and strategies to enhance performance, service level, and cost-per-piece.
- Ensure integrity of all inventory within the warehouse as well as the data base for which the WMS operates,
- Promoted and reinforced safety and security awareness and compliance and regulatory adherence among the supervisory staff and hourly employee groups
- Ensured maximum utilization of manpower and equipment.
- Oversaw all Inventory related aspects of the distribution center

including front store and pharmaceutical product.
- Oversee all Inventory related aspects of the distribution center including front store product and pharmaceuticals
- Manage and organize yearly physical inventories.
- Create exception reporting identifying inventory issues upon receipt.
- Work closely with receiving manager to maximize storage space within DC.
- Coordinated shift activities, across multiple departments, relative to workload and labor hours.
- Worked with WMS Programmers in testing new WMS system to support DC.

1991-1994 CVS Knoxville,TN

Central Warehouse Picking/Replenishment Supervisor

- Hired, developed, and motivated a staff of 68-70 hourly and temp employees.
- Oversaw all production aspects for Central Warehouse picking and replenishment activities including scheduling, staffing and all production changes.
- Coordinated shift activities across multiple departments, relative to workload and labor hours.
- Ensured adherence to company standards of quality and productivity
- Evaluated employee performance.
- Demonstrated proficiency with warehouse management system

1988-1991 CVS Knoxville, TN

Lead- Inventory Control

- Provided support and coverage for manager as lead supervisor and point person on the shift.
- Measured and reported the effectiveness of the department activities.
- Maintaining departmental work instructions for all tasks.
- Established or adjusted work procedures to meet warehouse demands as dictated by production schedules and work flow.
- Interpreted company policies to workers and enforcing safety regulations.
- Conferred with other supervisors to coordinate activities of individual departments and serving internal customers.

Education

Lenoir City High School Lenoir City,TN

1982

High School Diploma

University of Tennessee
Knoxville, TN 37996
1982-1987

Tusculum College
60 Shiloh Rd, Tusculum, TN 37745
June 2011- May 2013
Bachelors of Science Degree in Business Management with concentration in Human Resources.

CVS TN Distribution, LLC

Last Name	First Name	Supervisor	Position	Date Hired	FT	PT
White	Mack	Bill Mize	Expeditor	8/8/2016	Y	N
Hart	Shawn	Bill Mize	Expeditor	10/17/2016	Y	N
Murphy	DeLa	Bill Mize	Order Selector	1/31/2022	N	Y
Stanley	Amber	Bill mize	Order Selector	1/9/2023	N	Y
Davis	Eric	Bill Mize	Order Selector	1/30/2023	N	Y
Myers	Jessica	Bill Mize	Order Selector	6/19/2023	N	Y
Anderson	Christopher	Bill Mize	Order Selector	7/26/2021	N	Y
Patterson	Tramaine	Bill Mize	Order Selector	2/22/2021	N	Y
Anderson	Trinity	Bill Mize	Order Selector	12/20/2021	N	Y
Owens	Kinsey	Bill Mize	Order Selector	12/6/2021	Y	N
Moye	Amber	Bill Mize	Order Selector	8/22/2022	Y	N
Amaro	Elizabeth	Bill Mize	Order Selector	9/12/2022	Y	N
Smith	Nicole	Bill Mize	Order Selector	2/13/2023	Y	N
Radkova	Oxana	Bill Mize	Order Selector	3/6/2023	Y	N
Ryan	Daisy	Bill Mize	Order Selector	4/10/2023	Y	N
Sharp	Logan	Bill Mize	Order Selector	5/8/2023	Y	N
Cody	Jami	Bill Mize	Order Selector	5/15/2023	Y	N
Bright	Sarah	Bill Mize	Order Selector	5/2/2023	Y	N
Fitzgerald	Kayla	Bill Mize	Order Selector	5/2/2023	Y	N
Bowden	Carter	Bill Mize	Order Selector	5/30/2023	Y	N
Davis	Brandon	Bill Mize	Order Selector	6/26/2023	Y	N
Sava	Lidia	Bill Mize	Order Selector	12/3/2003	Y	N
Brickey	Martha	Bill Mize	Order Selector	1/30/2012	Y	N
Poudyal	Durga	Bill Mize	Order Selector	9/12/2016	Y	N
Elmore	Janielle	Bill Mize	Order Selector	2/10/2020	Y	N
Burke	Emma	Bill Mize	Order Selector	9/28/2020	Y	N
Bonilla Garcia	Beverly	Bill Mize	Order Selector	1/25/2021	Y	N
King	Cassandra	Bill Mize	Order Selector	8/30/2021	Y	N
Comalander	Jasmine	Bill Mize	Order Selector	9/20/2021	Y	N
Human	Joseph	Bill Mize	Stock Handler	6/27/2022	Y	N
Giese	Eric	Bill Mize	Stock Handler	7/6/2022	Y	N
Johnson	Desmond	Bill Mize	Stock Handler	8/8/2022	Y	N
Hodge	Jacob	Bill Mize	Stock Handler	7/6/2022	Y	N
Oden	Michelle	Bill Mize	Stock Handler	7/25/2006	Y	N
Neeley	Lisa	Bill Mize	Stock Handler	3/1/2011	Y	N
Wright	Katina	Bill Mize	Stock Handler	5/16/2016	Y	N
Roberts	Elijah	Bill Mize	Stock Handler	12/14/2020	Y	N
Franks	Samantha	Bill Mize	Stock Handler	1/25/2021	Y	N
Edwards	Daniel	Bill Mize	Stock Handler	8/9/2021	Y	N
Perkins	Phillip	Bill Mize	Tote Stocker	9/25/2017	Y	N
Pierce	Julia	Brian Hall	Order Selector	3/7/2022	N	Y
Guinn	Kathy	Brian Hall	Order Selector	1/2/2017	N	Y
Johnson	Lacey	Brian Hall	Order Selector	5/22/2017	N	Y
Pirkle	Mary	Brian Hall	Order Selector	7/19/2021	N	Y
Shultz	Sara	Brian Hall	Order Selector	8/30/2021	N	Y
Occil	Marthe	Brian Hall	Order Selector	1/3/2022	Y	N
Pabins	Christopher	Brian Hall	Order Selector	2/21/2022	Y	N
Svacha	Jiashu (Cameron)	Brian Hall	Order Selector	3/7/2022	Y	N
Landrum	Taylor	Brian Hall	Order Selector	6/27/2022	Y	N
Moran	Damari	Brian Hall	Order Selector	1/23/2023	Y	N

Russ	Mariah	Brian Hall	Order Selector	2/20/2023	Y	N
Brawner	Korra	Brian Hall	Order Selector	2/27/2023	Y	N
Watters	Rhiannon	Brian Hall	Order Selector	5/15/2023	Y	N
Frazier	Ian	Brian Hall	Order Selector	5/15/2023	Y	N
Turner	Haley	Brian Hall	Order Selector	5/30/2023	Y	N
VanWeerd	Paula	Brian Hall	Order Selector	8/7/2023	Y	N
Ramirez	Baybi	Brian Hall	Order Selector	8/21/2023	Y	N
Bruton	Janet	Brian Hall	Order Selector	6/2/1996	Y	N
Ryan	Kathy	Brian Hall	Order Selector	1/27/1999	Y	N
Williams	Rose	Brian Hall	Order Selector	9/17/2001	Y	N
Swicegood	Connie	Brian Hall	Order Selector	11/8/2005	Y	N
Grajqevci	Kimete	Brian Hall	Order Selector	3/13/2012	Y	N
Richards	Crystal	Brian Hall	Order Selector	3/10/2014	Y	N
Blazier	Laura	Brian Hall	Order Selector	8/8/2016	Y	N
Mayes	Tabitha	Brian Hall	Order Selector	6/26/2017	Y	N
Harrison	Alysa	Brian Hall	Order Selector	3/4/2019	Y	N
Haghdadi	Hajar	Brian Hall	Order Selector	11/11/2019	Y	N
Mullins	Jessica	Brian Hall	Order Selector	2/10/2020	Y	N
Morris	Susan	Brian Hall	Order Selector	8/31/2020	Y	N
Warren	Angela	Brian Hall	Order Selector	11/2/2020	Y	N
Bishop	Melissa	Brian Hall	Order Selector	11/9/2020	Y	N
Daby-Pabins	Stefanie	Brian Hall	Order Selector	7/6/2021	Y	N
Kimbrell	Kelly	Brian Hall	Order Selector	10/25/2021	Y	N
Long	Jamia	Brian Hall	Rx Picker	7/22/1997	N	Y
Woods	Chesney	Brian Hall	Warehouse Lead	3/1/2011	Y	N
Sexton	Allen	Johnson	Chaser	3/6/2023	N	Y
Boudreaux	John	Johnson	Chaser	6/20/2022	Y	N
Bethel	Sherri	Johnson	Chaser	12/5/2022	Y	N
Cline	Jon	Johnson	Chaser	1/9/2023	Y	N
Sneed	Kayla	Johnson	Chaser	2/13/2023	Y	N
McCarthy	Stephen	Johnson	Chaser	2/13/2023	Y	N
Warren	Joe	Johnson	Chaser	9/16/1999	Y	N
Thomas	Dustin	Johnson	Chaser	5/24/2005	Y	N
Powers	John	Johnson	Chaser	5/5/2010	Y	N
Cox	Brandon	Johnson	Expeditor	7/15/2019	Y	N
Berube	Bryan	Johnson	Expeditor	7/26/2021	Y	N
Wilson	Neil	Johnson	Stock Handler	4/29/2019	N	Y
Williams	David	Johnson	Stock Handler	6/13/2022	Y	N
Bryant	Tausha	Johnson	Stock Handler	10/31/2022	Y	N
Larson	Dana	Johnson	Stock Handler	5/7/1991	Y	N
Cornett	James	Johnson	Stock Handler	1/14/2002	Y	N
Walden	Heather	Johnson	Stock Handler	1/25/2006	Y	N
Bennett	Nicholas	Johnson	Stock Handler	6/1/2015	Y	N
Waters	Crystal	Johnson	Stock Handler	4/11/2016	Y	N
Symes	William	Johnson	Stock Handler	5/23/2016	Y	N
Walker	Kara	Johnson	Stock Handler	8/28/2017	Y	N
Johnson	Dominick	Johnson	Stock Handler	8/27/2018	Y	N
Johnson	Amanda	Johnson	Stock Handler	6/24/2019	Y	N
Johnson	Jerald	Johnson	Stock Handler	7/12/2021	Y	N
Berube	Rema	Johnson	Stock handler	8/9/2021	Y	N
Buckman	Kevin	Johnson	Tote Stocker	3/27/2002	Y	N
Shultz	Robert	Johnson	Tote Stocker	9/23/2003	Y	N

Russell	Arnold	Johnson	Utility	10/4/1982	Y	N
Nelson	Kenneth	Woods	FC Picker	1/19/2015	Y	N
Turner	Everette	Woods	FC Picker	11/9/2015	Y	N
Duncan	Jason	Woods	FC Picker	10/1/2018	Y	N
Helton	Keegan	Woods	Full Case	2/14/2022	Y	N
Caufield	Dakota	Woods	Loader	6/27/2022	Y	N
Loveridge	Jeff	Woods	Loader	4/10/2023	Y	N
Sharp	John	Woods	Loader	5/15/2023	Y	N
Williams	Brandon	Woods	Loader	5/15/2023	Y	N
Hensley	Christopher	Woods	Loader	6/6/2023	Y	N
Watkins	Zachery	Woods	Loader	8/10/2015	Y	N
Meyer	Ian	Woods	Loader	1/11/2016	Y	N
Austin	JR	Woods	Loader	4/4/2016	Y	N
Sexton	Richard	Woods	Loader	7/10/2017	Y	N
Woodward	Marc	Woods	Loader	6/8/2020	Y	N
Boone	Richard	Woods	Loader	10/26/2020	Y	N
Mendoza	Omar	Woods	Lodaer	7/26/2021	Y	N
Pitts	Joshua	Woods	Non-Con	8/8/2016	Y	N
Warren	Justin	Woods	Sorter Operator	1/14/2003	Y	N
Hodge	James	Woods	Warehouse Lead	7/20/1998	Y	N
Wilson	Tom	Chris Park	Ops Manager	6/26/2023	Y	N
Leonard	Robin	Chris Park	Production Admin	9/27/2005	Y	N
O'Domirok	Lori	Chris Park	Production Coordinator	8/27/1989	Y	N
Rollins	James	Sanford	Director		Y	N
Eads	Jordan	Whitham	AP Supervisor	1/23/2023	Y	N
Craig	Dexter	Whitham	Quality Auditor	2/22/2005	Y	N
Osmani	Leonora	Whitham	Quality Checker	6/11/2018	Y	N
Neely	Anthony	Doug Hill	Central Rack Picker	6/22/2020	Y	N
Hackler	Shawn	Doug Hill	Central Racks	4/2/2018	Y	N
Wilcox	Lisa	Doug Hill	Janitor	8/27/2018	N	Y
Ault III	Edward	Doug Hill	Putaway	6/5/1978	Y	N
Willis Jr	Glenn	Doug Hill	Putaway	3/13/1989	Y	N
Kerley	Mikel	Doug Hill	Putaway	9/17/1990	Y	N
Pendleton	Daniel	Doug Hill	Putaway	12/23/2003	Y	N
Bosworth	Aslan	Doug Hill	Receiver	7/1/2003	Y	N
Riggs	Melissa	Doug Hill	Receiver	9/9/2003	Y	N
Shell	Sandra	Doug Hill	Receiver	4/27/2004	Y	N
Brewer	Kathy	Doug Hill	Receiver	5/22/2000	Y	N
Parks	Jamey	Doug Hill	Receiver	9/8/2005	Y	N
King	Sarah	Doug Hill	Receiver	8/28/2017	Y	N
Riggs	Katelin	Doug Hill	Receiver	8/5/2019	Y	N
Ervin	Will	Doug Hill	Receiving Clerk	5/22/2007	Y	N
McNabb	Allison	Doug Hill	Returns	8/26/1996	Y	N
Godsey	James	Doug Hill	Shuttle Loader	7/20/2004	Y	N
Melton	Scott	Doug Hill	Supervisor	8/1/2022	Y	N
Johnson	Chad	Doug Hill	Supervisor	8/15/2023	Y	N
Williams	Everette	Doug Hill	Utility	9/14/2004	Y	N
Kirsch	Susan	Doug Hill	Warehouse Lead	12/19/2016	Y	N
Montgomery	Jeffery	Elsa Smith	Driver	1/30/2023	Y	N
Styles	Keyon	Elsa Smith	Driver	2/6/2023	Y	N
Wells	Nancy	Elsa Smith	Supervisor	12/16/1985	Y	N
Goforth	William	Elsa Smith	Supervisor	4/21/2014	Y	N

Poche	Brandon	Elsa Smith	Transportation Admin	8/7/2023	Y	N
Morgan	Kevin	Elsa Smith	Truck Driver	11/29/2021	Y	N
Shaw	Justin	Elsa Smith	Truck Driver	7/25/2022	Y	N
LaRue	Josh	Elsa Smith	Truck Driver	8/29/2022	Y	N
Okafor	Tony	Elsa Smith	Truck Driver	12/13/2022	Y	N
Nguyen	Louis	Elsa Smith	Truck Driver	7/26/2021	Y	N
Talmadge	James	Elsa Smith	Truck Driver	10/3/2022	Y	N
Phelps	Jordan	Elsa Smith	Truck Driver	10/24/2022	Y	N
Daniels	Matthew	Elsa Smith	Truck Driver	1/4/2023	Y	N
Smith	Jaleel	Elsa Smith	Truck Driver	3/13/2023	Y	N
Bash	Eric	Elsa Smith	Truck Driver	4/17/2023	Y	N
Blakeman	Ferrel	Elsa Smith	Truck Driver	5/15/2023	Y	N
Hawkins	Lucas	Elsa Smith	Truck Driver	5/15/2023	Y	N
Ehlers	Randall	Elsa Smith	Truck Driver	5/2/2023	Y	N
Higgins	David	Elsa Smith	Truck Driver	5/2/2023	Y	N
Talmadge	Eric	Elsa Smith	Truck Driver	6/26/2023	Y	N
Clark	William	Elsa Smith	Truck Driver	5/24/1977	Y	N
Franklin	Ronald	Elsa Smith	Truck Driver	4/6/1993	Y	N
Presley	Ron	Elsa Smith	Truck Driver	10/22/1991	Y	N
Samler	William	Elsa Smith	Truck Driver	2/14/1995	Y	N
Haynes	Ralph	Elsa Smith	Truck Driver	10/1/2004	Y	N
Dixon	Michael	Elsa Smith	Truck Driver	2/6/2005	Y	N
Kinkead	Mark	Elsa Smith	Truck Driver	4/10/2006	Y	N
Ferguson	Danny	Elsa Smith	Truck Driver	8/21/2006	Y	N
Cox	Rickey	Elsa Smith	Truck Driver	2/17/2010	Y	N
Selby	Daniel	Elsa Smith	Truck Driver	3/1/2010	Y	N
Franklin	Standford	Elsa Smith	Truck Driver	12/6/2010	Y	N
Evatt	Chadrick	Elsa Smith	Truck Driver	6/20/2011	Y	N
Smith	David	Elsa Smith	Truck Driver	1/20/2014	Y	N
Sather	Timothy	Elsa Smith	Truck Driver	8/26/2013	Y	N
Wolfe	Daniel	Elsa Smith	Truck Driver	4/20/2015	Y	N
Jordan	Andy	Elsa Smith	Truck Driver	8/3/2015	Y	N
Phillips	Michael	Elsa Smith	Truck Driver	8/28/2017	Y	N
Hooks	Jason	Elsa Smith	Truck Driver	11/26/2018	Y	N
Clark	Richard	Elsa Smith	Truck Driver	12/3/2018	Y	N
Bullard	Timothy	Elsa Smith	Truck Driver	12/21/2018	Y	N
Warren	Jeff	Elsa Smith	Truck Driver	3/2/2020	Y	N
Roberts	Edwin	Elsa Smith	Truck Driver	8/19/2019	Y	N
Williams	Nathaniel	Elsa Smith	Truck Driver	9/23/2019	Y	N
Lewis	William	Elsa Smith	Truck Driver	10/7/2019	Y	N
Isley	Steven	Elsa Smith	Truck Driver	8/24/2020	Y	N
Karnes	Steven	Elsa Smith	Truck Driver	10/11/2021	Y	N
Griffin	Christopher	Elsa Smith	Truck Driver	11/16/2020	Y	N
Jeffries	Jarod	Elsa Smith	Truck Driver	5/16/2011	Y	N
Nelis	David	Elsa Smith	Truck Driver	5/10/2021	Y	N
Mee	Brian	Elsa Smith	Truck Driver	12/6/2021	Y	N
Ray	Joseph	Elsa Smith	Truck Driver	6/2/2021	Y	N
Littleton	Kimber	Elsa Smith	Yard Jockey	2/24/2014	Y	N
Collier	James	Elsa Smith	Yard Jockey	11/5/2018	Y	N
Foley	Mark	Elsa Smith	Yard Jockey	12/30/2019	Y	N
Huffman	Kimberly	TERRY	Exception Clerk	7/1/2003	Y	N
Abbott	Pamela	TERRY	IC	6/27/1989	Y	N

Hawkins	Joseph	TERRY	IC	9/16/1992	Y	N
Ogle	Vicki	TERRY	IC	8/12/2003	Y	N
Moulden	Rosella	TERRY	IC	9/2/1986	Y	N
Hawkins	Lisa	TERRY	IC	7/22/1990	Y	N
Ray	Kimberly	TERRY	IC	12/14/2000	Y	N
Goins	Lillian	TERRY	IC	11/22/1999	Y	N
Raley	Patricia	TERRY	IC	3/19/1984	Y	N
Burnette	Janis	TERRY	IC	8/27/1979	Y	N
Gentry	Beth	TERRY	IC	6/27/2007	Y	N
Monger	Melissa	TERRY	IC	5/22/2000	Y	N
Lane	Tiffany	TERRY	IC	5/1/2000	Y	N
Raley	Richard	TERRY	IC	11/15/1983	Y	N
Warren	Stephanie	TERRY	IC	5/18/2004	Y	N
Arden	Tommy	TERRY	IC	10/10/1983	Y	N
Monroe	Lanelle	TERRY	IC	8/30/1978	Y	N
Coleman	Virginia	TERRY	IC	10/6/2014	Y	N
Inch-Newman	Jeanine	TERRY	IC	4/6/2015	Y	N
McNelly	Suzanne	TERRY	IC	12/4/2017	Y	N
Gilbert	Taneshia	TERRY	IC Clerk	8/23/2004	Y	N
Jeffers	Martha	TERRY	Return Goods	6/3/1976	Y	N
Joiner	Mavis	TERRY	Return Goods	7/31/1976	Y	N
Shope	Ann	TERRY	Return Goods	9/26/1977	Y	N
Richardson	Christopher	TERRY	UPS	10/22/2002	Y	N
Bryant	Susan	TERRY	Warehouse Lead	2/28/1983	Y	N
Weber	Richard	Frank Kiser	Manager	6/1/2003	Y	N
Pollino	Niki	Grace Boyd	HR Coordinator	4/18/2022	Y	N
Smith	Elsa	Farrell	Transportation Manager	3/31/1991	Y	N
Freels	Michael	Jim Rollins	Industrial Engineer	6/18/2012	Y	N
Justice	Yvette	Jim Rollins	IT Manager	9/4/1990	Y	N
Hill	Doug	Jim Rollins	Manager	11/16/1981	Y	N
Miller	Shannon	Jim Rollins	Manager	6/7/1993	Y	N
Kelley	Ron	Jim Rollins	Manager	8/22/1977	Y	N
Park	Christopher	Jim Rollins	Manager	6/4/1982	Y	N
Felker	Terry	Jim Rollins	Manager	10/10/1977	Y	N
Hall	Brian	Jim Rollins	Manager	4/20/2009	Y	N
McIntosh	Robert	Jim Rollins	Supervisor	3/13/2023	Y	N
Helton	Stacy	Jim Rollins	Supervisor	11/10/1994	Y	N
Mullins	Randy	Jim Rollins	Supervisor	8/16/1979	Y	N
Morrow	Christopher	Jim Rollins	Supervisor	1/20/2004	Y	N
Johnson	Liz	Jim Rollins	Supervisor	6/1/2004	Y	N
McCurry	John	Jim Rollins	Supervisor	10/23/2000	Y	N
Stinson	Greg	Jim Rollins	Supervisor	3/12/2007	Y	N
Eisenmann	Timothy	Jim Rollins	Supervisor	10/20/2009	Y	N
Studwell	Matthew	Jim Rollins	Supervisor	5/20/2013	Y	N
Mize	William	Jim Rollins	Supervisor	3/7/2016	Y	N
Coulter	David	Jim Rollins	Supervisor	10/10/2016	Y	N
Moye	Bailey	McCurry	Order Selector	2/28/2022	N	Y
Santacruz	Aura	McCurry	Order Selector	4/4/2022	N	Y
Clark	Carolette	McCurry	Order Selector	9/12/2022	N	Y
Cole	Shirley	McCurry	Order Selector	12/18/2006	N	Y
Evans	Destiny	McCurry	Order Selector	10/25/2021	N	Y
Cochran	Matthew	McCurry	Order Selector	6/27/2022	Y	N

Hayward	Thomas	McCurry	Order Selector	4/18/2022	Y	N
Mynatt	Jonathan	McCurry	Order Selector	2/28/2022	Y	N
Campbell	Andy	McCurry	Order Selector	7/6/2022	Y	N
Moye	Raylen	McCurry	Order Selector	8/22/2022	Y	N
Mills	Kanisha	McCurry	Order Selector	9/12/2022	Y	N
Magley	Vivian	McCurry	Order Selector	9/7/2022	Y	N
McGhee	Amber	McCurry	Order Selector	2/6/2023	Y	N
Wiseman	KeNiya	McCurry	Order Selector	4/3/2023	Y	N
Blades	Tabitha	McCurry	Order Selector	5/15/2023	Y	N
Scott	Nathaniel	McCurry	Order Selector	6/6/2023	Y	N
Mason	Adarria	McCurry	Order Selector	6/12/2023	Y	N
Morales	Adrian	McCurry	Order Selector	6/26/2023	Y	N
Hart	Cindy	McCurry	Order Selector	7/31/1978	Y	N
Myers	Sheila	McCurry	Order Selector	12/13/1999	Y	N
Hensley	Sheila	McCurry	Order Selector	9/24/2001	Y	N
Occil	Marie	McCurry	Order Selector	10/6/2009	Y	N
Scudder	Ada	McCurry	Order Selector	1/11/2011	Y	N
Davis	Hayes	McCurry	Order Selector	9/20/2021	Y	N
Burek	Timothy	McCurry	Stock Handler	3/27/2023	Y	N
Hackworth	Eddie	McCurry	Stock Handler	7/26/1999	Y	N
Sava	Vickie	McCurry	Stock Handler	12/3/2003	Y	N
Sava	Felician	McCurry	Stock Handler	11/2/2004	Y	N
Johnson	Scott	McCurry	Stock Handler	1/11/2011	Y	N
Smith	Sharon	McCurry	Stock Handler	4/7/2014	Y	N
Campbell	Christopher	McCurry	Stock Handler	10/22/2014	Y	N
Miller	Alex	McCurry	Stock Handler	9/21/2020	Y	N
Rose	Joshua	McCurry	Stock Handler	8/23/2021	Y	N
Womble	Robert	McCurry	Tote Stocker	6/10/2013	Y	N
Huckleby	David	McCurry	Utility	11/18/2003	Y	N
Kizer	Clarence	McCurry	Warehouse Lead	11/14/1979	Y	N
Whitham	David	Mortelliti	LP Manager	2/9/2015	Y	N
Best	Daniel	Liz Johnson	Order Selector	6/1/2022	N	Y
Henderson	Jacob	Liz Johnson	Order Selector	8/28/2022	N	Y
Moralez	Stephanie	Liz Johnson	Order Selector	6/19/2023	N	Y
Reich	Makayla	Liz Johnson	Order Selector	11/1/2021	N	Y
Ward	Tania	Liz Johnson	Order Selector	11/15/2021	Y	N
Posa	Lisa	Liz Johnson	Order Selector	5/16/2022	Y	N
Scott	Wanda	Liz Johnson	Order Selector	6/20/2022	Y	N
Webb	Dezarae	Liz Johnson	Order Selector	8/1/2022	Y	N
Chapman	Laurel	Liz Johnson	Order Selector	12/19/2022	Y	N
Allen	Tamara	Liz Johnson	Order Selector	10/3/2022	Y	N
Skinner	Melissa	Liz Johnson	Order Selector	2/13/2023	Y	N
Jump	Lora	Liz Johnson	Order Selector	2/20/2023	Y	N
Umphrey	Candice	Liz Johnson	Order Selector	3/27/2023	Y	N
McMahan	Cheyenne	Liz Johnson	Order Selector	4/17/2023	Y	N
Hipsher	Rori	Liz Johnson	Order Selector	4/24/2023	Y	N
Combs	Jeffrey	Liz Johnson	Order Selector	5/2/2023	Y	N
Magee	Daniel	Liz Johnson	Order Selector	6/19/2023	Y	N
Chavez	Alexis	Liz Johnson	Order Selector	6/19/2023	Y	N
Gallman	Charlean	Liz Johnson	Order Selector	7/31/2000	Y	N
Raby	Camille	Liz Johnson	Order Selector	9/9/2019	Y	N
Romero	Reyna	Studwell	Exception Clerk	9/4/2012	Y	N

Jarboe	Jamal	Studwell	Expeditor	5/21/2018	Y	N
Troxell	Paul	Studwell	Loader	5/2/2016	N	Y
Davis	Sidney	Studwell	Loader	6/29/2020	N	Y
Harrington	Tom	Studwell	Loader	8/1/2001	Y	N
Mendoza	Jaylene	Studwell	Order Selector	4/25/2022	Y	N
Russell	Alexis	Studwell	Order Selector	4/4/2022	Y	N
Thomason	Sharon	Studwell	Order Selector	8/28/2022	Y	N
Jones	Taylor	Studwell	Order Selector	1/3/2023	Y	N
Henry	Ava	Studwell	Order Selector	5/8/2023	Y	N
Nix	Destiney	Studwell	Order Selector	5/30/2023	Y	N
Thomas	Whitney	Studwell	Order Selector	5/30/2023	Y	N
Thomas	Whitney	Studwell	Order Selector	5/30/2023	Y	N
Taylor	Stefanie	Studwell	Order Selector	6/6/2023	Y	N
Cequea	Maria	Studwell	Order Selector	7/10/2023	Y	N
Gregory	Jackson	Studwell	Order Selector	7/24/2023	Y	N
Hooker	Anita	Studwell	Order Selector	12/5/2006	Y	N
Zambrana	Maria	Studwell	Order Selector	1/11/2011	Y	N
Axmacher	Cynthia	Studwell	Order Selector	6/19/2012	Y	N
Ozdemir	Nihal	Studwell	Order Selector	7/31/2017	Y	N
Rodriguez	Yuseni	Studwell	Order Selector	10/2/2017	Y	N
Khorsheed	Bayan	Studwell	Order Selector	8/20/2018	Y	N
Wade	Nicholas	Studwell	Order Selector	1/28/2019	Y	N
Parton	Eric	Studwell	Order Selector	9/13/2021	Y	N
Magnee	Samantha	Studwell	Order Selector	8/31/2020	Y	N
Smith	Nancy	Studwell	Receiver	7/21/2010	Y	N
Morgan	Scott	Studwell	Receiver	5/22/2017	Y	N
Hutchison	Daniel	Studwell	Rx Machine Operator	7/31/2007	Y	N
Queener	Norman	Studwell	Rx Receiver	6/17/2013	Y	N
Sharp	Brandon	Studwell	Rx Receiver	3/10/2014	Y	N
Heaton	Michael	Studwell	Stock Handler	8/7/2023	Y	N
Driggers	Justin	Studwell	Stock Handler	9/22/2014	Y	N
O'Hara	Sean	Studwell	Stock Handler	4/4/2016	Y	N
Gose	John	Studwell	Stock Handler	7/12/2021	Y	N
Whitsell	Derick	Studwell	Tote Stocker	3/11/2019	Y	N
Stombaugh	Devin	Studwell	Trailer Stripper	8/28/2022	Y	N
Martin	Grada	Studwell	Utility	10/25/2000	Y	N
Reott	Jeffrey	Studwell	Warehouse Lead	10/1/2006	Y	N
Burke	Robert	Freels	Admin	1/9/2023	Y	N
Russell	Tamara	Nancy Wells	Transportation Clerk	6/8/1984	Y	N
Carver	Robert	Nancy Wells	Transportation Clerk	1/13/2020	Y	N
Miller	Samuel	Coulter	Central Rack Picker	3/20/2023	N	Y
Bennett	Betsy	Coulter	Exception Clerk	3/6/1989	Y	N
Borthwick	Aaron	Coulter	Expeditor	4/5/2022	Y	N
Luttrell	Michael	Coulter	Machine Operator	2/24/2009	Y	N
Johnson	Stacy	Coulter	Machine Operator	2/8/2016	Y	N
Phillips	Morgan	Coulter	Machine Opertor	5/14/2019	Y	N
Best	Donna	Coulter	Stock Handler	2/24/2009	Y	N
Kirshman	Kara	Coulter	Stock Handler	8/15/2016	Y	N
Lawson	Amy	Coulter	Stock Handler	6/19/2017	Y	N
Carmen	Amy	Coulter	Stock Handler	10/5/2020	Y	N
Burnette	Billie	Coulter	Stock/Receiver	9/24/2012	Y	N
Stinnett, Jr.	Robert	Coulter	Stock/Receiver	8/25/2014	Y	N

Johnson	Christopher	Coulter	Tote Stocker	4/10/2023	Y	N
Aikens	Randall	Coulter	Truck Loader	11/13/2012	Y	N
Johnson	David	Coulter	Warehouse Lead	5/4/2015	Y	N
Hayward	Jack	Mullins	Chaser	7/11/2022	Y	N
Wells	Jeramie	Mullins	Chaser	9/19/2022	Y	N
Jones	John	Mullins	Chaser	10/3/2022	Y	N
Blair	Ashley	Mullins	Chaser	1/3/2023	Y	N
Bolin	Joshua	Mullins	Chaser	8/14/2023	Y	N
Boles	Daren	Mullins	Chaser	9/17/1979	Y	N
Smith	Gregory	Mullins	Chaser	4/30/1990	Y	N
Thompson	Chad	Mullins	Chaser	9/12/1994	Y	N
Sava	Daniela	Mullins	Chaser	12/3/2003	Y	N
Cox	Ronald	Mullins	Chaser	7/11/2001	Y	N
Sava	Ruben	Mullins	Chaser	11/2/2004	Y	N
Tapp	Daniel	Mullins	Chaser	11/9/2004	Y	N
Glass	Jerry	Mullins	Chaser	7/17/2007	Y	N
Cole	Ronda	Mullins	Chaser	3/1/2011	Y	N
Kirby	James	Mullins	Chaser	2/22/2016	Y	N
Long	Christopher	Mullins	Chaser	9/26/2016	Y	N
Sheadrick	Joe	Mullins	Chaser	6/8/2020	Y	N
Connatser	Noah	Mullins	Chaser	7/20/2020	Y	N
Cole	Dennis	Mullins	Chaser	10/26/2020	Y	N
Boykins	Melvin	Mullins	Chaser	10/18/2021	Y	N
Abbott	Timothy	Mullins	Equipment Operator	11/15/1979	Y	N
Colavecchio	David	Mullins	Equipment Operator	9/9/1991	Y	N
Cupp	Jerry	Mullins	Equipment Operator	5/17/1976	Y	N
Garner	John	Mullins	Equipment Operator	4/14/1997	Y	N
Garner	Todd	Mullins	Equipment Operator	9/20/1994	Y	N
Hill	James	Mullins	Equipment Operator	10/26/1993	Y	N
Lawson	Nicholas	Mullins	Machine Pick	8/5/2013	Y	N
Kirkland	David	Mullins	Man-Up	5/28/2013	Y	N
Davis	Robert	Mullins	Receiver/Putaway	9/12/1994	Y	N
Tarwater	James	Mullins	Warehouse Lead	1/14/2003	Y	N
Cross	Carolyn	Rick Weber	Janitor	1/25/1993	Y	N
Jones	Michael	Rick Weber	Janitor	1/21/2003	Y	N
Sliger	Eric	Rick Weber	Maintenance	6/9/2005	Y	N
Magnee	Hayden	Rick Weber	Maintenance	10/5/2015	Y	N
Gwinn	Jeremy	Rick Weber	Maintenance Mech I	10/17/2001	Y	N
Gardner	Richard	Rick Weber	Maintenance Mech II	6/13/1984	Y	N
Guyton	Richard	Rick Weber	Maintenance Mech II	6/18/1984	Y	N
Perkins	David	Rick Weber	Maintenance Mech II	10/30/1997	Y	N
Hackler	Jordyn	Rick Weber	Porter	12/19/2022	Y	N
Collette	Michael	Rick Weber	Porter	3/15/1993	Y	N
Harness	Tiffiny	Rick Weber	Porter	10/14/2003	Y	N
Ramsey	Daniel	Rick Weber	Porter	2/7/2006	Y	N
Ozdemir	Hilal	Rick Weber	Porter	7/24/2017	Y	N
Nelson	Michael	Rick Weber	Warehouse Lead	4/29/1998	Y	N
Dixon	Andre	Melton	Expeditor	10/5/2000	Y	N
Vyazovoy	David	Melton	Expeditor	11/16/2011	Y	N
Forrester	Otis	Melton	Putaway	10/9/2000	Y	N
Olson	Michael	Melton	Receiver	9/23/1991	Y	N
Amburn	Deana	Melton	Receiver	2/23/1987	Y	N

Clarkson	Tracy	Melton	Receiver	6/5/2002	Y	N
Powers	Kevin	Melton	Receiver	1/11/2011	Y	N
West- 10hr	Patricia	Melton	Receiving Clerk	11/2/1980	Y	N
Woods	Eric	Melton	Rx Receiver	3/2/2005	Y	N
Hauk	Justin	Melton	Rx Receiver	4/19/2010	Y	N
Spicoli	Maria	Melton	Rx Receiver	4/18/2008	Y	N
Byrd	Tony	Melton	Shuttle Loader	12/6/2010	Y	N
King	Tammie	Melton	Stock Handler	4/11/2002	Y	N
Shortridge	Karen	Melton	Stock Handler	5/11/2000	Y	N
Johnson	Connie	Melton	Stock Handler	9/24/2001	Y	N
Bryant	Ronald	Melton	Stock Handler	3/2/2004	Y	N
Lawson	Jimmy	Melton	Stock Handler	5/16/2006	Y	N
Tatum	Chandra	Melton	Stock Handler	4/7/2014	Y	N
Hasani	Agim	Melton	Stock Handler	10/10/2016	Y	N
Stroup	Zachery	melton	Stock Handler	11/28/2016	Y	N
Turner	Kimberly	Melton	Stock Handler	10/1/2018	Y	N
Bartell	Leticia	Melton	Stock Handler	3/26/2018	Y	N
Shafer	Bobby	Melton	Stock Handler	10/22/2018	Y	N
Carroll	Wendy	Melton	Stock Handler	1/24/2014	Y	N
Williams	Edward	Melton	Tote Stocker	6/3/1993	Y	N
Sweet	Steven	Melton	Trailer Stripper	5/24/2006	Y	N
Ray	Bryan	melton	Trailer Stripper	5/24/2006	Y	N
Mullins	Dylan	Melton	Trailer Stripper	2/11/2019	Y	N
Pietarila	James	Melton	Utility	3/13/2023	Y	N
Maynard	Lawrence	Melton	Utility	4/4/1986	Y	N
Baker	James	Melton	Warehouse Lead	11/16/2010	Y	N
Weiler	Tommy	Melton	Warehouse Lead	7/23/2018	Y	N
Burnette	Robert	Miller	Equipment Operator	9/17/1979	Y	N
Cross	Brian	Miller	Equipment Operator	5/24/1982	Y	N
Mullins	Derek	Miller	Receiver	7/6/2022	N	Y
Jago	Kimberly	Miller	Receiver	8/12/1985	Y	N
Long	Jeremy	Miller	Receiver	3/8/1999	Y	N
Kerr	Carl	Miller	Receiver	5/12/1988	Y	N
Dailey	Donna	Miller	Receiver	6/3/2003	Y	N
Shaw	Jason	Miller	Receiver	2/1/1999	Y	N
Mullins	Pokey	Miller	Receiving Clerk	7/19/1992	Y	N
Woods	Donavan	Miller	Receiving Clerk	5/8/1995	Y	N
Gilliam	Ian	Miller	Operator	2/17/2014	Y	N
Woody	James	Miller	Warehouse Lead	6/13/1985	Y	N
Cahye	Juniveth	Helton	Order Selector	2/14/2022	N	Y
Cable	Laura	Helton	Order Selector	5/16/2022	N	Y
Potter	Jennifer	Helton	Order Selector	4/25/2016	N	Y
Hedrick	April	Helton	Order Selector	1/7/2019	N	Y
Frady	Kimberly	Helton	Order Selector	5/24/2021	N	Y
Runge	Joy	Helton	Order Selector	10/18/2021	N	Y
Berube	Beverly	Helton	Order Selector	8/22/2022	Y	N
Johnson	Bryson	Helton	Order Selector	11/7/2022	Y	N
Williams	Jacee	Helton	Order Selector	12/5/2022	Y	N
Rios	Isaac	Helton	Order Selector	12/5/2022	Y	N
Lupasco	Violetta	Helton	Order Selector	1/3/2023	Y	N
McClellan	Susan	Helton	Order Selector	1/17/2023	Y	N
Cooper	Georgia	Helton	Order Selector	7/15/1990	Y	N

Cornett	Nancy	Helton	Order Selector	4/15/2002	Y	N
Brickey	Kim	Helton	Order Selector	7/20/2004	Y	N
Newberry	Karen	Helton	Order Selector	4/27/2004	Y	N
Marrow	Robin	Helton	Order Selector	9/28/2004	Y	N
Worthington	Carolyn	Helton	Order Selector	12/7/2004	Y	N
Marler	Sherri	Helton	Order Selector	5/10/2005	Y	N
Hackler	Pamela	Helton	Order Selector	5/2/2006	Y	N
Gibson	Katherine	Helton	Order Selector	8/26/2013	Y	N
Nelson	Courtney	Helton	Order Selector	7/14/2014	Y	N
Mainor	Lisa	Helton	Order Selector	10/27/2014	Y	N
Moore	Regina	Helton	Order Selector	7/5/2016	Y	N
Jones	Susan	Helton	Order Selector	8/13/2018	Y	N
McConkey	Kathy	Helton	Order Selector	7/8/2019	Y	N
Helms	Elizabeth	Helton	Order Selector	2/10/2020	Y	N
Nowlin	Lorie	Helton	Order Selector	12/28/2020	Y	N
Lane	Kristen	Helton	Order Selector	7/20/2021	Y	N
Edwards	Leanna	Helton	Order Selector	8/2/2021	Y	N
Martin	Kylee	Helton	Order Selector	8/30/2021	Y	N
Freyman	Cyndee	Helton	Order Selector	10/4/2021	Y	N
McCord	Sarah	Helton	Order Selector	10/18/2021	Y	N
Richey	Maria	Helton	Order Selector	1/3/2022	Y	N
McCullough	Sandra	Helton	Warehouse Lead	6/22/2005	Y	N
Henry	Kaitlyn	O'Brien	Trainer	5/18/2020	Y	N
Zambrana	Jose	Eisenmann	Chaser	9/21/2010	Y	N
Jones	Brian	Eisenmann	Full Case Picker	4/3/2023	Y	N
Young	Michael	Eisenmann	Loader	5/2/2022	N	Y
Kolesar	Elijah	Eisenmann	Loader	7/11/2022	N	Y
McClellan	Robert	Eisenmann	Loader	2/25/2019	N	Y
Baker	Shaun	Eisenmann	Loader	11/11/2019	N	Y
Hallman	Michael	Eisenmann	Loader	10/5/2020	N	Y
Chavarria	Kevin	Eisenmann	Loader	8/1/2022	Y	N
Vineyard	Daniel	Eisenmann	Loader	8/28/2022	Y	N
Givens	Nicholas	Eisenmann	Loader	1/3/2023	Y	N
Paling	Kevin	Eisenmann	Loader	1/30/2023	Y	N
Moser-Bryan	Landen	Eisenmann	Loader	2/6/2023	Y	N
Gray	Christopher	Eisenmann	Loader	3/6/2023	Y	N
Chesney	Joshua	Eisenmann	Loader	3/13/2023	Y	N
Powell	Clinton	Eisenmann	Loader	3/27/2023	Y	N
Jones	Zaria	Eisenmann	Loader	4/17/2023	Y	N
Van Buren	Jason	Eisenmann	Loader	4/24/2023	Y	N
Hall	De'Marius	Eisenmann	Loader	2/27/2023	Y	N
Scott	Brandon	Eisenmann	Loader	5/15/2023	Y	N
McKenna	Starr	Eisenmann	Loader	4/24/2023	Y	N
Hamberger	Scott	Eisenmann	Loader	1/27/2020	Y	N
Mullins	Jessica	Eisenmann	Loader	10/26/2020	Y	N
Marshall	Jerome	Eisenmann	Loader	7/22/2021	Y	N
Moore	Angel	Eisenmann	Loader	11/1/2021	Y	N
Salafzoun	Alireza	Eisenmann	Machine Operator	7/23/2018	Y	N
Hudson	Ronald	Eisenmann	Putaway	10/22/2002	Y	N
Trammell	Christine	Eisenmann	Receiver	12/30/2013	Y	N
Berry	Michael	Eisenmann	Sorter	2/27/2017	Y	N
Webb	Shawn	Eisenmann	Warehouse Lead	4/29/2019	Y	N

Jackson	Rodney	McIntosh	Order Selector	7/11/2023	N	Y
Turkman	Adul	McIntosh	Chaser	6/6/2022	N	Y
Corzo	Gracy	McIntosh	Chaser	1/3/2023	N	Y
Zavaleta	Miguel	McIntosh	Chaser	5/30/2023	N	Y
Pinchak	Samuel	McIntosh	Chaser	8/28/2022	Y	N
Itzen	Jessica	McIntosh	Chaser	5/30/2023	Y	N
Vingoe	Danielle	McIntosh	Chaser	6/19/2023	Y	N
Gray	Cody	McIntosh	Chaser	8/7/2023	Y	N
Harris	Raymond	McIntosh	Chaser	11/16/2011	Y	N
Nix	Robert	McIntosh	Order Selector	3/7/2022	N	Y
Bringhurst	Mark	McIntosh	Order Selector	5/2/2022	N	Y
Newport	Summer	McIntosh	Order Selector	6/13/2022	N	Y
Montgomery	Sarah	McIntosh	Order Selector	8/15/2022	N	Y
Rosenbaum	Lucas	McIntosh	Order Selector	10/3/2022	N	Y
Forester	Natosha	McIntosh	Order Selector	1/9/2023	N	Y
Barranco	Claudia	McIntosh	Order Selector	9/27/2021	N	Y
Lewis	Jacklen	McIntosh	Order Selector	10/3/2022	Y	N
Stiles	Courtney	McIntosh	Order Selector	3/27/2023	Y	N
Shell	Lauren	McIntosh	Order Selector	4/17/2023	Y	N
Scott	Johnny	McIntosh	Order Selector	4/24/2023	Y	N
Jean Pierre	Dichty	McIntosh	Order Selector	4/24/2023	Y	N
Snell	Ashley	McIntosh	Order Selector	6/19/2023	Y	N
Shelby	Samaria	McIntosh	Order Selector	8/7/2023	Y	N
Abdulwahid	Mohammad	McIntosh	Order Selector	7/12/2021	Y	N
Bahjat	Esam	McIntosh	Stock Handler	1/17/2023	N	Y
Guyton	Matthew	McIntosh	Stock Handler	3/27/2023	Y	N
Holland	Justin	McIntosh	Stock Handler	5/30/2023	Y	N
Adak	Meral	McIntosh	Stock Handler	8/21/2023	Y	N
Herrell	Troy	McIntosh	Tote Stocker	9/21/1998	Y	N
Taylor	Matthew	McIntosh	Utility	9/11/2017	Y	N
Ferrell	Joshua	McIntosh	Warehouse Lead	2/13/2012	Y	N
Lowe	Dustin	Justice	Computer Operator	12/5/2016	Y	N
Brown	Diane	Justice	Data Operator	10/16/1992	Y	N
Adams	Kyle	Justice	Data Operator	4/25/2016	Y	N
Foster	Mallory	Justice	Data/Order Selector	6/29/2020	Y	N

CVS TN DISTRIBUTION, LLC
LIST OF STATES WHERE LICENSE

Jurisdiction Name	LICENSE #	Expiration Date	Notes
Arizona	W001309	10/31/2023	Wholesaler Full Service License
Connecticut	CSW.0004424	06/30/2024	Wholesaler of Drugs
DEA	PR0205559	04/30/2024	DEA - Controlled Substance
District of Columbia	CF0000465	06/30/2024	Non-Res Controlled Substance
Florida	232567	03/31/2024	DRUG WHOLESALER
Georgia	PHWH000585	06/30/2025	Wholesaler Pharmacy
Iowa	2210382	12/31/2023	Whse CDS Non-Resident License
Iowa	40522	12/31/2023	Limited Distributor
Illinois	6045-27409	02/05/2024	VAWD Annual Renewal
Illinois	004002740	12/31/2024	Licensed Wholesale Drug Distributor
Illinois	304007089	12/31/2024	Non-Res Controlled Substance
Illinois	6045-27409 (every 3 yrs)	02/05/2025	Reaccreditation/Inspection Fee
Indiana	48001745A	09/30/2024	Wholesale Drug Distributor
Kansas	5-30873	06/30/2024	Distributor Certificate (BACK-UP)
Kentucky	W02229	09/30/2024	Wholesale Distributor
Louisiana	3997	12/31/2023	Distributor of Legend Drugs/Devices
Louisiana	CDS043100-DIS	05/03/2024	Non-Res Controlled Substance
Maryland	271535	10/31/2025	Non-Res Controlled Substance
Maine	WH70002842	12/31/2023	Wholesaler
Michigan	5306003946	10/09/2025	Manufacturer/Wholesaler w/Controlled Substance
Michigan	5315057720	10/09/2025	Non-Res Controlled Substance (For Backup)
Missouri	2019039716	10/31/2025	Wholesale Distributor
Mississippi	15879	12/31/2023	Wholesale Drug Distributor
Mississippi	CS-15879	12/31/2023	Non-Res Controlled Substance
North Dakota	Whol1656	06/30/2024	Wholesaler/Distributor
New Hampshire	06413	06/30/2024	Non-Resident Wholesale Distributor
New Jersey	5003921	01/31/2024	Drug and Medical Device Wholesaler Registration
New York	02A0933	10/13/2024	Non Res Controlled Substance
Ohio	011588700	06/30/2025	Wholesaler - Category 3 Controlled substances included)-
PA	PR0205559	09/21/2023	IPLEDGE/Isotretinoin Reg
Rhode Island	DIS02100	09/30/2023	Drug Wholesaler Out of State with Controlled Substance
South Carolina	4009941	04/01/2024	Non-Res Controlled Substance
South Carolina	9941	06/30/2024	Non- Res Wholesale Drug Distributor
South Dakota	600-2464	12/31/2023	Wholesale & Other Drug Distributor
South Dakota	66795	04/30/2024	Non-Res Controlled Substance
Tennessee	115	01/31/2024	Wholesale/Distributor/Controlled Substance Registration
Texas	1000461 Drug	08/19/2024	Out of State Wholesale Distriubutor of Prescription Drugs CSR

LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

DISTRIBUTOR OF LEGEND DRUGS OR LEGEND DEVICES

SUB-TYPES: Standard Distributor, Wholesale Distributor

CVS TN DISTRIBUTION, LLC

License No. **3997** effective **01/01/2023** *(Original issue date: 02/03/2005)*, Expiring **12/31/2023**
distributing from **10017 Kingston Pike, Knoxville, TN, 37922**
BUSINESS ADDRESS: 10017 KINGSTON PIKE, KNOXVILLE, TN, 37922
is duly licensed in the State of Louisiana with this Board under the provisions of Act 852 of 1988 (as amended).
This license is subject to regulation in the state of Louisiana
in accordance with La. R.S. 37:3461 through 3482 and LAC 46:XXXIV.101 through 1503.

Additional Third-Party Logistics Providers:
NA

Board Secretary

ORIGINAL LICENSE — DISTRIBUTOR
This License is NOT TRANSFERABLE and must be Conspicuously Displayed. This license must be renewed annually.

Louisiana Board of Drug and Device Distributors 12091 Bricksome Avenue, Suite B Baton Rouge, LA 70816	Phone: (225) 295-8567 Fax: (225) 295-8568	www.drugboard.la.gov Email: admin@drugboard.la.gov

SUB-TYPES:

Standard Distributor: Any entity that sales or facilitates the delivery of legend drugs or legend devices to persons other than the consumer or patient; including, but not limited to, manufacturers, repackagers, own-label distributors, jobbers, retail pharmacy warehouses, pharmacies, brokers, agents, freight forwarders, ship chandlers, reverse distributors, compounders/503b, and nuclear pharmacies.

Wholesale Distributor: Any entity that sales or facilitates the delivery of drug product (as defined by FDA) to persons other than the consumer or patient; not to include (not limited to) manufacturers, repackagers, third-party logistic providers, distributors of devices, medical gases, intravenous drugs for replenishment or irrigation, blood or blood components; radioactive drugs or biologicals, imaging drugs, homeopathic drugs, and compounded drugs.

Third-party Logistics Provider: Any entity that provides or coordinates warehousing, facilitates the delivery of, or other logistic services for a legend drug or legend device interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.

The Louisiana Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, and further, performs daily updates to the website. Therefore, the website is a secure and primary source for credential verification, as authentic as a direct inquiry to the Board.

Lookup Detail View

Name and Address

Name	PublicAddress
CVS TN Distribution, LLC	10017 Kingston Pike Knoxville, TN 37922-3322

Credential Information

License	License Type	Issue Date	Expiration Date	Status
CDS.043100-DIS	CDS License - Distributor	05/03/2013	05/03/2024	Current, without restriction or limitation

CDS Schedules and Restrictions

I	II	II-N	III	III-N	IV	V	Restrictions	Alternative Privileges
No	No	No	Yes	Yes	Yes	Yes		

Generated on: 7/12/2023 8:55:43 AM

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Wholesale Distributor

EFFECTIVE DATE: 02/26/2008

NUMBER: W02229

EXPIRATION DATE: 09/30/2024

Issued to:
CVS TN DISTRIBUTION, LLC

10017 KINGSTON PIKE
KNOXVILLE, TN 37922

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address, and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

Licensing Dept MC#1160
ONE CVS Drive
WOONSOCKET, RI 02895

eufemia.bryden@cvshealth.com

Distributor Certificate of Renewal of Permit

NOTICE: **Display this renewal with original certificate in a prominant location site**

APPLICANT MAILING ADDRESS

CHRISTOPHER PARK
CVS TN DISTRIBUTION LLC
ONE CVS DR, MC#1160
WOONSOCKET, RI 02895

Original Permit # 0-30873

Schedules 3, 3n, 4, 5

Company Name CVS TN DISTRIBUTION LLC

Address 10017 KINGSTON PIKE

City/State/Zip KNOXVILLE, TN 37922

Owner CVS TN DISTRIBUTION LLC

KANSAS STATE BOARD OF PHARMACY

2023 - 2024

Expires June 30, 2024
(This is a renewal, not an original registration)

Executive Secretary
(785) 296-4056

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS (850) 487-1395
2601 BLAIR STONE ROAD
TALLAHASSEE FL 32399-1047

CVS TN DISTRIBUTION LLC
ONE CVS DRIVE
MAIL CODE 1160
WOONSOCKET RI 02895

Congratulations! With this license you become one of the nearly one million Floridians licensed by the Department of Business and Professional Regulation. Our professionals and businesses range from architects to yacht brokers, from boxers to barbeque restaurants, and they keep Florida's economy strong.

Every day we work to improve the way we do business in order to serve you better. For information about our services, please log onto **www.myfloridalicense.com**. There you can find more information about our divisions and the regulations that impact you, subscribe to department newsletters and learn more about the Department's initiatives.

Our mission at the Department is: License Efficiently, Regulate Fairly. We constantly strive to serve you better so that you can serve your customers. Thank you for doing business in Florida, and congratulations on your new license!

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND
PROFESSIONAL REGULATION

232567 ISSUED: 03/24/2022

OUT-OF-STATE RX DRUG WHSL DISTR
CVS TN DISTRIBUTION LLC

HAS REGISTERED under the provisions of Ch.499 FS.
Expiration date : MAR 31, 2024 L2203240000150

DETACH HERE

RON DESANTIS, GOVERNOR MELANIE S. GRIFFIN, SECRETARY

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
FLORIDA DRUGS, DEVICES AND COSMETICS

LICENSE NUMBER
232567

The OUT-OF-STATE RX DRUG WHOLESALE DISTR.
Named below HAS REGISTERED
Under the provisions of Chapter 499 FS.
Expiration date: MAR 31, 2024

CVS TN DISTRIBUTION LLC
10017 KINGSTON PIKE
KNOXVILLE TN 37922

ISSUED: 03/24/2022 DISPLAY AS REQUIRED BY LAW SEQ # L2203240000150

STATE OF CONNECTICUT
DEPARTMENT OF CONSUMER PROTECTION

This is your registration certificate for your records. Such registration shall be shown to any properly interested person on request. Do not attempt to make any changes or alter this certificate in any way. This registration is not transferable. Questions can be emailed to the Drug Control Division at dcp.drugwholesalers@ct.gov.

In an effort to be more efficient and Go Green, the department asks that you keep your email information with our office current to receive correspondence. All renewal notifications and certificates will only be emailed to your last reported email on record. You can update your email, mailing address or print a duplicate certificate by logging into your account with your User ID and Password at www.elicense.ct.gov. Visit our website at www.ct.gov/dcp.

Mailing address:

CVS TN DISTRIBUTION LLC
MIA T. BRYDEN
ONE CVS DR # 1160
WOONSOCKET, RI 02895-6146

Email on file to be used for receiving all notices from this office:

Eufemia.Bryden@cvshealth.com

956642

STATE OF CONNECTICUT ✦ DEPARTMENT OF CONSUMER PROTECTION

Be it known that

CVS TN DISTRIBUTION LLC

10017 KINGSTON PIKE
KNOXVILLE, TN 37922-3322

has satisfied the qualifications required by law and is hereby issued a

WHOLESALER OF DRUGS, COSMETICS & MEDICAL DEVICES

Controlled Substances: Yes **Rx Legend Drugs: Yes** **Non Rx Legend Drugs: Yes** **Medical Devices: Yes**

Cosmetics: Yes **Medical Gases and Oxygen: No** **Durable Medical Equipment (DME): No**

Registration #: CSW.0004424
Effective Date: 07/01/2023
Expiration Date: 06/30/2024

verify online at www.elicense.ct.gov

Bryan T. Cafferelli, Commissioner

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 09/21/2021
Receipt Number: 2021113037
Receipt Amount $: 1000.00

Wholesaler - Full Service

PERMIT NO
W001309

EXPIRES
10/31/2023

Issued to :

CVS TN Distribution, LLC
CVS TN Distribution, Inc.
ONE CVS DRIVE LICENSING DEPT MC#1160
WOONSOCKET, RI 02895

CVS TN Distribution, LLC
10017 KINGSTON PIKE
KNOXVILLE, TN 37922

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : CVS TN Distribution, Inc.
LICENSE NUMBER : W001309
EXPIRES : 10/31/2023

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

GOVERNMENT
OF THE
DISTRICT OF COLUMBIA

License No: CF0000465
Issue Date: 08/01/2022
Expiration Date: 07/31/2024

DEPARTMENT OF HEALTH
HEALTH REGULATION AND LICENSING ADMINISTRATION

CERTIFICATE
OF
CONTROLLED SUBSTANCE REGISTRATION

REGISTRANT

CVS TN DISTRIBUTION,LLC
10017 KINGSTON PIKE
KNOXVILLE TN 37922

CERTIFICATE NUMBER: CF0000465

BUSINESS ACTIVITY

SCHEDULES
III, IIIN, IV, V

LaQuandra S. Nesbitt MD
LaQuandra S. Nesbitt, MD,MPH
Director, Department of Health

This certificate applies only to the registrant listed herein and is not transferable on change of ownership, control, location, or business activity.

1684

Licensee Information

Name: CVS TN Distribution LLC

Owner:

DBA:

Address: 10017 Kingston Pike
Knoxville TN 37922

Primary Source License Information

Profession:	Pharmacy	**License No:**	PHWH000585	**License Status:**	Active
License Type:	Wholesaler Pharmacy	**Obtained By Method:**	Application	**License Subtype:**	
Issue Date:	4/9/1998	**Expiration Date:**	6/30/2025	**Last Renewal Date:**	5/17/2023

Discipline Information
- Public Board Orders -

If a public board order exists, it may be listed below.
Public Board Order means that there is a public document concerning the licensee.
The existence of a public Board order does not necessarily mean the licensee is currently under any type of disciplinary action.

Please understand that the absence of a scanned order linked to this record does not necessarily mean that no public actions exist.

No scanned public board order documents exist.

Associated Licenses

No data available

You may close this window to return to your search results

Data current as of: September 5, 2023 16:38:4
This website is to be used as a primary source verification for licenses issued by the Boards of Dentistry and Pharmacy. Paper verifications are available for a fee. Please contact the Boards of Dentistry and Pharmacy at 404-651-8000.

IOWA BOARD OF PHARMACY
400 S.W. EIGHTH STREET, SUITE E
DES MOINES, IA 50309-4688
515/281-5944 FAX 515/281-4609
https://pharmacy.iowa.gov

2023

Limited Distributor License No. 40522

Intracompany Distributor

ISSUED 11/25/2022

EXPIRES 12/31/2023

LICENSE STATUS: Current/Active

MAILING ADDRESS
CVS TN Distribution LLC
One CVS Drive
MC#1160
Woonsocket,RI 02895

LICENSED LOCATION
CVS TN Distribution LLC
10017 Kingston Pike
Knoxville, TN 37922

Facility Manager: Christopher Wayne Park

1686

IOWA BOARD OF PHARMACY
400 S.W. EIGHTH STREET, SUITE E
DES MOINES, IA 50309-4688
515/281-5944 FAX 515/281-4609
https://pharmacy.iowa.gov

CSA

2023

CERTIFICATE OF REGISTRATION
IOWA CONTROLLED SUBSTANCES ACT

REGISTRATION NUMBER **2210382**
DRUG SCHEDULES REGISTERED **33N45**

REGISTRATION ISSUED **10/19/2021**
REGISTRATION EXPIRES **12/31/2023**
REGISTRATION STATUS: **Current/Active**

NAME, MAILING ADDRESS
CVS TN Distribution LLC
One CVS Drive
MC#1160
Woonsocket RI 02895

NAME, REGISTERED LOCATION
CVS TN Distribution LLC
10017 Kingston Pike
Knoxville TN 37922

Distributor

COUNTY 0 Outside Iowa

Christopher Wayne Park, Responsible Individual

DEA REGISTRATION NO. **PR0205559**

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
304.007089
004.002740

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2024

LICENSED CONTROLLED SUBSTANCE DRUG DIST

III IV V

CVS TN DISTRIBUTION LLC
10017 KINGSTON PIKE
KNOXVILLE, TN 37922-3322

MARIO TRETO, JR.
SECRETARY

CECILIA ABUNDIS
DIRECTOR

The official status of this license can be verified at IDFPR.Illinois.gov

17407439

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 1791469

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.002740

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2024

LICENSED WHOLESALE DRUG DISTRIBUTOR

CVS TN DISTRIBUTION LLC
CHRISTOPHER WAYNE PARK
10017 KINGSTON PIKE
KNOXVILLE, TN 37922-3322

MARIO TRETO, JR.
SECRETARY

CECILIA ABUNDIS
DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

17404183

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 1791469

State of Indiana

DEMOGRAPHIC INFORMATION

Name: CVS TN Distribution, LLC

ADDRESS INFORMATION

Line 1:
Line 2: 10017 Kingston Pike
City/State/Zip: Knoxville TN 37922
County: Knox

LICENSE INFORMATION

Lic #:	48001745A	Profession:	Pharmacy Board	Type:	Wholesale Drug Distributor	Secondary:
Status:	Active	Issued:	3/13/2007	Expiration:	9/30/2024	
Method:	Application					

DISCIPLINE INFORMATION

-

RELATED LICENSES

No Related Licenses

State of Maine

DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY

License Number WH70002842

Be it known that

CVS TN DISTRIBUTION LLC

has qualified as required by Title 32 MRS Chapter 117 and is licensed as:

PHARMACEUTICAL WHOLESALER

Located at: 10017 KINGSTON PIKE
KNOXVILLE TN

Anne L. Head
Commissioner

ISSUE DATE
November 23, 2022

EXPIRATION DATE
December 31, 2023

✂ Detach

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY

License Number WH70002842
CVS TN DISTRIBUTION LLC
PHARMACEUTICAL WHOLESALER

ISSUED 11/23/2022 **EXPIRES** 12/31/2023

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION
35 State House Station
Augusta, Maine 04333-0035
(207) 624-8603

Anne L. Head
Commissioner

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

CVS TN DISTRIBUTUTION LLC
10017 KINGSTON PIKE
KNOXVILLE, TN 37922

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

CVS TN DISTRIBUTUTION LLC
10017 KINGSTON PIKE
KNOXVILLE, TN 37922

LICENSE NO.
5306003946

EXPIRATION DATE
10/09/2025

23194160714

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

CVS TN DISTRIBUTUTION LLC
10017 KINGSTON PIKE
KNOXVILLE, TN 37922

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
CONTROLLED SUBSTANCE LICENSE

*THIS LICENSE IS ONLY VALID IF PROFESSIONAL LICENSE IS ACTIVE

CVS TN DISTRIBUTUTION LLC
10017 KINGSTON PIKE
KNOXVILLE, TENNESSEE 37922

LICENSE NO.
5315057720

EXPIRATION DATE
10/09/2025

23194160715

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

State of Missouri

Division of Professional Registration
Licensed Drug Distributor
Out of State Wholesale

VALID THROUGH OCTOBER 31, 2023
ORIGINAL CERTIFICATE/LICENSE NO. 2019039716
CVS TN DISTRIBUTION LLC
CVS TN DISTRIBUTION LLC
CHRISTOPHER WAYNE PARK, MIC
10017 KINGSTON PIKE
KNOXVILLE TN 37922
USA

CVS TN DISTRIBUTION LLC
CVS TN DISTRIBUTION LLC
CHRISTOPHER WAYNE PARK, MIC
10017 KINGSTON PIKE
KNOXVILLE TN 37922
USA

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy
Licensed Drug Distributor
Out of State Wholesale

VALID THROUGH OCTOBER 31, 2023
ORIGINAL CERTIFICATE/LICENSE NO. 2019039716
Christopher Wayne Park
CVS TN DISTRIBUTION LLC
CVS TN DISTRIBUTION LLC
CHRISTOPHER WAYNE PARK, MIC
10017 KINGSTON PIKE
KNOXVILLE TN 37922
USA

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

MISSISSIPPI

Board of Pharmacy

Registration #
CS-15879

Controlled Substance Registration

CVS TN Distribution, LLC

10017 Kingston Pike
Knoxville, TN 37922

This registration is not transferable or assignable.

Issued: 11/20/2019
Renewed: 11/16/2022
Expires: 12/31/2023

Susan McCoy
Executive Director

Mississippi Board of Pharmacy | 6360 I-55 North | Suite 400 | Jackson, MS 39211
Phone: 601-899-8880 | Fax: 601-899-8851

1695

MISSISSIPPI

Board of Pharmacy

Permit #
15879 / 16.5a

Drug Facility

Wholesale Distributor (Non-Resident)

CVS TN Distribution, LLC

10017 Kingston Pike
Knoxville, TN 37922

Permit Holder:
Christopher W. Park

This permit is not transferable or assignable.

Issued: 06/05/2017
Renewed: 12/19/2022
Expires: 12/31/2023

Susan McCoy
Executive Director

Mississippi Board of Pharmacy | 6360 I-55 North | Suite 400 | Jackson, MS 39211
Phone: 601-899-8880 | Fax: 601-899-8851

1696

North Dakota
State Board of Pharmacy

Chain drug warehouse

This is to certify

CVS TN Distribution, LLC

10017 Kingston Pike
Knoxville, TN 37922

Has registered with the Board of Pharmacy of the State of North Dakota in accordance with Chapter 19-02.1-02(15) and 43-15.3 of the North Dakota Century Code and has been granted

License No. Whol1656

Until ***June 30, 2024*** *unless otherwise suspended or revoked.*
This license is not transferable.

Steven P. Irsfeld, R.Ph.
President
Diane Halvorson, R.Ph.Tech.
Senior Member
Tanya L. Schmidt, Pharm D.
Ron Horner

Tyler G. Lannoye, Pharm D.
Shane R. Wendel, Pharm D.
Carolyn Bodell, R.Ph.
Mark J. Hardy, Pharm D.
Executive Director

1697

State of New Hampshire

Board of Pharmacy

Authorized as

MAN/DIST/WHOLE/BROKER

Issued To

CVS TN DISTRIBUTION, LLC

License Number: 06413
Active

Issue Date: 10/06/2017

Expiration Date: 06/30/2024

1698

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0748687

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

ONE CVS DR MAIL DROP #23062A WOONSOCKET, RI 02895-
10017 KINGSTON PIKE KNOXVILLE,TN 37922-

Reg. No.
5003921

CVS PHARMACY, INC
CVS TN. DISTRIBUTION, LLC
ATTN: EUFEMIA T BRYDEN, LIC
ONE CV DR, MAIL DROP #23062A
WOONSOCKET, RI 02895-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2024

Establishment Copy

1699

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2025.

CVS TN DISTRIBUTION, LLC

10017 KINGSTON PIKE

KNOXVILLE, TN 37922

License Number: 011588700

Wholesaler - Category 3

Expiration Date: June 30, 2025

CLASS: Wholesaler - Category 3
BUSINESS TYPE: FS – Full Service

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
CHRISTOPHER W. PARK	Christopher W Park

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

State of Rhode Island
Department of Health

RHODE ISLAND BOARD OF PHARMACY

This is to certify that CVS TN DISTRIBUTION LLC located at 10017 KINGSTON PIKE, KNOXVILLE TN 37922, .. having given satisfactory evidence that said agency is qualified in conformity with Chapter 5-19 of the General Laws of 1956, as amended, is hereby granted a license to operate as a

Drug Wholesaler-Out of State

with a **Controlled Substances Registration** in the State of Rhode Island, for the period ending: **09/30/2023**

License Number: ***DIS02100***

1701

60
CVS TN DISTRIBUTION LLC
ONCE CVS DRIVE MC#1160
WOONSOCKET RI 02895

PERMIT NO. 9941
DATE ISSUED: 05/23/2023

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

Non-Resident Wholesaler Distributor/Manufacturer Permit

2023-2024

Expires 06/30/2024

CVS TN DISTRIBUTION LLC

Permit Holder: LINDA M. CIMBRON
10017 KINGSTON PIKE
KNOXVILLE TN 37922

Lauren B. Thomas, Board Chair

Heather C. Harris, Vice Chair

Traci Collier, Administrator

CERTIFICATE OF REGISTRATION
ISSUED PURSUANT TO THE
SOUTH CAROLINA CONTROLLED SUBSTANCES ACT
THIS CERTIFICATE MUST BE MAINTAINED IN A READILY RETRIEVABLE MANNER AT ALL TIMES.

	DATE OF ISSUE	REGISTRATION FEE	CODE	EXPIRATION DATE
DC01517 -5	02/27/2023	550.00		04/01/2024

SCHEDULES OF CONTROLLED SUBSTANCES AUTHORIZED*	DEA REGISTRATION NUMBER	STATE REGISTRATION NUMBER
33N45	PR0205559	40-09941

CVS TN DISTRIBUTION, LLC
10017 KINGSTON PIKE

KNOXVILLE TN 37922

*2-II-NARCOTIC; 2N-II-NON-NARCOTIC; 3-III-NARCOTIC; 3N-III-NON-NARCOTIC; 4-SCHEDULE IV-ALL; 5-SCHEDULE V-ALL
THIS CERTIFICATE IS NOT TRANSFERABLE UPON CHANGE OF OWNERSHIP OR ADDRESS
S.C. DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF DRUG CONTROL
2600 BULL STREET
COLUMBIA, SOUTH CAROLINA 29201

DHEC 1176 (04/2000)

South Dakota
Department of Health
Controlled Substance Certificate

Issued To: CVS TN DISTRIBUTION, LLC

10017 KINGSTON PIKE

KNOXVILLE TN 37922

Registration Number

66795

Business Activity

Distributor

Schedules

III , IIIN , IV

This registration will expire on 04/30/2024 or if registrant fails to maintain registration with his/her professional board, retires from active practice of profession, or is found to be in violation of SDCL 34-20B and/or ARSD 44:58.

Secretary of Health

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF: OWNERSHIP, CONTROL LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

1704

SOUTH DAKOTA BOARD OF PHARMACY

In conformance with the laws of South Dakota, a license to engage in the wholesale or other distribution of prescription drugs within this state is hereby granted to the entity named below.

CVS TN DISTRIBUTION LLC

10017 KINGSTON PIKE
KNOXVILLE TN 37922

as a

WHOLESALE OR OTHER DRUG DISTRIBUTOR

License No 600-2464

Issued:	**12/14/2022**
Expiration:	**12/31/2023**
Initial Issue Date:	**08/19/2015**
Fee :	**$250.00**

Responsible Person for this facility is CHRIS W PARK

Kari Swanson-Koerner

EXECUTIVE DIRECTOR

SOUTH DAKOTA BOARD OF PHARMACY
4001 W Valhalla Blvd, Suite 106
Sioux Falls, SD 57106
Phone: 605-362-2737 www.pharmacy.sd.gov

Any issues, concerns, or complaints about focility, please contact the SD Baard of Pharmacy

- If any information is incorrect on the license, please fill out the notification form on the Wholesalers page on the SD Board of Pharmacy website at www.pharmacy.sd.gov or use this link: http://doh.sd.gov/boards/pharmacy/assets/NotificationForm.pdf. Once the form is completed, return to SD Board of Pharmacy.
- This license must be displayed at the address licensed.
- A change of ownership of a licensed place of business will require submission of a new application and fee.
- If you have any questions or desire additional information concerning the application process or this license, please contact the South Dakota Board of Pharmacy, 4001 W Valhalla Blvd, Suite 106, Sioux Falls, SD 57106, phone (605) 362-2737.

TEXAS Department of State Health Services

License Number: 1000461 ***Current Date: 09/05/2023 03:23 PM***

Name:	**CVS TN DISTRIBUTION LLC**
License Type:	**Rx Out of State**
License Status:	**Current**
Expiry Date:	**08/19/2024**
Effective Rank Date:	**09/07/2010**
Modifier(s):	**Wholesales Distributor**
	Prescription
	Non Prescript
	Controlled Substance

Addresses

Physical Loc — Address

CVS TN DISTRIBUTION LLC
10017 KINGSTON PIKE
KNOXVILLE , TN
OUT OF STATE/UNKNOWN
37922
US

Mailing Address — Address

CVS CORP - LICENSING DEPT MC 1160
WOONSOCKET , RI
OUT OF STATE/UNKNOWN
02895
US

Food & Drug Owner

Licensee's Role:	**Food & Drug License**
Related Party Role:	**Food & Drug Owner**

Related Party Name	License	Address
CVS TN DISTRIBUTION LLC	**Owner #** **Status:** **Current** **Expiration Date:**	**WOONSOCKET , RI** **OUT OF STATE/UNKNOWN** **02895** **US**

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler	* If making a change, provide current license number:	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Dentsply LLC

Physical Address: 1301 Smile Way

City: York State: PA Zip: 17404

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 717-767-8500 Website: www.dentsplysirona.com

Name of Designated Representative (DR): Jonathan M. Coleman

Licensing Company Email: N/A DR Email: dsstatelic@dentsplysirona.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	

Reason/Charge
N/A

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:

Not applicable

Original Signature (electronic, copies or stamps not accepted)

07/25/23

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Novocol Pharmaceutical of Canada, Inc.
Address: 25 Wolseley Court City: Cambridge, Ontario State: CAN Zip: N1R 6X3

Name: Recipharm Karlskoga AB
Address: Bjorkbornsvagen 5 City: Karlskoga State: SWE Zip: 69133

Name: Sciarra Laboratories, Inc.
Address: 48509 S Broadway City: Hicksville State: NY Zip: 11801

Name: Xttrium Laboratories, Inc.
Address: 1200 E. Business Center Drive City: Mount Prospect State: IL Zip: 60056

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Dentsply Sirona Inc.
Corporation Name: Dentsply Sirona Inc.
Mailing Address: 13320-B Ballantyne Corporate Place
City: Charlotte State: NC Zip: 28277
Telephone: 704-587-0453 Email: dsstatelic@dentsplysirona.com
Contact Person Name: Robert Anthony Johnson

Date of SEC Registration: 02/29/2016 | SEC Registration Number: CLK00008182479 | Stock Exchange Symbol: XRAY

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Dentsply LLC

Facility Name

Jonathan M. Coleman

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

07/25/23

Date

Board Use Only	Date Received: 8.14.23	Amount: 1,000 CC

Annual Registration Successful

Facility: DENTSPLY LLC, York, Pennsylvania, UNITED STATES

You have successfully updated your registration and listing information for 2023.

Your registration will be valid through Dec 31, 2023.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2023.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 2511302.

Facility Information

Registration Number:
2424472

Initial Importer:
Y

Facility Name:
DENTSPLY LLC

Legal Name:

Address:
1301 SMILE WAY,
York, Pennsylvania, 17404, UNITED STATES

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):
1. DENTSPLY Pharmaceutical
2. Sultan Healthcare
3. Dentsply Sirona Preventive
4. Professional Division
5. DENTSPLY Rinn
6. DENTSPLY Professional

7. Dentsply Sirona

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:
2511302

Contact Name:
Courtney Clark

Company:
DENTSPLY SIRONA INC

Address: **221 WEST PHILADELPHIA ST., SUITE 60W**
York, PENNSYLVANIA, 17401, UNITED STATES

Telephone:
248 - 8954379

Fax:
717 - 8494343

E-mail: **corporate-ra@dentsplysirona.com**

DUNS Number:

Official Correspondent Information

Contact Name:
Courtney Clark

Company:
DENTSPLY SIRONA INC

Address: **221 WEST PHILADELPHIA ST., SUITE 60W**
York, PENNSYLVANIA, 17401, UNITED STATES

Telephone:
248 - 8954379

Fax:
717 - 8494343

E-mail: **corporate-ra@dentsplysirona.com**

DUNS Number:

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D461240	K170093		OYH	Orthodontic vibratory accessory	Complaint File Establishment

D152355	K121698		EJR	AGENT, POLISHING, ABRASIVE, ORAL CAVITY	Specification Developer
D461239	K172164		DZJ	DRIVER, WIRE, AND BONE DRILL, MANUAL	Complaint File Establishment
D323360	Import for Export		PEM	Dental barriers and sleeves	Manufacturer
D086767	K082973		ELC	Scaler, ultrasonic	Manufacturer
D163496	K940252		EIH	POWDER, PORCELAIN	Specification Developer
D086768	K903298		ELC	Scaler, ultrasonic	Manufacturer
A873891		510(k) exempt	KYX	DISPENSER, LIQUID MEDICATION	Manufacturer
E375355		510(k) exempt	ECB	UNIT, SYRINGE, AIR AND/OR WATER	Manufacturer Specification Developer
D277283	K161330		EBI	RESIN, DENTURE, RELINING, REPAIRING, REBASING	Specification Developer
B251925		510(k) exempt	EJP	ARTICULATORS	Manufacturer
D271858	K932134		IZX	Collimator, manual, radiographic	Manufacturer
D042977	K970123		ELC	Scaler, ultrasonic	Manufacturer
D041416	K984427		EIH	POWDER, PORCELAIN	Specification Developer
D043841	K790935		EBC	SEALANT, PIT AND FISSURE, AND CONDITIONER	Specification Developer
D043840	K864996		ELC	Scaler, ultrasonic	Manufacturer
D043843	K951296		EBC	SEALANT, PIT AND FISSURE, AND CONDITIONER	Specification Developer

D043844	K842392		EBC	SEALANT, PIT AND FISSURE, AND CONDITIONER	Specification Developer
D043847	K052334		ELC	Scaler, ultrasonic	Manufacturer
D043846	K831380		EBC	SEALANT, PIT AND FISSURE, AND CONDITIONER	Specification Developer
D043849	K970342		ELC	Scaler, ultrasonic	Specification Developer Manufacturer
D043850	K030111		ELC	Scaler, ultrasonic	Manufacturer
R037844		510(k) exempt	EKD	INSTRUMENT, CUTTING, OPERATIVE	Complaint File Establishment
D244582	K150535		ELC	Scaler, ultrasonic	Manufacturer
E322099		510(k) exempt	EJR	AGENT, POLISHING, ABRASIVE, ORAL CAVITY	Specification Developer Manufacturer
E322098		510(k) exempt	KMT	TRAY, FLUORIDE, DISPOSABLE	Specification Developer
D043854	K033705		ELC	Scaler, ultrasonic	Manufacturer
D043853	K014188		KOJ	AIRBRUSH	Specification Developer
D043863	K991909		EBC	SEALANT, PIT AND FISSURE, AND CONDITIONER	Specification Developer
D275232	K160825		EKX	Handpiece, direct drive, ac-powered	Manufacturer
D470236		510(k)	EBF	Material, tooth shade, resin	U.S. Manufacturer of Export Only Devices
D043864	K023697		ELC	Scaler, ultrasonic	Manufacturer
D043866	K903163		ELC	Scaler, ultrasonic	Specification Developer

D043868	K920758		DZM	NEEDLE, DENTAL	Specification Developer
D041584	K803310		EIH	POWDER, PORCELAIN	Specification Developer
D035427	K942031		EBF	Material, tooth shade, resin	Specification Developer
D041104	Preamendment		EFB	Handpiece, air-powered, dental	Manufacturer
D041108	K792302		EFB	Handpiece, air-powered, dental	Manufacturer
D041109	K902413		ELC	Scaler, ultrasonic	Manufacturer
D043892	K920499		ECB	UNIT, SYRINGE, AIR AND/OR WATER	Specification Developer Manufacturer
E334891		510(k) exempt	EFD	AMALGAMATOR, DENTAL, AC-POWERED	Contract Manufacturer Manufacturer
E334892		510(k) exempt	EFT	CLEANSER, DENTURE, OVER THE COUNTER	Specification Developer
A893898		510(k) exempt	FLG	Cleaner, ultrasonic, medical instrument	Specification Developer
D356336	K191427		KLE	AGENT, TOOTH BONDING, RESIN	Specification Developer
			EBD	Coating, filling material, resin	
			EBI	RESIN, DENTURE, RELINING, REPAIRING, REBASING	
D042581	K900393		EIH	POWDER, PORCELAIN	Specification Developer
D453789		510(k) exempt	PZY	Additively manufactured, preformed, resin denture tooth	Specification Developer

D041381		510(k) exempt	EHA	Aligner, beam, x-ray	Manufacturer
D436189	K183018		OYH	Orthodontic vibratory accessory	Complaint File Establishment Specification Developer
A197842		510(k) exempt	EKQ	PREPARER, ROOT CANAL ENDODONTIC	Specification Developer
B048949		510(k) exempt	IXG	Phantom, anthropomorphic, radiographic	Manufacturer
A873884		510(k) exempt	EHK	CUP, PROPHYLAXIS	Specification Developer Manufacturer
B048944		510(k) exempt	EHY	TRAY, IMPRESSION, PREFORMED	Specification Developer
D350062	K182422		EBI	RESIN, DENTURE, RELINING, REPAIRING, REBASING	Specification Developer
D350063	K190043		EBI	RESIN, DENTURE, RELINING, REPAIRING, REBASING	Specification Developer
D041297		510(k) exempt	ELM	Denture, plastic, teeth	Specification Developer
A199394		510(k) exempt	EHZ	Evacuator, oral cavity	Specification Developer Manufacturer
D233099	K030603		EGS	Handpiece, contra- and right-angle attachment, dental	Specification Developer Manufacturer
D470313		510(k)	KLE	AGENT, TOOTH BONDING, RESIN	U.S. Manufacturer of Export Only Devices
D470312		510(k) exempt	ELM	Denture, plastic, teeth	U.S. Manufacturer of Export Only Devices

D041092	K792445		EGS	Handpiece, contra- and right-angle attachment, dental	Manufacturer
D156246	K122331		LBH	VARNISH, CAVITY	Specification Developer
A925358		510(k) exempt	IXC	Illuminator, radiographic-film	Manufacturer
D081481	K091706		EIH	POWDER, PORCELAIN	Specification Developer
D199850	K130862		ELC	Scaler, ultrasonic	Manufacturer
A925352		510(k) exempt	EGZ	Holder, film, x-ray	Manufacturer
D272411	K161269		EIH	POWDER, PORCELAIN	Specification Developer
D268297	K160232		PEM	Dental barriers and sleeves	Manufacturer Specification Developer
D048459	K002843		EMA	CEMENT, DENTAL	Repackager/Relabeler
D048453	K061716		FXX	Mask, surgical	Specification Developer
A873084		510(k) exempt	EJB	HANDLE, INSTRUMENT, DENTAL	Complaint File Establishment
D048463	K020612		JOJ	Indicator, physical/chemical sterilization process	Specification Developer
			MED	Sterilant, medical devices	
D048462	K990703		MED	Sterilant, medical devices	Specification Developer
D128055	K110753		EKX	Handpiece, direct drive, ac-powered	Manufacturer Specification Developer

Imported Products and Manufacturers

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
DENTSPLY DETREY GmbH	DETREY STRASSE 1, KONSTANZ, Baden-Wurttemberg, 78467, GERMANY	KLE	AGENT, TOOTH BONDING, RESIN	K070538
VOCO GMBH	ANTON-FLETTNER-STRASSE 1-3, CUXHAVEN, Lower Saxony, D-27472, GERMANY	EBG	CROWN AND BRIDGE, TEMPORARY, RESIN	K040769
GS MEDICAL PACKAGING, INC.	82 AKRON ROAD, UNIT 2, ETOBICOKE, Ontario, M8W 1T2, CANADA	KCT	Sterilization wrap containers, trays, cassettes & other accessories	K953829
SHENZHEN CODYSON ELECTRICAL CO, LTD	No.7 Building, Zhuli East Industrial Park, Longtian Street, Pingshan District, Shenzhen, Guangdong, 518118, CHINA	FLG	Cleaner, ultrasonic, medical instrument	
VIPI INDUSTRIA,COMERCIO,EXPORTACAO E IMPORTACAO DE PRODUTOS ODONTOLOGICOS LTDA.	RUA CARLOS TASSONI 4521, DISTRITO INDUSTRIAL, PIRASSUNUNGA, Sao Paulo, 13633-418, BRAZIL	ELM	Denture, plastic, teeth	
VIPI INDUSTRIA,COMERCIO,EXPORTACAO E IMPORTACAO DE PRODUTOS ODONTOLOGICOS LTDA.	RUA CARLOS TASSONI 4521, DISTRITO INDUSTRIAL, PIRASSUNUNGA, Sao Paulo, 13633-418, BRAZIL	EBG	CROWN AND BRIDGE, TEMPORARY, RESIN	K102341
VIPI INDUSTRIA,COMERCIO,EXPORTACAO E IMPORTACAO DE PRODUTOS ODONTOLOGICOS LTDA.	RUA CARLOS TASSONI 4521, DISTRITO INDUSTRIAL, PIRASSUNUNGA, Sao Paulo, 13633-418, BRAZIL	EBI	RESIN, DENTURE, RELINING, REPAIRING, REBASING	K182422
EXEL INTERNATIONAL, CO.	2500 Santa Fe Ave, Redondo Beach, California, 90278, UNITED STATES	DZM	NEEDLE, DENTAL	K861150
Suzhou Pac-Dent Technology Co., Ltd	18 Yuanqi Road, SUZHOU CITY, Jiangsu, 215133, CHINA	PEM	Dental barriers and sleeves	K160232

Date of Initial Registration: 1983-12-16 00:00:00.0

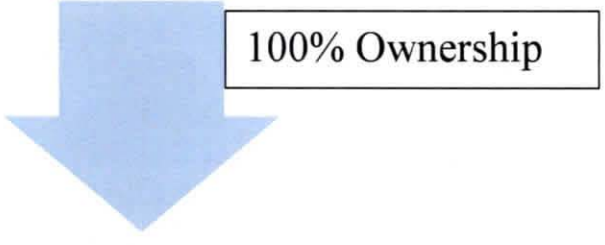
Beneficial Ownership of DENTSPLY LLC Chart

DENTSPLY LLC is a wholly owned subsidiary of DENTSPLY SIRONA Inc.:

DENTSPLY SIRONA Inc.
(Delaware)

CEO: Simon D. Campion

(FEIN 39-1434669)



DENTSPLY LLC
(Delaware)

Chief Executive Manager: Robert Anthony Johnson
Vice President: Andrew Johnson

Vice President and Assistant Secretary: Jennifer Shugars

(FEIN 16-1778565)

ALL OWNERSHIP PERCENTAGES 100%
CONFIDENTIAL AND PROPRIETARY

List of Officers and Managers of Dentsply LLC (NOT OWNERS):

Robert Anthony Johnson, Chief Executive Manager (Officer)

- Business address: 13320-B Ballantyne Corporate Place, Charlotte, NC 28277
- Personal address: [redacted]ake St., Libertyville, IL 60048
- DOB: [redacted]
- Phone: [redacted]
- Tony.Johnson@dentsplysirona.com

Andrew Stephen Johnson, Vice President

- Business address: 38 West Clarke Avenue, Milford, DE 19963
- Personal address: [redacted]eregrine Road, Lewes, DE 19958
- DOB: [redacted]
- Phone: [redacted]
- Andy.Johnson@dentsplysirona.com

Jennifer F. Shugars, Vice President and Assistant Secretary

- Business address: 221 W Philadelphia Street, Ste. 60W, York, PA 17401
- Personal address: [redacted]Marion View Drive, Harrisburg, PA 17112
- DOB: [redacted]
- Phone: [redacted]
- Jennifer.Shugars@dentsplysirona.com

List of DENTSPLY SIRONA Inc. Section 16 Officers (NOT OWNERS)

Business address for Corporation and Section 16 Officers:
DENTSPLY SIRONA Inc.
13320-B Ballantyne Corporate Place
Charlotte, NC 28277
Phone: 704-587-0453

Senior Vice President	Rosenzweig, Richard
Corporate Development	Rosenzweig, Richard
General Counsel	Rosenzweig, Richard
Secretary	Rosenzweig, Richard
Executive Vice President	Coleman, Glenn
Chief Financial Officer	Coleman, Glenn
Chief Executive Officer	Campion, Simon D.
President	Campion, Simon D.
Vice President	Wagner, Richard
Chief Accounting Officer	Wagner, Richard
Executive Vice President Product Group	Frank, Andreas
Senior Vice President	Johnson, Robert Anthony
Chief Supply Chain Officer	Johnson, Robert Anthony
Senior Vice President	Frohning, Andrea
Chief Human Resources Officer	Frohning, Andrea
Senior Vice President	Brackett, Erania
Customer Experience	Brackett, Erania

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DENTSPLY LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF APRIL, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "DENTSPLY LLC" WAS FORMED ON THE THIRTEENTH DAY OF DECEMBER, A.D. 2005.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4076195 8300

SR# 20231519718

Authentication: 203170849

Date: 04-19-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

1725

Certificate of Licensure

Certificate No. 8000001924
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Drug & Device Registration
2525 North 7th Street
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

Category:

Wholesaler/Distributor

DENTSPLY LLC
1301 SMILE WAY
YORK, PA 17404

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: January 16, 2008
Expiration Date: The Last Day of March, 2024

Susan Coble
Acting Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

1726

Certificate of Registration

Certificate No. 3000008249
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Distributor (Prescription) Devices

Drug & Device Registration
2525 North 7th Street
Suite 210D
HARRISBURG, PA 17110
(717) 787-1779

DENTSPLY LLC
1301 SMILE WAY
YORK, PA 17404

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: January 16, 2008
Expiration Date: The Last Day of March, 2024

Susan Coble
Acting Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES

1727

Certificate of Registration

Certificate No. 6000001330

(A certificate starting with a number 4, 5 or 6 does not permit the possession or sale of controlled substances or prescription drugs.)

Category:

Devices

Device Registration

DENTSPLY LLC
1301 SMILE WAY
YORK, PA 17404

The above business is registered in the required category to conduct [illegible] in accordance with the provisions of the Controlled Substance, Drug, Device and [illegible] Act #64, approved September 9, 1972.

Issuance Date: October 01, 1984

Expiration Date: The Last Day of September, 2023

Susan Coble
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

[illegible] Klinepeter
[illegible] Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 04/27/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	**CONTACT NAME:** Willis Towers Watson Certificate Center **PHONE (A/C, No, Ext):** 1-877-945-7378 **FAX (A/C, No):** 1-888-467-2378 **E-MAIL ADDRESS:** certificates@willis.com

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Insurance Company of the State of Pennsylv	19429
INSURER B:	Allianz Global Corporate & Specialty SE (U	B5244
INSURER C:	Great American Assurance Company	26344
INSURER D:	Zurich Insurance PLC UK Branch	D2213
INSURER E:	QBE Insurance Corporation	39217
INSURER F:		

INSURED
Dentsply Sirona Inc.
Susquehanna Commerce Center
Attn: Jake Rappoldt
221 West Philadelphia Street Suite 60W
York, PA 17401

COVERAGES **CERTIFICATE NUMBER:** W28841612 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER POLICY PRO-JECT LOC OTHER			800279444	05/01/2023	05/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 5,000,000 $ 2,000,000 $ 100,000 $ 1,000,000 $ 10,000,000 $ 10,000,000
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $			B080117605023	05/01/2023	05/01/2024	EACH OCCURRENCE AGGREGATE	$ 25,000,000 $ 25,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
C	Excess 1st Layer			EXC 4901921	05/01/2023	05/01/2024	Each Occurrence Aggregate SIR	$25,000,000 $25,000,000 $0

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

SEE ATTACHED

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Kathleen T. Berg

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AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Southeast, Inc.		Dentsply Sirona Inc. Susquehanna Commerce Center Attn: Jake Rappoldt 221 West Philadelphia Street Suite 60W York, PA 17401
POLICY NUMBER See Page 1		
CARRIER See Page 1	NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Sirona Dental Systems GmbH is a named insured as evidenced by the attached named insured schedule.

INSURER AFFORDING COVERAGE: Zurich Insurance PLC UK Branch NAIC#: D2213
POLICY NUMBER: B080117627U23 EFF DATE: 05/01/2023 EXP DATE: 05/01/2024

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess 2nd layer	Each Occurrence:	$50,000,000
	Aggregate	$50,000,000
	SIR	$0

INSURER AFFORDING COVERAGE: QBE Insurance Corporation NAIC#: 39217
POLICY NUMBER: B080123402U23 EFF DATE: 05/01/2023 EXP DATE: 05/01/2024

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess 3rd Layer	Each Occurrence	$25,000,000
	Aggregate	$25,000,000
	SIR	$0

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Dentsply Sirona Inc.
13320-B Ballantyne Corporate PL
Charlotte, NC 28277
USA

Dentsply Sirona

May 2, 2023

RE: Letter regarding Insurance Coverage

To Whom it May Concern:

DENTSPLY SIRONA Inc. (the "**Company**") maintains a robust global insurance coverage program for its facilities and operations located around the world. Specifically, the Company maintains Commercial General Liability Coverage totaling approximately $130 million USD. That total includes Primary coverage of $5 Million USD, as well as Umbrella and Excess Coverage Limits of $125 Million USD. This coverage extends to the Company's subsidiaries and affiliates. Please see the attached Certificate of Liability Insurance which (1) details the Primary, Umbrella, and Excess Coverage, and (2) lists the subsidiaries to which the insurance coverage applies.

The Company developed its global insurance coverage program with the help of leading third-party advisors, after an examination of the market and extensive benchmarking. The benchmarking focused on a peer group of seventeen (17) Healthcare, Manufacturing & Life Science entities and demonstrates that the Company carries higher Commercial General Liability coverage limits than both the median and mean of the peer group. Dentsply Sirona's excess limit is just slightly less than the third quarter. The Company's review and benchmarking ensure that its Commercial General Liability Coverage is reasonable and appropriate to protect the Company and to protect and respond to customers and consumers based upon the risk profile of its products.

Please see the attached document reflecting the Company's benchmarking and demonstrating the higher limits of the Company's Commercial General Liability Coverage compared to the peer group.

Additional information concerning the Company's risks and insurance coverage can be found in the Company's public announcements and filings, including its Form 10-K for the fiscal year ended December 31, 2022, filed on March 1, 2023, which can be found on the US Securities and Exchange Commission's EDGAR system at the following location:

https://www.sec.gov/ix?doc=/Archives/edgar/data/818479/000081847923000017/xray-20221231.htm

Best Regards,

Dane Baumgardner

Vice President, Legal & Assistant Secretary

Umbrella / Excess Liability

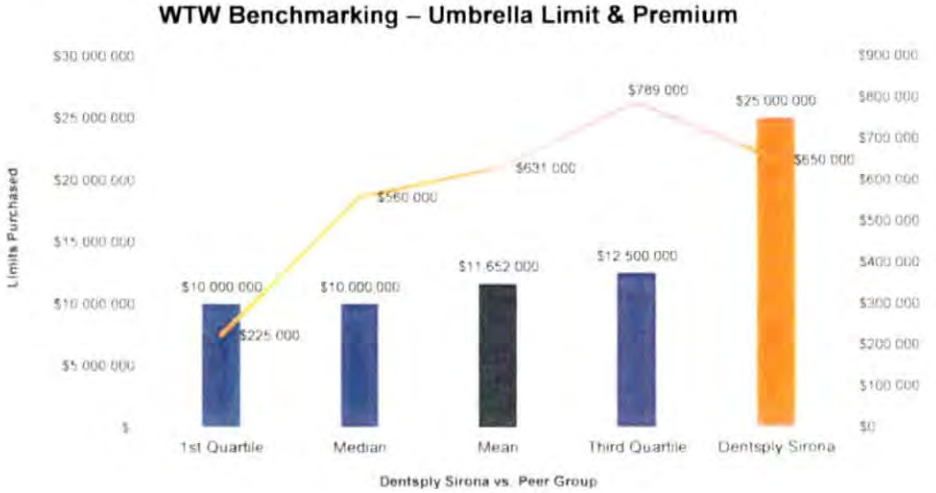
Benchmarking

Dentsply Sirona

- Limit: $125M
- Umbrella Limit: $25M
- Umbrella Carrier: Allianz
- Premium: 650,000

Benchmark

- Peer Group: Healthcare, Manufacturing & Life Science
- Peer Group: 17 Clients
- Peer Group: 100+ Vehicles





Dentsply Sirona's umbrella limit is above the 3rd quartile. Very few carriers are willing to offer umbrella capacity of $25M since the market hardening. The norm has become $10M. The premium is higher than all but the third quartile. The reason is the limit is double all other metrics

Dentsply Sirona's excess limits of $125M is slightly less than the 3rd quartile.

wtwco.com
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Subsidiaries of DENTSPLY SIRONA Inc. (the "Company") – December 31, 2022

1. Augma Bio Materials Ltd. (Israel, 20%)
2. Barracuda Partners, L.P. (Delaware, 25%)
3. Byte AU Pty. Ltd. (Australia)
4. Byte AU Unit Trust (Australia)
5. Byte LLC (Nevada)
6. Byteme Aligners Limited (United Kingdom)
7. Datum Biotech Ltd. (Israel)
8. Datum Dental Ltd. (Israel)
9. DeguDent GmbH (Germany)
10. Dentsply - Sirona Poland SP.z.o.o (Poland)
11. Dentsply (Tianjin) International Trading Co. Ltd. (China)
12. Dentsply Argentina S.A.C.e.I. (Argentina)
13. Dentsply BX Sarl (Luxembourg)
14. Dentsply Canada Ltd. (Canada)
15. Dentsply CH Sarl (Luxembourg)
16. Dentsply Chile Comercial Limitada (Chile)
17. Dentsply De Trey GmbH (Germany)
18. Dentsply Dental (Tianjin) Co. Ltd. (China)
19. Dentsply Dental B.V. (Netherlands)
20. Dentsply Dental S.a.r.l. (Luxembourg)
21. Dentsply Europe S.a.r.l. (Luxembourg)
22. DENTSPLY Finance Co. LLC (Delaware)
23. Dentsply GAC Europe SAS (France)
24. Dentsply Germany Investments GmbH (Germany)
25. Dentsply IH A/S (Denmark)
26. Dentsply IH AB (Sweden)
27. Dentsply IH AS (Norway)
28. Dentsply IH GmbH (Germany)
29. Dentsply IH Holdings GmbH (Germany)
30. Dentsply IH Inc. (Delaware)
31. Dentsply IH Ltd (United Kingdom)
32. Dentsply IH Oy (Finland)
33. DENTSPLY Implants (China) Co. Limited (Hong Kong)
34. DENTSPLY Implants (HK) Co. Limited (Hong Kong)
35. Dentsply Implants Manufacturing GmbH (Germany)
36. Dentsply Implants NV (Belgium)
37. Dentsply India Pvt. Ltd. (India)
38. Dentsply Industria e Comercio Ltda. (Brazil)
39. Dentsply Israel Ltd. (Israel)
40. Dentsply Limited (Cayman Islands)
41. Dentsply LLC (Delaware)
42. Dentsply Mexico, S.A. de C.V. (Mexico)
43. Dentsply Nordics AB (Sweden)
44. DENTSPLY North America LLC (Delaware)
45. Dentsply Russia Limited (United Kingdom)
46. Dentsply Sirona (N.Z.) Limited (New Zealand)
47. DENTSPLY SIRONA (PHILS.), INC. (Philippines)
48. Dentsply Sirona (Thailand) Co., Ltd. (Thailand)
49. Dentsply Sirona Austria GmbH (Austria)
50. Dentsply Sirona Benelux B.V. (Netherlands)

51. Dentsply Sirona Dental Solutions (Shanghai) Co. Ltd. (China)
52. Dentsply Sirona Deutschland GmbH (Germany)
53. Dentsply Sirona Europe GmbH (Austria)
54. Dentsply Sirona France S.A.S. (France)
55. Dentsply Sirona Holdings Inc. (Delaware)
56. Dentsply Sirona Iberia S.A. (Spain)
57. Dentsply Sirona Implants Taiwan Co., Ltd. (Taiwan)
58. Dentsply Sirona Italia SrL (Italy)
59. DENTSPLY Sirona K.K. (Japan)
60. DENTSPLY Sirona Korea Limited (Korea)
61. Dentsply Sirona Malaysia Sdn Bhd (Malaysia)
62. Dentsply Sirona O.O.O. (Russia)
63. Dentsply Sirona Orthodontics Inc. (Delaware)
64. Dentsply Sirona Pty. Ltd. (Australia)
65. Dentsply Sirona Real Estate GmbH (Germany)
66. Dentsply Sirona Schweiz AG (Switzerland)
67. Dentsply Sirona Singapore Pte. Ltd. (Singapore)
68. Dentsply Sirona Slovakia s.r.o. (Slovakia)
69. Dentsply Sirona South Africa (Proprietary) Limited (South Africa)
70. Dentsply Sirona Switzerland Sarl (Switzerland)
71. Dentsply Sirona SZ I GmbH (Switzerland)
72. Dentsply Sirona SZ II GmbH (Switzerland)
73. Dentsply Sirona US LLC (Delaware)
74. Dentsply Sirona Vietnam Company Limited (Vietnam)
75. Dentsply South Africa (Pty.) Ltd. (South Africa)
76. Dentsply Sweden AB (Sweden)
77. Dentsply Turkey Diş Hekimliği Ürünleri A.Ş (Turkey)
78. Dentsply Ukraine LLC (Ukraine)
79. Dentsply US Inc. (Delaware)
80. DS Dental Instruments Sarl (Switzerland)
81. DS Dental Instruments SRL (Barbados)
82. DS International Services Inc. (Delaware)
83. DS Rep B.V. (Netherlands)
84. E.S. Healthcare NV (Belgium)
85. E.S. Tooling NV (Belgium)
86. GAC Deutschland GmbH (Germany)
87. JCM International Inc. (Delaware)
88. Maillefer Instruments Holding S.a.r.l. (Switzerland)
89. Maillefer Instruments Plus Sarl (Switzerland)
90. Megalopolis Dental S.A. de C.V. (Mexico)
91. MHT Optic Research AG (Switzerland)
92. Minnesota Medical Technologies Corporation (Minnesota – 10.71%)
93. MIS Asia Pacific Limited (Hong Kong)
94. MIS Implants Technologies HK Limited (Hong Kong)
95. MIS Implants Technologies Ltd. (Israel)
96. MİSDENT Implants Diş Ürünleri Sanayi Ticaret Anonim Şirketi (Turkey)
97. New Britain Medical Supplies, Inc. (Connecticut)
98. Oasis Medikal Urunler Kimya Turizm Sanayi Ve Ticaret Anonim Sirketi (Turkey)
99. Ohio IC Company (Delaware)
100. OraMetrix GmbH (Germany)
101. OraMetrix S.R.L. (Costa Rica)
102. Ortho Concept Sarl (France)
103. Orthodental, S.A. de C.V. (Mexico)

104. Prident (Shanghai) Dental Medical Devices Co., Ltd. (China)
105. Prident International, Inc. (California)
106. PT Dedent Supply (Indonesia)
107. PT Dentsply Indonesia (Indonesia)
108. Qi An Hua Rui (Beijing) Technology Ltd. (China)
109. SCI 2R (France)
110. Sirona Dental Comércio de Produtos e Sistemas Odontológicos Ltda. (Brazil)
111. Sirona Dental GmbH (Austria)
112. Sirona Dental Limited Sirketi (Turkey)
113. Sirona Dental Mexico, S. de R.L. de C.V. (Mexico)
114. Sirona Dental Services GmbH (Germany)
115. Sirona Dental Systems (Foshan) Co., Ltd. (China)
116. Sirona Dental Systems Co., Ltd (Thailand, 74.649%)
117. SIRONA Dental Systems GmbH (Germany)
118. Sirona Dental Systems LLC (Delaware)
119. Sirona Dental Systems O.O.O. (Russia)
120. Sirona Dental Systems Private Ltd. (India)
121. Sirona Dental Systems Trading, LLC (United Arab Emirates, 49%)
122. Sirona Dental, Inc. (Delaware)
123. SIRONA Immobilien GmbH (Germany)
124. Sirona Technologie GmbH & Co. KG (Germany)
125. SIRONA Verwaltungs GmbH (Germany)
126. Societe de Recherche Techniques Dentaires SAS (France)
127. Straight Smile Limitada (Costa Rica)
128. Straight Smile, LLC (Delaware)
129. Teeth Network Limited (United Kingdom)
130. The Dental Trading Co., Ltd. (Thailand, 100%)
131. Trevally Holdings Limited (United Kingdom, 20%)
132. Tulsa Dental Products LLC (Delaware)
133. Tuzodent S.A. de C.V. (Mexico)
134. VDW GmbH (Germany)
135. VIPI Indústria, Comércio, Exportação e Importação de Produtos Odontológicos Ltda. (Brazil)
136. Wellspect AB (Sweden)
137. Wellspect AG (Switzerland)
138. Wellspect ApS (Denmark)
139. Wellspect AS (Norway)
140. Wellspect B.V. (Netherlands)
141. Wellspect GmbH (Germany)
142. Wellspect Healthcare GmbH (Austria)
143. Wellspect Inc. (Delaware)
144. Wellspect Ltd. (United Kingdom)
145. Wellspect Oy (Finland)
146. Wellspect S.A.S. (France)
147. Wellspect S.L. (Spain)
148. Wellspect Srl (Italy)
149. Zetta Digital Healthcare Technology (Suzhou) Ltd. (China)
150. Zetta25 AG (Switzerland)
151. Zhermack GmbH Deutschland (Germany)
152. Zhermack SpA (Italy)
153. ZST Holdings Inc. (Canada, 16.2%)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Dentsply LLC MDEG License # (if applicable) _____

Physical Address 1301 Smile Way

City York State PA Zip 17404

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 717-767-8500 Website www.dentsplysirona.com

Licensing Company Email dsstatelic@dentsplysirona.com

Section 2: Personal Information

First Jonathan Middle Maurice Last Coleman

Alias(es, nicknames, name changes, etc.) Not applicable

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]Smile Way

City York State PA Zip 17404

Telephone 717-767-8533 Email dsstatelic@dentsplysirona.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Drexel University		01/09 - 12/14	
Address	City	State	Zip
3141 Chestnut Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
M.S. Engineering Management			

School Name		From - To (MM/YY – MM/YY)	
The Pennsylvania State University		08/98 - 08/03	
Address	City	State	Zip
201 Shields Building	University Park	PA	16802
Diploma/Degree obtained, if any			
B.S. Aerospace Engineering			

School Name		From - To (MM/YY – MM/YY)	
West Philadelphia Catholic High School		09/94 - 06/98	
Address	City	State	Zip
4501 Chestnut Street	Philadelphia	PA	19139
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Not applicable			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Not applicable			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/22 - Present	[redacted]Wetherburn Drive	York	PA	17404
09/18 - 10/22	[redacted]Basswood Court	Laurel	MD	20708
12/12 - 09/18	[redacted] Springfield Circle	Middletown	DE	19709
N/A	N/A			
N/A	N/A			
N/A	N/A			
N/A	N/A			
N/A	N/A			
N/A	N/A			
N/A	N/A			

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Dentsply Sirona			07/22 - 07/23	
Business Address		City	State	Zip
1301 Smile Way		York	PA	17404
Phone	Title		Number of Employed Hours	
717-767-8533	Senior Manager, Quality and Regulatory		1,880	
Description of Duties				
Serve as Head of Quality Assurance and Regulatory Compliance for York Smile Way's medical device and virtual pharmaceutical manufacturing operations.				

Business Name			From - To (MM/YY – MM/YY)	
Emergent BioSolutions			07/18 - 06/22	
Business Address		City	State	Zip
1111 South Paca Street		Baltimore	MD	21230
Phone	Title		Number of Employed Hours	
800-441-4225	QA Manager		7,520	
Description of Duties				
Lead biotechnology / pharma QA Operations to deliver oversight of aseptic manufacturing, inspection & packaging, Quality Control laboratories, etc. and fill / finish drug products for 40+ clients representing large to small firms.				

Business Name			From - To (MM/YY – MM/YY)	
Not applicable				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Not applicable				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Not applicable				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Not applicable			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Not applicable			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Not applicable			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Not applicable			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Not applicable			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Not applicable				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Not applicable				
Reason/Charge				
Not applicable				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Not applicable				
Name of Business/Industry/Entity				
Not applicable				

Provide explanation below:

Not applicable

Original Signature (electronic, copies or stamps not accepted)

07/25/2023

Date

I, Jonathan M. Coleman, **certify that as the MDEG Administrator for**

Dentsply LLC,

that I (initial that you have read and meet the following requirements):

1. JMC Have a high school diploma or its equivalent;
2. JMC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JMC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JMC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Coleman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/25/2023
Date

Board Use Only	Date Received:

Last Name	First Name
Bracken	Alicia
Walker	Candace
Tirado	Damaris
Hornberger	Carl
Garcia	Camille
Cirilo	Eduardo
Moran	Vicky
Williams	Edgar
Candelaria-Vega	Angel
Son	Yong
Lauver	Mikayla
Sanchez	Tamera
Gurnavage	Hannah
McDowell	Stacey
Gingerich	Benjamin
Kile	Jeremy
Velez	Evans
Wymer	Jeff
Rivera	Anthony
Dunlap	Deborah
Howard	Michelle
Ruiz Mercado	Richard
Hospador	David
Templin	Pauline
Rinehart	Lisa
Pantoja	Idalis
Hawley	Derick
Bromley	Sarah
Anderson	Rhonshia
Warfel	Stephanie
rojas Martinez	Amanda
Betancur	Juan
Almeyda	Monique
Riedel	Judith
Piette	Nathan
Brown	Khalil
Rhoades	Lori
Williams	Shayla
Dorm	Vanglyn
Platts	Diana
Armolt	Karen
Rudisill	Lonnie
Long	Wendy
Bakah	Clement
Butts	Christina
Crane	Mi Cha

Mathias	Sandra
Garcia	Ana
Knepp	Kari
Diaz Collado	Dennise
Maradiaga	Julio
Brant	Michael
Bream	Thomas
Sanchez Vidal	Edgardo
Boutin	Sara
Wildasin	Scott
Rossum	Oscar
Barnhart	Kevin
Secrist	Lori
Mckinsey	Kristen
Feudale	Debbie
Kornbau	Stacy
Marren	Daniel
Mongiello	Kimberly
Werner	Peter
Kelly	Yanira
Rudisill	Gail
Kurtz	Kevin
Malone	Gail
Allen	Mark
Litvak	Louis
Murray	Galakpai
Fetrow	Beth
Beady	Nakoya
Ramos	Milagros
Arias	Juan
Lewis	Carla
Gauntt	Dana
Viands	David
Harlacher	Brenda
Bull	Bradley
Williams	LaKeisha
Zeigler	Tina
Nichols	Corey
Donohue	Angela
Bentzel	Angela
Stewart	Danielle
Hay	Michael
Kurtz	Michael
Bright	Gregory
Nguyen	Chi
Jones	Chad
Huber	Linda

Johnson	Robert
Girven	Justin
Smith	Kristie
Wills	Mark
Lartz	Judy
Reynoso	Freddy
Duquette	Laura
Readinger	Tiffany
Brown	Jennifer
Vega Peraza	Wanda
Rossum	Casey
Vulatic	Seth
Rhoades	Robert
Sharp	Jodi
Dietrich	Michael
Santos	Emileo
Leber	Donald
Hawck	Susan
Miller	Mary Jane
Christman	Justin
Ness	Tracey
Lebron	Aldrin
Rodriguez	Israel
Simonton	Thomas
Michener	Sharon
Beauvais	Kattia
Miller	Judith
BOAKYE	RICHARD
Jones	Patricia
Kitzmiller	Callie
Stielper	Paul
Erb	Jodi
Oum	Timothy
Lash	Michele
Dent	Bradley
Coleman	Jonathan
Taylor	Denise
Kamau	James
Carter	Karine
Wentz	Sandra
Polanco	Minelys
Webb	Daniel
Oyola	Michael
Abouellail	Yassmin
Rinehart	Robert
Lehr	Robin
Seidenstricker	Dane

Zamora	Joel
Gonzalez	Maria
Sneeringer	Isaac
Lentz	Jeffrey
Reinoso	Martha
Thoman	Amy
Lai	Tuan
Sheppard	Deborah
Wilson	Jackie
Coffman	Adam
Tarkington	Philip
Varnalis	Nikolas
Cruz	Yamilet
Densel	Tosha
Dietz	Christopher
Ilgenfritz	Adana
Sweitzer	William
Wolf	Kevin
Mason	Dixie
Klinefelter	Brian
Stahle	Lori
Catanzaro	Kathleen
Smeltzer	Michael
Nazario	Nora
Mcintyre	Jessica
Estrella	Santiaga
Culberson	Jeanne
Weiss	Natallia
Hoover	Amanda
Kierce	David
Boeckel	Dawn
Santiago	Felix
Martinez-de Jesus	Denny
Latchaw	Erica
Damen	Judith
Jones	Melinda
Strickhouser	Kenneth
Maldonado	Ismael
Ferguson	Jennifer
Rogers-Fetterhoff	Amanda
Stern	Lori
Koller	Steven
Rambeau	Hunter
Simil	Marie
Holt	Michelle
Torres Burgos	Jason
Patel	Kalpesh

Stevenson	Lisa
Burton	Oliver
Daniels	Ashley
Pivarnik	Thomas
Santos	Jose
Lovelace	Melissa
Shelton	Christina
Hotea	Petronela
Urresta	Luis
Gross	Sherrie
Moore	Melissa
Ankers	Adam
Zhang	Yaqin
Cusick	Justine
Dickman	Sandra
Wivell	Kelly
Grimm	Tanya
Woodyard	Ray
Yoder	Cory
McClellan	Roxann
Howard	Darvin
Hall	Rebecca
Hepner-Harris	Billie
Fritsch	Brian
Pena Santiago	Angel
Brydels	Douglas
Mcwilliams	Sherry
Eagan	Michael
Dipuglia	Victor
Myers	Alexander
Helstowski	Michelle
Hyser	Jennifer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2022**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number **0-16211**

DENTSPLY SIRONA Inc.

(Exact name of registrant as specified in its charter)

Delaware	**39-1434669**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
13320 Ballantyne Corporate Place, Charlotte, North Carolina	**28277-3607**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(844) 848-0137**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $.01 per share	**XRAY**	**The Nasdaq Stock Market LLC**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☒	Accelerated Filer ☐	Non-Accelerated Filer ☐	Smaller Reporting Company ☐
Emerging Growth Company ☐		If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐		

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The aggregate market value of the voting common stock held by non-affiliates of the registrant computed by reference to the closing price as of the last business day of the registrant's most recently completed second quarter ended June 30, 2022, was $7,664,602,549. Based on the closing price on June 30, 2022. For purpose of this calculation only, without determining whether the following are affiliates of the registrant, the registrant has assumed that (i) its directors and executive officers are affiliates, and (ii) no party who has filed a Schedule 13D or 13G is an affiliate.

The number of shares of the registrant's common stock outstanding as of the close of business on February 16, 2023 was 215,361,909.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the definitive Proxy Statement of DENTSPLY SIRONA Inc. (the "Proxy Statement") to be used in connection with the 2023 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K to the extent provided herein. Except as specifically incorporated by reference herein the Proxy Statement is not deemed to be filed as part of this Form 10-K.

DENTSPLY SIRONA Inc.
Table of Contents

		Page
	PART I	
Item 1	Business	3
Item 1A	Risk Factors	14
Item 1B	Unresolved Staff Comments	35
Item 2	Properties	35
Item 3	Legal Proceedings	36
Item 4	Mine Safety Disclosures	36
	PART II	
Item 5	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	37
Item 7	Management's Discussion and Analysis of Financial Condition and Results of Operations	39
Item 7A	Quantitative and Qualitative Disclosures About Market Risk	57
Item 8	Financial Statements and Supplementary Data	59
Item 9	Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	132
Item 9A	Controls and Procedures	132
Item 9B	Other Information	134
Item 9C	Disclosure Regarding Foreign Jurisdiction that Prevent Inspections	134
	PART III	
Item 10	Directors, Executive Officers and Corporate Governance	135
Item 11	Executive Compensation	135
Item 12	Security Ownership of Certain Beneficial Owners and Management and Related Stock Matters	135
Item 13	Certain Relationships and Related Transactions and Director Independence	135
Item 14	Principal Accountant Fees and Services	135
	PART IV	
Item 15	Exhibits and Financial Statement Schedule	136
Item 16	Form 10-K Summary	141
Signatures		141

PART I

FORWARD-LOOKING STATEMENTS

Information included in or incorporated by reference in this Form 10-K, and other filings with the U.S. Securities and Exchange Commission (the "SEC") and the Company's press releases or other public statements, contains or may contain forward-looking statements. Please refer to a discussion of our forward-looking statements and associated risks in Item 1 "Business- Forward-Looking Statements and Associated Risks" and Item 1A "Risk Factors" of this Form 10-K.

GENERAL

Unless otherwise stated herein or the context otherwise indicates, reference throughout this Form 10-K to "Dentsply Sirona", or the "Company," "we," "us" or "our" refers to financial information and transactions of DENTSPLY SIRONA Inc., together with its subsidiaries on a consolidated basis.

INDUSTRY AND MARKET DATA

Unless indicated otherwise, the information concerning our industry contained in this Form 10-K is based on our general knowledge of and expectations concerning the industry. The Company's market position, market share and industry market size are based on data from various industry analyses, our internal research and data, and adjustments and assumptions we believe to be reasonable. The Company has not independently verified data from industry analyses and cannot guarantee their accuracy or completeness. In addition, we believe that data regarding the industry, market size and its market position and market share within such industry provide general guidance but are inherently imprecise. Further, the Company's estimates and assumptions involve risks and uncertainties and are subject to change based on various factors, including those discussed in Item 1A "Risk Factors" of this Form 10-K. These and other factors could cause results to differ materially from those expressed in the estimates and assumptions.

Item 1. Business

Overview

DENTSPLY SIRONA Inc. ("Dentsply Sirona" or the "Company") is the world's largest manufacturer of professional dental products and technologies, with a 136-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures, and markets comprehensive solutions including technologically-advanced dental equipment as well as dental and healthcare consumable products under a strong portfolio of world class brands. Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care and deliver better, safer and faster dentistry. The Company introduced the first dental electric drill over 131 years ago, the first dental X-ray unit approximately 100 years ago, the first dental computer-aided design/computer-aided manufacturing ("CAD/CAM") system approximately 30 years ago, and numerous other significant innovations including pioneering ultrasonic scaling to increase the speed, effectiveness and comfort of cleaning and revolutionizing both file and apex locater technology to make root canal procedures easier and safer. Dentsply Sirona continues to make significant investments in research and development ("R&D"), and its track record of innovative and profitable new products continues today. Dentsply Sirona's worldwide headquarters is located in Charlotte, North Carolina and its shares of common stock are listed in the United States on Nasdaq under the symbol XRAY.

The Company conducts its business through two reportable segments: (1) Technologies & Equipment ("T&E") and (2) Consumables. For the year ended December 31, 2022, T&E net revenues represented approximately 59.1% of worldwide net revenues, while Consumables net revenues represented the remaining 40.9% of worldwide net revenues.

The business is conducted in the United States of America ("U.S." or "United States"), as well as in over 150 foreign countries, principally through its foreign subsidiaries. Dentsply Sirona has a long-established presence in the European market, particularly in Germany, Sweden, France, the United Kingdom ("UK"), Switzerland and Italy. The Company also has a significant market presence in the Asia-Pacific region, Central and South America, the Middle-East region, and Canada.

Principal Products and Product Categories

The worldwide professional dental industry encompasses the diagnosis, treatment and prevention of disease and ailments of the teeth, gums and supporting bone. The Company offers a broad suite of products which together provide digital workflows for dental practitioners to make the highest use of technological advancements throughout each stage of patient care. Dentsply Sirona's principal product categories are dental technology and equipment products and dental consumable products. Additionally, the Company manufactures and sells healthcare consumable products for urological applications. As part of its technology and equipment solutions, the Company also offers an open, cloud-based platform for digital services. These products and solutions are produced by the Company globally and are distributed throughout the world under some of the most well-established brand names and trademarks in these industries, including but not limited to: AH PLUS, ANKYLOS, AQUASIL ULTRA, ARTICADENT, ASTRA TECH, ATLANTIS, AXANO, AXEOS, BYTE, CALIBRA CEMENTS, CAULK, CAVITRON, CELTRA, CERAMCO, CERCON, CEREC, CEREC MCX, CITANEST, CONFORM FIT, DAC, DELTON, DENTSPLY, DETREY, DS CORE, DYRACT, ESTHET.X, FRIOS, IMPLANT EV, INLAB, INTEGO, IPN, LOFRIC, LUCITONE, MAILLEFER, MIDWEST, MIS, MTM, NAVINA, NUPRO, OMNICAM, OMNITAPER EV, ORAQIX, ORIGO, ORTHOPHOS, OSSEOSPEED, OSSIX, PALODENT, PRIME & BOND, PROFILE, PRIMEMILL, PRIMEPRINT, PRIMESCAN, PRIMETAPER EV, PROGLIDER, PROTAPER ULTIMATE, RECIPROC, PUREVAC, SANI-TIP, SCHICK, SIDEXIS, SIMPLANT, SINIUS, SIROLASER, SIRONA, SLIMLINE, SMARTLITE PRO, SPECTRA ST, STYLUS, SULTAN, SUREFIL, SURESMILE, SYMBIOS, T1, T2, T3, T4, TENEO, THERMAFIL, TRIODENT, TRUBYTE, TRUNATOMY, VDW, VIPI, WAVEONE, WELLSPECT, XENO, XIVE, XYLOCAINE and ZHERMACK.

Technologies & Equipment Segment

Equipment & Instruments

The Equipment & Instruments product category consists of basic and high-tech dental equipment such as treatment centers, imaging equipment, motorized dental handpieces, and other instruments for dental practitioners and specialists. Imaging equipment serves as the starting point for the Company's digital workflow offerings and consists of a broad range of diagnostic imaging systems for 2D or 3D, panoramic, and intra-oral applications. Treatment centers comprise a broad range of products from basic dental chairs to sophisticated chair-based units with integrated diagnostic, hygiene and ergonomic functionalities, as well as specialist centers used in preventive treatment and for training purposes. This product group also includes other lab equipment such as amalgamators, mixing machines and porcelain furnaces.

Implants

The Implants product offering includes technology to support signature digital workflows for implant systems, a portfolio of innovative dental implant products, bone regenerative and restorative solutions, and educational programs, all of which provide dental professionals with a completely new way of practicing implantology. The Implants business is supported by key technologies including custom abutments, advanced tapered immediate load screws and regenerative bone growth factor.

CAD/CAM

Dental CAD/CAM technologies are products designed for dental offices to support numerous digital dental procedures including dental restorations. This product category includes a full-chairside economical restoration of esthetic ceramic dentistry offering called CEREC, as well as stand-alone CAD/CAM, digital impressions ("DI") intra-oral scanners, mills, and services. The full-chairside offering enables dentists to practice same day or single visit dentistry.

Orthodontics

The Company's Orthodontics product category primarily includes a dentist-directed aligner solution, SureSmile, and a direct-to-consumer aligner solution, Byte. The Orthodontics product category also includes a High Frequency Vibration ("HFV") technology device known as VPro or as HyperByte within Byte's product offering. The aligner offerings include software technology that enables aligner treatment planning and for SureSmile seamless connectivity of a digital workflow from diagnostics through treatment delivery.

Healthcare

This category consists mainly of urology catheters and other healthcare-related consumable products.

Consumables Segment

Dental consumable products consist of value-added dental supplies and small equipment used in dental offices for the treatment of patients. It also includes specialized treatment products used within the dental office and laboratory settings including products used in the preparation of dental appliances by dental laboratories.

Endodontic & Restorative Products

The Company's Endodontie & Restorative products frequently work together to provide a tandem solution in high-tech dental procedures. The Endodontic products include drills, filers, sealers, irrigation needles and other tools or single-use solutions which support root canal procedures. Restorative products include dental prosthetics, such as artificial teeth, dental ceramics, digital dentures, precious metal dental alloys, and crown and bridge porcelain products.

Other Consumables

The remaining consumables products include small equipment products such as intraoral curing light systems, dental diagnostic systems and ultrasonic scalers and polishers, as well as other dental supplies including dental anesthetics, prophylaxis paste, dental sealants, impression materials, teeth whiteners and topical fluoride.

Net sales for each product category as a percentage of the Company's total net sales for the year ended December 31, 2022, were as follows:

	% of Net Sales
Equipment & Instruments	17.3 %
Implants	14.5 %
CAD/CAM	12.8 %
Orthodontics	7.6 %
Healthcare	6.9 %
Technology & Equipment segment revenue	59.1 %
Endodontic & Restorative	29.8 %
Other consumables	11.1 %
Consumables segment revenue	40.9 %
Total net sales	100.0 %

Dental Industry, Sales and Distribution

The Company believes that the dental industry is attractive and will grow over the long-term based on the following factors:

- Increasing worldwide population, including a shift towards aging demographics, which will require greater dental care.
- Natural teeth are being retained longer - individuals with natural teeth are much more likely to visit a dentist than those without any natural teeth.
- Increasing demand for aesthetic dentistry and the use of aligners as an orthodontic treatment.
- Continued opportunities in emerging markets related to the rise in discretionary incomes making dental services an increasing priority.
- Increasing demand for single visit dentistry versus historical multi-visit procedure requirements, and for higher quality of patient care in terms of comfort and ease of product use and handling.
- Increasing demand for earlier preventive care - dentistry has evolved from a profession primarily dealing with pain, infections, and tooth decay to one with increased emphasis on earlier diagnosis, preventive care, and the role oral health plays in overall health.

- Increasing opportunity for digital collaboration between General Practitioners ("GPs"), specialists, labs, and patients is creating widening demand for fully integrated solutions such as cloud-based platforms and services facilitated by GPs.
- Increasing demand for more efficiency and better workflow in the dental office, including digital tools such as the enhanced power of diagnostic equipment through 3D imaging. The rapid pace of digital technology adoption including the digitization of clinical workflows is becoming a category standard versus traditional manual processes.

The Company is able to navigate macroeconomic challenges and is well positioned to execute on its strategy of enabling dentists to have superior integrated workflows through its robust market offerings in all key areas of dental procedures (implants, endodontic, restorative and aligners) as well as digital infrastructure (CAD/CAM and imaging) utilized in dental practices around the globe.

As of December 31, 2022, Dentsply Sirona employed approximately 5,000 highly-trained, sales and technical staff specialized in each of our various products and solutions to provide comprehensive marketing, sales, and technical support services to meet the needs of our distributors, dealers and end-users.

Sales and Distribution

Dentsply Sirona distributes approximately two-thirds of its dental consumable and technology and equipment products through third-party distributors. Certain highly technical products such as dental technology equipment, dental ceramics, crown and bridge porcelain products, endodontic instruments and materials, orthodontic aligners and appliances, and dental implants are often sold directly to the dental laboratory or dental professionals in some markets. Additionally, the Company's Byte business produces aligners which are sold direct to consumers under doctor-directed, personalized treatment plans.

For the year ended December 31, 2021, no customer accounted for 10% or more of consolidated net sales or consolidated accounts receivable balance. Customers that accounted for 10% or more of net sales and accounts receivable for the years ended December 31, 2022 and 2020 were as follows:

	2022		2020	
	% of net sales	% of accounts receivable	% of net sales	% of accounts receivable
Henry Schein, Inc.	11 %	15 %	14 %	N/A
Patterson Companies, Inc.	N/A	12 %	10 %	18 %

Although a significant portion of the Company's sales are made to distributors, dealers and importers, Dentsply Sirona focuses much of its marketing efforts on the dentists, dental hygienists, dental assistants, dental laboratories and dental schools which are the end-users of its products. As part of this end-user "pull through" marketing approach, the Company conducts extensive distributor, dealer and end-user marketing programs. Additionally, the Company trains laboratory technicians, dental hygienists, dental assistants and dentists in the proper use of its products and introduces them to the latest technological developments at its educational courses conducted throughout the world. The Company also maintains ongoing consulting and educational relationships with various dental associations and recognized worldwide opinion leaders in the dental field.

Operating Principles

The Company's focus includes the creation of more meaningful solutions for dentists built around the following five key operating principles:

- *Approach customers as one:* Put the customer at the center of how Dentsply Sirona is organized. The Company has an integrated approach to customer service, direct and indirect selling, and clinical education to strengthen the relationship with the customer and better serve the customers' needs.
- *Create innovative solutions that customers love to use:* A comprehensive R&D program that prioritizes strategic spending building the next generation of digital workflow technologies and service offerings, resulting in more impactful innovations each year.
- *Think and act with positive intent and the highest integrity:* Execute the business in a way that empowers our people, respects the communities in which we do business, and establishes trust with our partners and stakeholders.

- *Operate sustainably in everything we do:* Take a thoughtful, proactive approach to creating a sustainable company through investments in our employees, customers, and the environment.
- *Use size and global breadth to our advantage:* The Company is focused on integrating its dental product portfolios to unlock operational efficiencies, including performance improvements in procurement, logistics, manufacturing, sales force and marketing programs; and at the same time simplifying the business on a worldwide scale. In combination, these initiatives will improve organizational efficiency and better leverage the Company's selling, general and administrative infrastructure.

Product Development

While the Company enjoys market leadership in several of its product categories, continuous innovation and product development are critical for it to continue to grow its share in markets it serves. Many of Dentsply Sirona's existing products are undergoing brand extensions, and the Company also continues to focus efforts on successfully launching innovative products that have a more significant impact on bow dental and clinical professionals treat their patients. In particular, the Company has continued to prioritize investments supporting digitally enhanced workflows through each stage of patient care, including imaging and scanning technologies used in diagnosis, treatment planning software, and customized products to deliver treatment. During 2022, the Company unveiled its cloud solution DS Core, an open platform developed in collaboration with Google Cloud that integrates digital dentistry workflows across its devices, services, and technologies. The DS Core digital platform is designed to enable more precise and simplified cloud storage, optimize diagnostic capabilities, and streamline existing workflows and collaboration with laboratory partners and specialists. Through R&D investments, the Company has accelerated a number of other new product developments during the year which enhance the digital dentistry offering for both equipment and consumables products. Innovations include the Company's Primeprint Solution to provide medical-grade 3D printing, Primescan Connect which offers a laptop-based version of Primescan, the SmartLite Pro EndoActivator which serves as a new irrigation solution for root canal procedures, and the Axano treatment center combining smart design with efficient workflows. During the year, the Company also introduced its premium EV Implants System for providing implants that are harmonized, simplified and digitally enabled, as well as its enhanced orthodontic offering SureSmile Solutions that includes the addition of a whitening kit, retainers, and the VPro orthodontic device which uses high-frequency vibration to reduce discomfort in aligner treatment.

During 2021, product launches included software upgrades for CEREC and SureSmile introduction of PrimeTaper, a self-tapping implant with a tapered design; and ProTaper Ultimate, the next generation of endodontic files. The Company also acquired key supporting technologies in OSSIX bone regenerative collagen through the purchase of Datum Dental, and the new VPro aligner treatment devices through the acquisition of substantially all of the assets of Propel Orthodontics LLC ("Propel"). During 2020, the Company introduced Axeos, a new digital imaging product with a 3D wide field of view and Primemill, a time saving grinding and milling restoration machine. New products introduced within the past three years accounted for approximately 14% of 2022 sales.

R&D investments include activities to accelerate product and clinical innovation and discipline, and develop potential improvements to the manufacturing process. These investments also support engineering efforts that incorporate customer feedback into continuous improvement for current and next-generation products, with an objective to achieve more frequent development and release cycles. The Company also undertakes pre-commercialization trials and testing of technological improvements prior to inception of the manufacturing process. As is true across its other functions, the Company is continually transforming how R&D is conducted by identifying best practices, driving efficiencies, and optimizing cost structure to enable a more effective development process with a strategic focus on innovation process discipline. We are also looking to increasingly utilize an enterprise approach to funding that employs a returns-based mindset and allocates R&D spend towards those areas with the highest return.

In addition to internal product development, the Company also pursues external R&D opportunities, including acquisitions, licensing, or other arrangements with third parties. Initiatives to support technological development also include collaborations with research institutions and dental and medical schools. The Company annually supports the achievements of dental students conducting innovative research through its *Student Competition for Advancing Dental Research and its Application Awards* program. The Company is also committed to participation in clinical research demonstrating the efficacy of our products prior to market introduction, and in supporting the clinical education and technical training of dental professionals. Dentsply Sirona has 55 academies and education centers that are home to state-of-the-art training facilities for dental professionals who seek a comprehensive variety of clinical and technical continuing education curriculum. The academies offering hands-on teaching, live lectures, and on-demand webinars and courses which are taught by a diverse range of internationally known experts in all fields of dentistry. The Company provides over 7,000 training courses through our DS Academy annually, with approximately 300,000 dental professionals participating.

Through our internal research centers as well as through our collaborations with external research institutions, dental and medical schools, the Company directly invests in the development of new products, improvement of existing products and advances in technology. These investments include an emphasis on research in digital data sharing technology, including the incorporation of long-term artificial intelligence and machine learning. The continued development of these areas is a critical step in meeting the Company's strategic goal as a leader in defining the future of dentistry. The Company's long-term plans for investment in product development include an objective to maintain a level of R&D spend that is at least 4% of annual net sales with a focus on innovation and expansion of digital, software, services, and other platform offerings.

Acquisition Activities

Dentsply Sirona believes that the dental technology and consumable products industries continue to experience consolidation with respect to both product manufacturing and distribution, although they remain fragmented thereby creating a number of acquisition opportunities.

The Company views acquisitions as a key part of its long-term growth strategy. These acquisition activities are intended to supplement the Company's organic growth and assure ongoing expansion of its business to capitalize on significant growth drivers, including new technologies, additional products, organizational strength and geographic breadth. During the first quarter of the year ended December 31, 2021, the Company purchased Datum Dental, Ltd., a producer and distributor of specialized regenerative dental material based in Israel, which provided the Company with a key technology to serve the implants markets. The Company followed in the second quarter of the year ended December 31, 2021 with the purchase of substantially all of the assets of Propel, a U.S. based company which manufactures and sells orthodontic devices and provides in-office and at-home orthodontic accessory devices, this investment is expected to further accelerate the growth and profitability of the Company's combined aligners business. In the third quarter of the year ended December 31, 2021, the Company completed its acquisition of a partially owned affiliate based in Switzerland that primarily develops highly specialized software, whicb is expected to further accelerate the development of the Company's specialized software related to CAD/CAM systems. During the year ended December 31, 2020, the Company made various investments, including the acquisition of Byte, a direct-to-consumer aligners business, which complements the Company's existing aligner product by adding a digital component and is expected to enhance scale and accelerate the growth of the Company's combined aligners business going forward. This acquisition was representative of the Company's strategy of matching technological advancement in digital dentistry with innovative marketing and delivery in order to reach areas of high-growth potential for customer demand. For more information regarding the Company's acquisition activity, refer to Note 6, Business Combinations, in the Notes to the Consolidated Financial Statements in Part II, Item 8 of this Form 10-K.

Operating and Technical Expertise

Dentsply Sirona believes that its manufacturing capabilities are important to its success. The manufacturing processes of the Company's products require substantial and varied technical expertise. Complex materials technology and processes are necessary to manufacture the Company's products. Where the Company can improve quality and customer service and lower costs, we endeavor to automate our global manufacturing operations.

Financing

Information about Dentsply Sirona's working capital, liquidity and capital resources is provided in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-K.

Competition

The Company conducts its operations, both domestic and foreign, under highly competitive market conditions. Competition in the dental and healthcare consumable products and dental technology and equipment products industries is based primarily upon product performance, quality, safety and ease of use, as well as price, customer service, innovation and acceptance by clinicians, technicians and patients. Dentsply Sirona believes that its principal strengths include its well-established brand names, its reputation for high quality and innovative products, its leadership in product development and manufacturing, its global sales force, the breadth of its product line and distribution network, its commitment to customer satisfaction and support of the Company's products by dental and medical professionals.

The size and number of the Company's competitors vary by product line and from region to region. There are many companies that produce some, but no competitor produces all of the same types of products as those produced by the Company.

Regulation

The development, manufacture, sale and distribution of the Company's products are subject to comprehensive governmental regulation both within and outside the U.S. The following sections describe certain, but not all, of the significant regulations that apply to the Company. For a description of the risks related to the regulations that the Company is subject to, please refer to Item 1A. "Risk Factors" of this Form 10-K.

The majority of the Company's products are classified as medical devices and are subject to restrictions under domestic and foreign laws, rules, regulations, self-regulatory codes, circulars and orders, including, but not limited to, the U.S. Food, Drug, and Cosmetic Act (the "FDCA"), Council Directive 93/42/EEC on Medical Devices ("MDD") (1993) in the European Union ("EU"), which will be updated to the EU Medical Device Regulation ("MDR") in 2021 (and implementing and local measures adopted thereunder) and similar international laws and regulations. The FDCA requires these products, when sold in the U.S., to be safe and effective for their intended use and to comply with the regulations administered by the U.S. Food and Drug Administration ("FDA"). Certain medical device products are also regulated by comparable agencies in non-U.S. countries in which they are produced or sold.

Dental and medical devices sold by the Company in the U.S. are generally classified by the FDA into a category that renders them subject to the same controls that apply to all medical devices, including regulations regarding alteration, misbranding, notification, record-keeping and good manufacturing practices. In the EU, the Company's products are subject to the medical device laws of the various member states, which are based on a Directive of the European Commission. Such laws generally regulate the safety of the products in a similar way to the FDA regulations. The Company products in Europe bear the CE mark showing that such products comply with European regulations. The Company's products classified by EU MDD were mandated to be certified under the new MDR. These regulations also applied to all medical device manufacturers who market their medical devices in the EU and all such manufacturers had to perform significant upgrades to quality systems and processes including technical documentation and subject them to new certification under EU MDR in order to continue to sell those products in the EU. Although all medical device manufacturers were required to certify their Class I (as defined in the EU MDR regulations) products by May 2021, the EU MDR regulations for additional Classes of medical devices is mandated to be fully enforceable by May 2024. This also includes completion of certified quality management systems to manufacturers quality management systems. The Company remains focused on ensuring that all its products that are considered to be medical devices will be fully certified as required by the EU MDR dates and timelines.

Recently, the Chinese government launched a national program for volume-based, centralized medical device and consumables procurement with minimum quantity commitments in an attempt to negotiate lower prices from drug manufacturers and reduce the price of medical devices and other products. Under the program, the government will award contracts to the lowest bidders who are able to satisfy the quality and quantity requirements. The successful bidders will be guaranteed a sale volume for at least a year, giving the winner an opportunity to gain or increase market share. The volume guarantee is intended to make manufacturers more willing to cut their prices in order to win a bid and may also enable successful bidders to lower their distribution and commercial costs. Many types of drugs are covered under the program, including drugs made by international pharmaceutical companies and generics made by domestic Chinese manufacturers. The program, which is anticipated to take effect in the first half of 2023, could in the future result in reduced margins on covered devices and products, required renegotiation of distributor arrangements, and incurrence of inventory-related charges. The Company currently expects that sales of our Implants products in China will be negatively affected by price reductions.

The Company is also subject to domestic and foreign laws, rules, regulations, self-regulatory codes, circulars and orders regarding anti-bribery and anti-corruption, including, but not limited to, the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.S. Federal Anti-Kickback Statute ("AKS"), the UK's Bribery Act 2010 (c.23), Brazil's Clean Company Act 2014 (Law No. 12,846) China's National Health and Family Planning Commission ("NHFPC") circulars No. 40 and No. 50, and similar international laws and regulations. The FCPA and similar anti-bribery and anti-corruption laws applicable in non-U.S. jurisdictions generally prohibit companies and their intermediaries from improperly offering or paying anything of value to foreign government officials for the purpose of obtaining or retaining business. Some of the Company's customer relationships are with governmental entities and therefore may be subject to such anti-bribery laws. The AKS and similar fraud and abuse laws applicable in non-U.S. jurisdictions prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a health care program, such as, in the U.S., Medicare or Medicaid.

The Company's production and sale of products is further subject to regulations concerning the supply of conflict minerals, various environmental regulations such as the Federal Water Pollution Control Act (the "Clean Water Act") and others enforced by the Environmental Protection Agency ("EPA") or equivalent state agencies, and the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (the "Health Care Reform Law"). In the sale, delivery and servicing of the Company's products to other countries, it must also comply with various domestic and foreign export control and trade embargo laws and regulations, including those administered by the Department of Treasury's Office of Foreign Assets Control ("OFAC"), the Department of Commerce's Bureau of Industry and Security ("BIS") and similar international governmental agencies, which may require licenses or other authorizations for transactions relating to certain countries and/or with certain individuals identified by the respective government. Despite the Company's internal compliance program, policies and procedures may not always protect it from reckless or criminal acts committed by its employees or agents. Violations of these requirements are punishable by criminal or civil sanctions, including substantial fines and imprisonment. Due in part to its direct-to-consumer model, the Company's Byte aligner business in the U.S. is subject to various state laws, rules and policies which govern the practice of dentistry within such state. Byte contracts with an expansive nationwide network of independent licensed dentists and orthodontists for the provision of clinical services, including the oversight and control of each customer's clinical treatment in order to comply with these regulations and ensure that the business does not violate rules pertaining to the corporate practice of dentistry.

The Company is subject to domestic and foreign laws, rules, regulations, self-regulatory codes, circulars and orders governing data privacy and transparency, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (the "HITECH Act"), the California Consumer Privacy Act, the European General Data Protection Regulation (the "GDPR"), China's Personal Information Protection Law, the Physician Payments Sunshine Provisions of the Patient Protection and Affordable Care Act, the EU Directive 2002/58/EC (and implementing and local measures adopted thereunder), France's Data Protection Act of 1978 (rev. 2004) and France's Loi Bertrand, certain rules issued by Denmark's Health and Medicines Authority, and similar international laws and regulations. HIPAA, as amended by the HITECH Act, the GDPR and similar data-privacy laws applicable in non-U.S. jurisdictions, restrict the use and disclosure of personal health information, mandate the adoption of standards relating to the privacy and security of individually identifiable health information and require us to report certain breaches of unsecured, individually identifiable health information. The Physician Payments Sunshine Provisions of the Patient Protection and Affordable Care Act require the Company to record all transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services for public disclosure. Similar reporting requirements have also been enacted in several states, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals.

The Company believes it is in substantial compliance with the laws and regulations that regulate its business. There are, however, significant uncertainties involving the application of various legal requirements, the violation of which could result in, among other things, sanctions. See Item 1A, "Risk Factors" of this Form 10-K for additional detail.

Sources and Supply of Raw Materials and Finished Goods

The Company manufactures the majority of the products that it sells. The Company sources the necessary raw materials from various suppliers, and no single supplier accounts for more than 10% of our supply requirements.

Intellectual Property

Products manufactured by Dentsply Sirona are sold primarily under its own tradenames and trademarks. Dentsply Sirona also owns and maintains more than 5,000 patents throughout the world and has also licensed a number of patents owned by others.

Our policy is to protect its products and technology through patents and trademark registrations both in the U.S. and in significant international markets. The Company monitors trademark use worldwide and promotes enforcement of its patents and trademarks in a manner that is designed to balance the cost of such protection against obtaining the greatest value for the Company. Dentsply Sirona believes its patents and trademark properties are important and contribute to the Company's marketing position but it does not consider its overall business to be materially dependent upon any individual patent or trademark. Additional information regarding certain risks related to our intellectual property is included in Item 1A "Risk Factors" of this Form 10-K and is incorporated herein by reference.

Human Capital

Our employees are core to our Company, and their contributions enable the success of our business. As of December 31, 2022, our organization and its subsidiaries employed over 15,000 employees across the globe. Of these employees, approximately 3,600 were employed in the U.S. Some employees outside of the U.S. and particularly in Europe are covered by collective bargaining, union contracts, worker councils or other similar programs. Our talent strategy prioritizes attracting, engaging, developing, and retaining talent to support our business strategy. We strive to foster a diverse and inclusive environment where every employee can grow and perform at their best.

Attract, Engage, Develop & Retain

In 2022, we continued to evolve our talent strategy to support business priorities. We continued deployment of our Emerging Talent program focused on attracting early-career employees through strategic partnerships with Historically Black Colleges and Universities and local trade schools. The comprehensive program provides rotational assignments, on-the-job experiences, networking events, development sessions and executive interactions. We offer global learning and development opportunities including a partnership with LinkedIn Learning which offers thousands of on-demand learning modules in multiple languages and our custom leadership development framework to assess, develop and coach leaders at multiple levels. Our robust set of tools for goal setting and development planning is designed to support future-focused growth including our employee-led career mapping and global mentor matching programs. We also offer regular performance feedback, development planning and talent review processes in an automated format for our professional employees.

To keep employees connected, engaged and informed, we continued to hold virtual town halls and live video chats. These events provide multiple opportunities for our global workforce to submit questions to our executive leadership team. Employee feedback is an important element of our culture. We launch global engagement surveys at least every 18 months and strategically deploy pulse and lifecycle surveys throughout the year. We leverage insights from these surveys to drive actions that improve the employee experience, supporting talent attraction, engagement, and retention.

Compensation and Benefits

As part of the our total rewards philosophy, we offer competitive compensation and benefit programs designed to attract and retain top talent. We are committed to providing and administering these programs in a way that treats our employees at all levels fairly and equitably. Our total rewards offerings vary by country and include an array of programs that support our employees' financial, physical, and mental well-being, including annual performance incentive opportunities, pension and retirement savings programs, health and welfare benefits, paid time off (including for charitable actions), leave programs, flexible work schedules and employee assistance programs.

Diversity, Equity & Inclusion

Diversity in our organization is a source of great strength. We provide opportunities for all employees to bring their perspective, experience, and lens to the workplace. Our commitment to a diverse workforce helps us create robust solutions to our customers' challenges and drive innovation. We strive to foster an environment in which our teams feel inspired and empowered to do their best work and bring new ideas to the table. We have a Diversity, Equity & Inclusion strategy focused on embedding diversity, equity & inclusion into our culture.

As part of our sustainability program, BEYOND-Taking Action for a Brighter World, we are striving to achieve global gender pay equity and global gender parity by 2025. We are members of the Paradigm for Parity cross-sector diversity commitment – a coalition of more than 130 CEOs, executives, board members, founders and experts dedicated to providing women and men equal opportunity and power and achieving gender parity by 2030.

Diversity, Equity & Inclusion Council

Our Diversity, Equity & Inclusion Council is a group of demographically and functionally diverse employees from across the world dedicated to enabling our diversity, equity & inclusion efforts and championing initiatives that support the organization internally and externally. A top priority of the Diversity, Equity & Inclusion Council is to equip leaders to discuss and be accountable for driving sustained diversity, equity, and inclusion progress.

Employee Resource Groups

The purpose of our employee resource groups is to foster a diverse, equitable, and inclusive environment enabling employees to bring their best to work as they participate in successfully executing our strategy. As of December 31, 2022, our employees have led the successful establishment of seven employee resource groups consisting of approximately 2,000 members from across the globe. Our employee resource groups focus on developing talent, increasing employee engagement, and creating awareness through allyship. We consistently recognize high participation in employee resource group-led events.

Training and Awareness

We offer a catalog of on-demand diversity, equity & inclusion training options aimed at strengthening awareness. A standout offering is our ongoing "Conversations of Understanding" sessions. Employees are invited to register for these small group discussions where internal volunteers share experiences on varying diversity, equity, & inclusion topics to generate healthy discussion and awareness.

Talent Acquisition

Our organization has talent sourcing guidelines requiring diverse and internal candidate interview slates for Director-level and above roles. To increase internal mobility, we offer career development options and utilize our talent review processes to highlight diverse talent. We educate our hiring managers on inclusive hiring practices.

Measuring Progress

Our executive leadership team regularly monitors and actions on diversity metrics, including attraction, engagement, advancement, and retention of diverse talent. We actively partner with an external consultancy to identify available talent pools in all our geographic markets and establish benchmarks for diverse representation across function, geography and level. All executive leaders create annual action plans and progress is reviewed quarterly.

Employee Health & Safety Matters

The health and safety of our employees are of utmost importance to us. We have a dedicated Employee Health & Safety ("EHS") program that provides global processes and trainings and monitors our progress against set goals. Our actions are in line with EHS frameworks and certifications such as OHSAS 18001 and ISO 45001. We also have a Corporate Crisis Management Team, prepared to respond to crisis situations we may be confronted on a global scale with in a prompt and efficient manner.

Other Factors Affecting the Business

The Company's business is subject to quarterly fluctuations in demand due to price changes, marketing and promotional programs, management of inventory levels by distributors, and implementation of strategic initiatives which may impact sales levels in any given period. Demand can also fluctuate based on the timing of dental tradeshows where promotions are offered, major new product introductions, and variability in dental patient traffic, which can be exacerbated by seasonal or severe weather patterns, or other demographic disruptions such as the recent COVID-19 pandemic. Some dental practices in certain countries may also delay purchasing equipment and restocking consumables until year-end due to tax planning which can impact the timing of our consolidated net sales, net income and cash flows. Sales for the industry and the Company are generally strongest in the second and fourth quarters and weaker in the first and third quarters, due to the effects of the items noted above and due to the impact of holidays and vacations, particularly throughout Europe.

Although the backlog on products is generally not material to the financial statements due in part to the Company's efforts to maintain short lead times within its manufacturing, levels can fluctuate and affect sales in certain periods due to supply chain disruption and unavailability of required inputs.

Securities Exchange Act Reports

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The public can obtain any documents that the Company files with the SEC at http://www.sec.gov. The Company files annual reports, quarterly reports, proxy statements and other documents with the SEC under the Securities Exchange Act of 1934, as amended ("Exchange Act").

Dentsply Sirona also makes available free of charge through the investor section of its website at www.dentsplysirona.com its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such materials are filed with or furnished to the SEC. The information contained on, or that may be accessed through, the Company's website is not incorporated by reference into, and is not a part of, this report.

Forward-Looking Statements and Associated Risks

All statements in this Form 10-K that do not directly and exclusively relate to historical facts constitute "forward-looking statements." These statements represent current expectations and beliefs, and no assurance can be given that the results described in such statements will be achieved. Such statements are subject to numerous assumptions, risks, uncertainties and other factors that could cause actual results to differ materially from those described in such statements, many of which are outside of our control. No assurance can be given that any expectation, belief, goal or plan set forth in any forward-looking statement can or will be achieved, and readers are cautioned not to place undue reliance on such statements which speak only as of the date they are made. We do not undertake any obligation to update or release any revisions to any forward-looking statement or to report any events or circumstances after the date of this Form 10-K or to reflect the occurrence of unanticipated events.

You should carefully consider these and other relevant factors, including those risk factors in Item 1A, "Risk Factors" of this Form 10-K and any other information included or incorporated by reference in this report, and information which may be contained in the Company's other filings with the SEC, when reviewing any forward-looking statement. Investors should understand it is impossible to predict or identify all such factors or risks. As such, you should not consider either the foregoing lists, or the risks identified in the Company's SEC filings, to be a complete discussion of all potential risks or uncertainties associated with an investment in the Company.

Item 1A. Risk Factors

Summary

The following is a summary of the significant risk factors that could materially impact our business, financial condition or future results, including risks related to our businesses, our international operations, our regulatory environments, ownership of our common stock, COVID-19, and other general risks:

- Management identified material weaknesses in our internal control over financial reporting that resulted in errors in previously issued financial statements. If we fail to remediate these material weaknesses or experiences additional material weaknesses in the future, we may be unable to accurately and timely report financial results or comply with the requirements of being a public company, which could cause the price of our common stock to decline and harm our business.
- We restated certain of our previously issued consolidated financial statements, which resulted in unanticipated costs and may affect investor confidence and raise reputational issues.
- We may be subject to litigation and regulatory examinations, investigations, proceedings or court orders as a result of or relating to our internal investigation and if any of these items are resolved adversely against us, it could harm our business, financial condition and results of operations.
- Our failure to timely file our periodic reports with the SEC limits our access to the public markets to raise debt or equity capital, and restricts our ability to issue equity securities.
- Lack of global standardized processes, centralization of transaction management and/or execution could result in control deficiencies and impact management's assertions and financial reporting.
- We rely heavily on information and technology to operate both our businesses and our technology dependent product solutions portfolios, and any continued cyber incidents with respect to our supporting information and technology infrastructure, whether by deliberate attacks or unintentional events, could harm our operations.
- Privacy concerns and laws, evolving regulation of cross-border data transfer restrictions and other regulations may adversely affect our business.
- We may be unable to develop innovative products and solutions or stimulate customer demand.
- Our ongoing business operations may be disrupted for a significant period of time, resulting in material operating costs and financial losses.
- We may be unable to execute key strategic initiatives due to competing priorities and strategies of our distribution partners and other factors, which may result in financial losses and operational inefficiencies.
- The success of our business depends in part on achieving our strategic objectives, including through acquisitions, dispositions, and strategic investments and initiatives.
- We may fail to realize the expected benefits of our strategic initiatives, including announced or potential future restructuring and transformation efforts.
- We have recognized substantial goodwill and indefinite-lived intangible asset impairment charges, most recently in Q3 and Q4 2022, and may be required to recognize additional goodwill and indefinite-lived intangible asset impairment charges in the future.
- Our failure to obtain patents and, consequently, to protect our proprietary technology could have an adverse impact on our competitive position.
- Our profitability could suffer if third parties infringe upon our intellectual property rights or if our products are found to infringe upon the intellectual property rights of others.
- Changes in our credit ratings or macroeconomic impacts on credit markets may increase our cost of capital and limit financing options.
- A breach of the covenants under our debt instruments outstanding from time to time could result in an event of default under the applicable agreement.
- We may not be able to repay our outstanding debt in the event that we do not generate sufficient cash flow to service our debts and cross default provisions may be triggered due to a breach of covenants under our existing indebtedness.
- Our foreign currency hedging and cash management transactions may be ineffective or only partially mitigate the impact, exposing us to unexpected interest rate volatility.
- Due to the international nature of our business, including increasing exposure to markets outside of the U.S., political or economic changes or other factors could harm our business and financial performance.
- Due to our international operations, we are exposed to the risk of changes in foreign exchange rates.
- Changes in or interpretations of tax rules, operating structures, transfer pricing regulations, country profitability mix and regulations may adversely affect our effective tax rate.
- We may be unable to obtain necessary product approvals and marketing clearances.
- Inadequate levels of reimbursement from governmental or other third-party payers for procedures using our products may cause our revenue to decline.

- Challenges may be asserted against our products due to real or perceived quality, health or environmental issues.
- If we fail to comply with laws and regulations relating to health care fraud, we could suffer penalties or be required to make significant changes to our operations, which could adversely affect our business.
- Our business is subject to extensive, complex and changing domestic and foreign laws, rules, regulations, self-regulatory codes, directives, circulars and orders that failure to comply with which, if not complied with, could subject us to civil or criminal penalties or other liabilities.
- Our quarterly operating results and market price for our common stock may continue to be volatile.
- Certain provisions in our governing documents, and of Delaware law, may make it more difficult for a third party to acquire us.
- Our revenue, results of operations, cash flow, and liquidity may be materially adversely impacted by the ongoing COVID-19 outbreak.
- Our business may be adversely affected by changes in global economic conditions, including inflation, rising interest rates, and supply chain shortages.
- The loss of members of our senior management and the resulting management transition might have an adverse impact on our future operating results.
- Talent gaps and failure to manage and retain top talent may impact our ability to grow the business.
- We face the inherent risk of litigation and claims.
- Climate change and related natural disasters could negatively impact our business and financial results.
- Expectations relating to environmental, social and governance considerations may expose us to potential liabilities, increased costs, reputational harm, and other adverse effects on our business.

Below is a full description of each of such significant risk factors.

RISKS RELATED TO OUR RESTATEMENT AND INTERNAL CONTROLS

Management identified material weaknesses in our internal control over financial reporting that resulted in errors in previously issued financial statements. If we fail to remediate these material weaknesses or experiences additional material weaknesses in the future, we may be unable to accurately and timely report financial results or comply with the requirements of being a public company, which could cause the price of our common stock to decline and harm our business.

Management identified material weaknesses in internal controls over financial reporting in conjunction with the Audit and Finance Committee's investigation as described in the Explanatory Note of Amendment No. 1 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "2021 Form 10-K/A"). The description of the material weaknesses that were determined to exist as of December 31, 2021 is included under Item 8 of this Form 10-K. Management began implementing the remediation efforts in 2022; however, as of December 31, 2022, the material weaknesses previously identified have not yet been remediated.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected in a timely basis.

While we are devoting substantial resources to the planning and ongoing implementation of remediation efforts to address the identified material weaknesses and prevent additional material weaknesses from occurring, it cannot be assured that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate these material weaknesses or to avoid potential future material weaknesses. We cannot estimate how long the remediation process will take at this time, and may identify deficiencies or other material weaknesses, in addition to the ones already identified, that we may not be able to remediate in a timely manner. Accordingly, there is a reasonable possibility that the material weaknesses identified, or other material weaknesses or deficiencies identified in the future, could result in a misstatement of accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis or cause us to fail to meet our obligations under securities laws, stock exchange listing rules, or debt instrument covenants to file periodic financial reports on a timely basis.

Further, because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud, even our remediated and effective internal control over financial reporting may not prevent or detect all misstatements and may not provide reasonable assurances with respect to the preparation and presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become either obsolete or inadequate as a result of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

400

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: RxSight, Inc.

Physical Address: 100 Columbia, Suite 120

City: Aliso Viejo State: CA Zip: 92656

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (949) 521-7830 Website: www.rxsight.com

Name of Designated Representative (DR): N/A (Publicly Traded Corporation)

Licensing Company Email: _____ DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): _____

Corporation Name: RxSight, Inc.

Mailing Address: 100 Columbia, Suite 120

City: Aliso Viejo State: CA Zip: 92656

Telephone: 949-439-7927 Email: sthunen@rxsight.com

Contact Person Name: Shelley Thunen

Date of SEC Registration: July 9, 2021 | SEC Registration Number: 333-257790 | Stock Exchange Symbol: RXST

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

RxSight, Inc.

Facility Name

Shelley Thunen

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

August 31, 2023

Date

Board Use Only	Date Received: 9/1/23	Amount: 1006 - CC

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
RxSight Inc.
100 Columbia
Aliso Viejo, CA 92656
Registration Number: 3012712027
FEI Number*: 3012712027
Status: Active
Date Of Registration Status: 2023

Owner/Operator:
RxSight Inc.[6]
100 Columbia
Aliso Viejo, CA US 92656
Owner/Operator Number: 10028051[7]

Official Correspondent:
Debe Deck
100 Columbia
Aliso Viejo, CA 92656
Phone: 1-949-5217869-140

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10028051&OwnerOperatc

Page Last Updated: 08/28/2023

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Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10028051&OwnerOperatc

Verified 9/6/23

Wholesaler Application (Publicly Traded Corporation)

Section 8 and 9 Documents

Section 8

Copy of FDA Registration:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm



Section 9

List of all Officers and Directors:

Name	Title
Andy Corley	Board of Director
Julie Andrews	Board of Director
Juliet Bakker	Board of Director
Robert Palmisano	Board of Director
Robert Warner	Board of Director
Ron Kurtz, MD	Board of Director, President, and Chief Executive Officer
Shweta Maniar	Board of Director
Tamara Fountain, MD	Board of Director
William Link, PhD	Board of Director
Eric Weinberg	Chief Commercial Officer
Ilya Goldshleger, PhD	Chief Operations Officer
Shelley Thunen	Chief Financial Officer

List the top four corporation shareholders and their percent ownership:

Wholesaler is providing list reported in 13F and/or Proxy sources as of June 30, 2023.

Shareholder	Position	Percent Ownership
RA Capital Management, LP	3,052,796	8.55%
Artisan Partners Limited Partnership	2,078,470	5.82%
H.I.G. Capital, LLC	2,010,037	5.63%
Wolfen (Richard M)	1,827,349	5.12%

List the top four corporation shareholders and their percent ownership:

Wholesaler is providing list reported in 13F and/or Proxy sources as of June 30, 2023.

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H.I.G. Capital, LLC	2,010,037	5.63%
Wolfen (Richard M)	1,827,349	5.12%

Certificate of Good Standing Obtained from the Secretary of State's Office in the State where the Business is Domiciled, Dated Within the Last 12 Months:

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	RXSIGHT, INC.
Entity No.:	4771177
Registration Date:	07/28/2021
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	DELAWARE
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of May 22, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 111028720

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

Copy of Your License, Certification, Permit, or Registration Issued to Your Wholesaler Business from the Regulatory Board or Licensing Authority of the State or Territory in Which the Wholesaler is Located. (REQUIRED FOR OUT-OF-STATE WHOLESALERS, if Applicable):



STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

RxSight, Inc.
100 Columbia
Aliso Viejo, CA 92656

LICENSE NUMBER: 79283
EXPIRATION DATE: 9/6/2025

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 3/30/2023

OSP 07 102308

Medical Devices, Equipment and Gases (MDEG) Administrator form must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957):

See MDEG Administrator form.

Supply a Copy of Proof of Insurance (NAC 639.6957. The MDEG Wholesaler Shall Maintain Liability Insurance of At Least One Million Dollars ($1,000,000.00):

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/2/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Stacy Zamalloa
Woodruff-Sawyer & Co. 2 Park Plaza, Suite 500 Irvine CA 92614	PHONE (A/C, No, Ext): 949-435-7412 FAX (A/C, No): E-MAIL ADDRESS: szamalloa@woodruffsawyer.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Federal Insurance Company	20281
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED CALHVIS-01
RxSight, Inc.
100 Columbia, Suite 120
Aliso Viejo, CA 92656

COVERAGES **CERTIFICATE NUMBER:** 1472208705 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			35796107	11/1/2022	11/1/2023	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N / A						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Product Liability & Errors & Omissions			73237207	11/1/2022	11/1/2023	Each Occurence Products-Comp/OP AGG Ded. Each Event	$10,000,000 $10,000,000 $50,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

File Copy

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Stacy Zamalloa

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Copy of Current SEC 10K or 8K (First 1S Pages Only):

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 001-40690

RxSight, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**94-3268801**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Columbia **Aliso Viejo, California**	**92656**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (949) 521-7830

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	RXST	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

As of June 30, 2022, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $310 million based upon the closing price of $14.08 on the Nasdaq Global Market on such date.

The number of shares of registrant's Common Stock outstanding as of February 15, 2023 was 33,775,718.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the registrant's 2023 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2022. Except with respect to information specifically incorporated by reference, the Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

Table of Contents

		Page
PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	26
Item 1B.	Unresolved Staff Comments	85
Item 2.	Properties	85
Item 3.	Legal Proceedings	85
Item 4.	Mine Safety Disclosures	85
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	86
Item 6.	[Reserved]	86
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	87
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	97
Item 8.	Financial Statements and Supplementary Data	98
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	127
Item 9A.	Controls and Procedures	127
Item 9B.	Other Information	128
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	129
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	130
Item 11.	Executive Compensation	130
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	130
Item 13.	Certain Relationships and Related Transactions, and Director Independence	131
Item 14.	Principal Accountant Fees and Services	131
PART IV		
Item 15.	Exhibit and Financial Statement Schedules	132
Item 16.	Form 10-K Summary	136

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following discussion and analysis should be read together with our consolidated financial statements and the notes to those statements included elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are based on our management's beliefs and assumptions and on information currently available to our management. In this Annual Report on Form 10-K, "we," "us" and "our" refer to RxSight, Inc.

The forward-looking statements are contained principally in the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this Annual Report on Form 10-K. Forward-looking statements include, but are not limited to, statements concerning the following:

- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements, including our expectation that we do not anticipate the need to raise additional capital or incur additional debt in order to reach profit from operations, as disclosed in the Company's future Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q as filed with the Securities and Exchange Commission ("SEC"), provided that we may opportunistically access our at-the-market ("ATM") facility under advantageous circumstances;
- our plans to conduct further clinical trials and any expectations related to such trials;
- our plans and expected timeline related to our products, or developing new products, to address additional indications or otherwise;
- the expected acceptance and use of our products by doctors;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products we create;
- the expected growth of our business and our organization;
- our intentions regarding investment in our business as we pursue growth;
- our expected uses of our existing resources;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, including single- and sole-source suppliers;
- our ability to manufacture sufficient quantities of our products with appropriate quality;
- our ability to obtain, maintain and enforce intellectual property protection for our products and protect our intellectual property rights;
- our ability to expand our business into new geographic markets;
- our ability to comply with applicable SEC rules and Nasdaq continued listing requirements;
- our ability to comply with existing and future government laws, rules and regulations both in the U.S. and internationally;
- our expectations regarding allocation of resources toward expenses associated with being a public company;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;

- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") and a smaller reporting company under the Exchange Act;
- the volatility of the trading price of our common stock;
- our ability to identify and develop new and planned products and/or acquire new products;
- development and projections relating to our competitors or our industry, including anticipated growth rates for the conventional and premium intraocular lens ("IOL") markets;
- the impact of local, regional, national or political conditions and events;
- the impact of the COVID-19 pandemic, including currently known and unknown coronavirus variants, on our business or personnel; and
- the impact of worldwide political and economic conditions and unknown future events could have a material adverse impact on our business, financial condition and results of operations.

Forward-looking statements include statements that are not historical facts and can be identified by terminology such as "may," "will," "should," "could," "would," "expects," "plans," "intends," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue," or the negative of such terms and other same terminology.

Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in Part I, Item 1A, "Risk Factors," elsewhere in this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Annual Report on Form 10-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

DISCUSSION AND ANALYSIS OF OUR FINANCIAL CONDITION

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to revenue recognition, the realization of income tax assets and estimates of tax liabilities, and obsolete, excess and slow-moving inventory. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ materially from these estimates.

INDUSTRY, BUSINESS AND MARKET DATA

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and market opportunity, including data regarding the estimated size of the market. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

TRADEMARKS, SERVICE MARKS AND TRADE NAMES

This Annual Report on Form 10-K contains references to trademarks and service marks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of it by, any other companies.

PART I

Item 1. Business

Overview

We are a commercial-stage medical technology company dedicated to improving the vision of patients following cataract surgery. Our proprietary RxSight® Light Adjustable Lens system ("RxSight system") is the first and only commercially available premium cataract technology that enables doctors to customize and optimize visual acuity for patients after surgery. The RxSight system is comprised of our RxSight Light Adjustable Lens® ("LAL®"), RxSight Light Delivery Device ("LDD™") and accessories. Our LAL is a premium intraocular lens ("IOL") made of proprietary photosensitive material that changes shape in response to specific patterns of ultraviolet ("UV") light generated by our LDD.

We designed our RxSight system to address the shortcomings of competitive premium IOL technologies and provide a solution that doctors can trust to improve visual outcomes and achieve high levels of patient satisfaction. Competitive premium IOLs require patients to specify their visual priorities before surgery and be willing to accept various optical trade-offs associated with those choices. Once a patient has selected a competitive premium IOL, the surgeon must rely on a series of preoperative diagnostic tests and predictive formulae to choose the appropriate lens power. If the doctor's prediction is suboptimal, then the patient may experience suboptimal results that could necessitate a subsequent corneal refractive procedure or certain other compromises in order to reach vision targets.

In contrast, with the RxSight system, the surgeon implants the LAL as they would in any other cataract procedure, determines refractive error with patient input several weeks following surgery and then uses the LDD to modify the LAL with the precise visual correction needed to achieve the patient's desired vision outcomes. We believe our RxSight system provides doctors and patients increased confidence and peace of mind by eliminating the high-stakes preoperative guesswork common to competitive premium IOLs and allowing patients to iterate their final vision characteristics with customized post-surgical adjustments.

A cataract is the loss of transparency in the eye's natural lens, which causes blurry or hazy vision and can eventually lead to blindness. Approximately 50% of all individuals develop some form of cataracts by age 60, usually in both eyes, and prevalence increases with age. Among the world's most commonly performed procedures, cataract surgery involves removing the cloudy natural lens and replacing it with a clear IOL. Prior to surgery, patients can opt for either a spherical monofocal IOL, which usually results in improved vision but requires glasses for best vision, or a premium IOL, which also corrects for astigmatism and/or presbyopia, thereby reducing spectacle dependence. In the United States, Medicare and private insurers typically cover the full cost of spherical IOL procedures, while premium IOL procedures require patients to pay an incremental out-of-pocket fee, typically ranging from $1,000 to $4,000 per eye depending on the specific premium IOL used. In the United States, the world's largest premium IOL market, 2022 premium procedures represented about 25% of all cataract procedures and generated approximately $760 million in revenue, a figure that is projected to grow at a 12% compound annual growth rate ("CAGR") by 2027, according to the Market Scope 2022 Premium Cataract Surgery Market Report.

We believe that the premium cataract surgery market remains underpenetrated due to both doctors' reluctance to recommend competitive premium IOLs to the full universe of eligible patients and patients' confusion in assessing the associated trade-offs and side effects with competitive premium IOLs. We believe competitive premium IOLs often fail to deliver on patients' expectations for quality vision across a range of distances without glasses. In our most recent Phase IV commercial data over 90% of patients were able to achieve 20/20 or better at distance without glasses, which is approximately twice the rate of any of the alternative IOLs. In addition, over 90% of patients were also able to read 5-point font at near vision, which is typically the size of footnotes on a page.

We believe our RxSight system offers doctors and patients a significantly more reliable approach that can consistently deliver optimal, fully customized visual outcomes with few compromises, ultimately driving broad adoption and establishing it as the standard of care for premium cataract procedures. The key benefits of our solution include:

- **Allowing full customization and optimization of patient vision after surgery.** Our LAL uses a proprietary silicone formulation that enables changing the mechanical and optical properties of the lens following implantation. Our LDD uses proprietary software and algorithms to deliver a short UV light exposure treatment that polymerizes specific portions of the lens and allows doctors to adjust spherical and cylindrical refraction in 0.25 diopter increments, similar to the adjustment increments used to refract patients for glasses or contact

lenses, as well as in other refractive procedures like LASIK. All other premium IOLs are fixed-power lenses that cannot be adjusted following surgery;

- **Delivering superior visual outcomes with low risk of side effects.** In our Food and Drug Administration ("FDA") clinical trial, 70% of LAL patients achieved 20/20 or better uncorrected visual acuity without glasses, while in similar trials of other premium IOLs, only about 40% of patients achieved this performance level. Additionally, LAL patients do not experience increased incidence of glare or halos that are common with other premium IOLs;

- **Providing accuracy and precision to optimize vision with both eyes.** Most LAL patients choose minor differences in the refractive correction of each eye, resulting in glasses-free vision across a full range of distances. In our most recent Phase IV commercial study data over 90% of patients were able to achieve 20/20 or better at distance without glasses, which is approximately twice the rate of any of the alternative IOLs. In addition, over 90% of patients were also able to read 5-point font at near vision, which is typically the size of footnotes on a page;

- **Enabling patients to preview and compare possible vision outcomes.** LAL patients are the only premium IOL patients able to test-drive their vision after surgery but before selecting a final refractive outcome. With up to three possible UV light treatments to adjust the LAL, patients direct their optimal visual acuity through an interactive and iterative process; and

- **Empowering doctors to grow their practices with a premium IOL they can trust and confidently recommend.** Our RxSight system has been shown to deliver excellent visual outcomes across a broad range of patient types and preferences. In our 2022 RxSight customer survey, 89% of respondents said they thought our RxSight system delivered the highest quality vision, 98% said they would recommend the LAL to others and 75% said they would select it for their own eyes.

Our commercial efforts began in 2019 and have been primarily focused in the United States, where we are building a "razor and razor blade" business model to drive new customer adoption and ongoing LAL volume growth. Our U.S. commercial organization includes a direct sales team of LDD sales personnel and LAL account managers, as well as clinical specialists, field service engineers and marketing personnel. Our sales efforts are concentrated on the roughly 3,000 U.S. cataract surgeons that perform 70%-80% of all premium IOL procedures. As of December 31, 2022, we had established an installed base of 400 LDDs in ophthalmology practices and, since our inception though December 31, 2022, surgeons have implanted over 42,000 LALs.

We plan to grow our business primarily by expanding the size of our LDD installed base and driving increased utilization of our LAL through heightened awareness of the superior clinical outcomes our RxSight system provides patients. To continue to strengthen our competitive position in the premium IOL market, our research and development activities are focused primarily on programs that improve clinical outcomes, improve customer experience, expand our indications for use, reduce manufacturing costs and lifecycle management.

Our market and industry

Cataracts and other common vision conditions

Common vision conditions can be roughly divided by two defining factors: 1) the typical age of onset and 2) whether the condition is more closely linked to the cornea, the front surface of the eye that controls about two-thirds of its focusing ability, or the natural lens, which sits behind the iris and is responsible for the eye's remaining focusing power. From childhood through the fourth decade of life, refractive conditions related primarily to the cornea – myopia, hyperopia and astigmatism – typically have the greatest impact on visual acuity and are usually addressed with glasses and contact lenses. In adults with these conditions, corneal procedures like LASIK can reduce dependence on glasses and contact lenses.

By age 50, most people also experience presbyopia, which manifests itself as increased difficulty seeing at near and intermediate distances without glasses or contact lenses. Presbyopia occurs because the natural lens is losing its elasticity and, therefore, its ability to focus light rays on near objects. By age 60, approximately half of all individuals also develop some form of cataracts, in which the normally clear lens loses its transparency and increasingly obstructs or otherwise interferes with the passage of light to the retina. The result is blurry or hazy vision and increased sensitivity to light, particularly at night, that cannot be treated with glasses or contact lenses. Cataracts are irreversible, progressive and usually affect both eyes. Cataracts can significantly interfere with daily activities, affect quality of life and eventually cause

blindness. According to the National Eye Institute, despite the availability of effective surgical treatment, cataracts are the leading cause of blindness worldwide.



Cataract surgery

Cataract surgery is among the most common surgical procedures performed in the world and involves replacement of the patient's natural cloudy lens with a clear artificial IOL. In the United States, the procedure is commonly performed in an outpatient setting, such as an Ambulatory Surgery Center ("ASC"), by an ophthalmologist specializing in cataract surgery and often requires only 5 to 15 minutes to complete. In most cases, surgery begins with removal of the cataractous lens through a process known as phacoemulsification. During phacoemulsification, the ophthalmic surgeon makes a small surgical incision in the cornea and inserts an ultrasonic probe that breaks up, or emulsifies, the lens while a hollow needle removes the pieces of the lens (see image 1 below). After the cataract is removed, the surgeon inserts the replacement IOL through the same surgical incision (see image 2 below). Following implantation, the IOL sits firmly in place just behind the iris (see image 3 below).



Conventional vs. premium cataract surgery

Cataract surgery is often bifurcated into two categories based on IOL type, as follows:

- ***Conventional:*** The patient receives a monofocal IOL, which is designed to provide vision at one pre-defined distance without correction for other visual problems that often affect cataract surgery patients such as corneal astigmatism and presbyopia. Nearly all patients undergoing conventional cataract surgery will need to rely on glasses following cataract surgery to achieve the best distance, intermediate and near vision.
- ***Premium:*** The patient receives a premium IOL, which is designed to address the shortcomings of conventional monofocal lenses by also correcting for the additional visual problems of astigmatism and/or presbyopia. Premium IOLs reduce the need for glasses relative to conventional IOLs but may impose trade-offs related to their ability to provide glasses-free near, intermediate and distance vision, as well as the potential for increased incidence of halos, glare and other side effects related to monofocal IOLs.

Healthcare payors typically cover the full cost of conventional cataract procedures. In the United States, a healthcare payor (primarily Centers for Medicare and Medicaid Services ("CMS")) typically provides reimbursement for a conventional cataract procedure of approximately $500 for a surgeon fee and approximately $1,000 for a facility fee, which includes the cost of a conventional monofocal IOL. Accounting for reductions in CMS reimbursement and for inflation, reimbursement

rates have decreased by two thirds since 1991. The surgeon fee covers all pre-operative cataract testing, the cataract operation and follow-up care for three months.

For U.S. premium cataract procedures, the healthcare payor (primarily CMS) reimburses the same surgeon and facility fees, but the patient pays the surgeon an additional fee between $1,000-$2,000 for implantation of a toric IOL and an average between $2,000-$4,000 for implantation of other premium lenses, which includes the cost of the premium IOL. Consequently, premium cataract procedures are between 10 and 15 times more profitable for the doctors and ophthalmology practices than conventional cataract procedures and are less impacted by changes in reimbursement rates. At the same time, because premium cataract patients pay an additional out-of-pocket fee, they tend to have high expectations that the surgeon will satisfy their desire for quality, glasses-free vision.

Our market opportunity

According to the Market Scope 2022 Premium Cataract Surgery Market Report and 2022 Market Scope IOL Report:

- Approximately 28 million cataract surgeries were performed globally in 2022, including 4.6 million in the United States. The number of procedures worldwide is projected to grow at a CAGR of 6.3% to over 38 million by 2027. In the United States, procedures are expected to grow at a CAGR of 4.3% to 5.3 million by 2027;
- The United States is the world's largest premium IOL market. In 2022, premium IOL procedures represented approximately 2S% and 12% of cataract surgeries in the United States and worldwide, respectively;
- In 2022, premium IOL revenue was approximately $2.1 billion globally and $760 million in the United States, and is expected to grow at a CAGR of 13% and 12%, respectively, through 2027. Key growth drivers include the increasing number of patients who prefer to be glasses-free, technological innovations, increased access to healthcare and rising disposable income; and
- In the United States, there are approximately 10,000 ophthalmic surgeons that perform cataract surgery, including approximately 3,000 that perform roughly 70%-80% of premium IOL cataract procedures.

We believe there is an opportunity to gain market share in the premium IOL market segment and also increase the penetration of premium IOLs in the broader market by converting doctors and patients currently electing for conventional cataract surgery. We believe that the premium cataract surgery market remains underpenetrated due to both doctors' reluctance to recommend premium IOL offerings to the full universe of eligible patients and patients' confusion in assessing the trade-offs associated with the wide range of commercially available premium IOL offerings. Furthermore, we believe current non-adjustable premium IOL offerings often cannot deliver on patient expectations regarding their desire to see at near, intermediate and far distances without reliance on glasses and to avoid troubling side effects such as glare, halos and loss of contrast sensitivity.

We are currently focused on driving awareness and penetration of our RxSight system in the premium cataract market, and primarily concentrating our near-term commercial efforts on the United States. We believe the United States is the most compelling market given the large population of individuals over the age of 60 that are covered by health insurance, the concentrated base of cataract surgeons experienced with premium IOL offerings, the high gross domestic product per capita and the favorable U.S. healthcare reimbursement system, which has a well-established history of covering a portion of the cost for cataract surgery.

Non-adjustable premium IOLs and their limitations

Prior to the commercial availability of our RxSight system, doctors and patients chose from two primary types of premium IOLs, as follows:

- **Multifocal Lenses.** Multifocal lenses have two or more corrective zones, which allow the patient to receive focused light from different distances. Although multifocal lenses provide patients with a wider range of vision compared to the standard monofocal IOLs, multifocal lenses split light across the multiple corrective zones on the lens, sometimes impacting visual quality. For example, approximately two to three times as many patients who choose a multifocal lens over a monofocal lens experience side effects such as glare and halos, as well as reduced contrast vision, which are especially problematic in low light situations such as driving at night. For some patients these become more pronounced and can lead to explantation (removal of the IOL and replacement with another type of IOL). Extended-depth-of-focus ("EDOF") lenses are similar to multifocals, except they have

only one corrective zone. They create an elongated focal point that allows for a broader range of vision, although patients will still often require glasses for distance and near vision. EDOF lenses will still typically result in glare and halos, as well as reduced contrast vision, although generally less severe than those experienced with multifocal lenses; and

- **Astigmatism-Correcting or Toric Lenses.** Toric lenses correct for astigmatism, a condition in which the cornea is not uniformly curved leading to distortion of near and distance vision. According to the 2022 Market Scope IOL Report, approximately 70% of the population has clinically significant astigmatism of 0.5 diopters or more. Corrective toric lenses can provide additional distance, intermediate or near vision correction depending on the power of the lens selected and if their optical design incorporates either multifocal or EDOF features.

When preparing patients for premium cataract surgery, surgeons must have a comprehensive understanding of available premium IOL options and how to best match a patient to the technology that fits their priorities. Patient decisions are based on several factors and tend to be heavily influenced by surgeon recommendations, as well as the patient's motivation for independence from glasses and willingness to tolerate side effects. During an initial consultation, surgeons often ask patients to fill out a survey regarding their vision experiences and expectations to determine if the patient is a good premium IOL candidate. If so, the surgeon helps select the appropriate premium IOL based on the patient's lifestyle and the type of vision they most value (i.e., near, intermediate or distance). Significant time is often required to educate patients on the various trade-offs with respect to the visual outcomes associated with each type of premium IOL. Following this consultation, surgery is usually scheduled within several weeks or months.

Prior to surgery, the patient's eyes are measured using one or more diagnostic devices to help the surgeon predict the lens focusing power best suited to achieve the optimal postoperative outcome. Focusing power, expressed in diopters (D), refers to bow a lens focuses light to a point (spherical power) or a line (cylindrical or astigmatic power). Accurately predicting lens power is critical to reducing postoperative residual refractive error and delivering the best possible visual outcomes. Because the lens power of competitive premium IOLs cannot be changed after implantation, doctors rely on a series of preoperative diagnostic tests and predictive formulae to determine the lens power. Typically, the patient returns a day after surgery to have their eye evaluated and ensure healing is underway. After approximately one month, premium cataract patients that are dissatisfied with their results may be fitted for glasses or elect to undergo a secondary, remedial procedure to meet desired vision targets. A separate LASIK procedure is the most common surgical procedure to correct any residual visual errors following the cataract procedure.

A key limitation of these competitive premium IOLs is that they cannot be adjusted after the surgery and, as such, require the patient to commit to a desired visual outcome prior to the procedure. However, in discussing vision optimization options with patients ahead of the procedure, it can be difficult to effectively demonstrate different visual outcomes. Once a premium IOL is selected, another key limitation is the ability of the surgeon to precisely predict the correct lens power and then implant the IOL with the level of accuracy required to deliver the patient's expected outcome. Additionally, the incision made to remove the cloudy lens and insert the IOL along with the resultant healing process often creates additional levels of astigmatism, which cannot be predicted with precision before cataract surgery.

We believe that the need to commit to a visual outcome before surgery combined with the limited ability to make adjustments following the procedure are key factors contributing to the low levels of premium IOL penetration. When expectations regarding postoperative visual acuity and independence from glasses are not met, patients are often disappointed. As a result, even though 60% of cataract patients rate "being glasses free after cataract surgery" as extremely important, surgeons are often hesitant to recommend existing premium IOLs to their patients.

Our solution

We designed our RxSight system to address the shortcomings of existing premium IOL technologies and provide a solution that doctors can trust to improve visual outcomes and achieve high levels of patient satisfaction. We began commercializing our solution in the United States in 2019 and are focused on establishing the RxSight system as the standard of care for premium IOL procedures. As of December 31, 2022, we had an installed base of 400 LDDs in ophthalmology practices, and since our inception over 42,000 surgeries have been performed with our RxSight system.

Overview of the RxSight system

Our RxSight system is the first and only FDA-approved IOL technology that enables doctors to customize and optimize visual acuity for patients after cataract surgery. With the RxSight system, the doctor performs a standard cataract procedure to implant the LAL, determines refractive error with patient input after healing is complete, then uses the LDD to reshape the

LAL to achieve the patients' desired vision outcomes. Our RxSight system is comprised of two key components, along with other intraoperative and postoperative accessories:

- **RxSight Light Adjustable Lens:** The LAL is our proprietary IOL that can be adjusted postoperatively to improve uncorrected visual acuity. Our IOL is made of special photosensitive material that changes shape and power when a specific pattern of UV light is delivered from the LDD.
- **RxSight Light Delivery Device:** The LDD is our proprietary office-based light treatment device that delivers UV light in a precisely programmed pattern to induce a predictable change in the shape and refractive properties of the LAL, enabling surgeons to precisely modify the LAL based on the visual correction needed to achieve the patient's desired vision after cataract surgery.



Light Adjustable Lens (LAL)



Light Delivery Device (LDD)

Our foundational technology

We have developed our RxSight system over the last 20 years, incorporating expertise and proprietary technologies across multiple disciplines, including optics, material science, chemistry, software and hardware engineering. The proprietary RxSight technology that enables post-operative adjustability is based on the principles of photochemistry. The LAL is made of a photosensitive material that changes shape and power when a specific pattern of UV light is delivered to the LAL.

Our LAL, which we manufacture using our proprietary silicone formulation, leverages the unique material properties of silicone. A silicone molecule consists of an inorganic silicon-oxygen backbone, which is a chain of alternating silicon and oxygen atoms with an attached side group, which is a pair of organic molecules bonded to each silicon atom in the chain. Through a process called polymerization, silicone monomers (short chain molecules) are reacted together to form silicone polymers (long chain molecules), which may be cross-linked at multiple points resulting in three-dimensional, rather than linear, structures. By varying chain length, attached side group and cross-linking design, silicone polymers can be tailored to have unique properties, leading to their broad use across a wide array of applications. We have developed a novel application of silicone to optimize the mechanical and optical properties of IOLs in order to improve vision in patients following cataract surgery.

To create the LAL, we use a composition of silicone polymers and monomers, the latter which we call "macromers" mixed with photo-active molecules and other compounds. The initial composition of our lens material is a viscous liquid that is thermally cured in a lens mold. Thermal curing and photopolymerization use temperature and ultraviolet light, respectively, to initiate and propagate a polymerization reaction. To avoid polymerizing the macromers in the composition, the thermal curing is performed at a low temperature. The partial polymerization of the LAL results in a solid but soft silicone lens, leaving the photosensitive macromers unpolymerized and distributed throughout the lens. While the resulting lens is optically clear, the macromers and photo-active molecules remain free to continuously move within the lens.

After packaging and sterilization, the LAL is ready to be implanted as part of a standard cataract surgical procedure to replace the patient's natural lens. Once wound healing is complete, a short exposure of UV light is applied to the LAL to adjust the refractive properties of the lens. When the UV light is directed to a specific portion of the lens, the exposed macromers in that portion of the lens are polymerized and become stationary. This creates an excess concentration of free macromers in the unexposed portion of the lens and sets up a diffusion gradient over which the unpolymerized macromers move from the concentrated area to the less concentrated area. Over the next one to two days, the unpolymerized macromers

redistribute across the lens to achieve a uniform distribution. The redistribution of the macromers causes the exposed portion of the lens to swell relative to the unexposed portion of the lens, enabling refractive power change.

The movement of the macromers causes a highly predictable change in the curvature of the lens. If the central portion of the lens is exposed to UV light, unpolymerized macromers in the periphery of the lens move into the central portion. As a result, the central portion of the lens swells, creating a lens shape for correction of hyperopia. Conversely, if the periphery of the lens is exposed to UV light, unpolymerized macromers in the central portion of the lens migrate into the periphery. As a result, the periphery of the lens swells, creating a lens shape for correction of myopia. In addition to spherical correction for myopia or hyperopia, customized cylinder adjustments along any axis of the lens can be targeted to correct for astigmatism.

To achieve the desired refractive change in the LAL, our LDD uses proprietary software and algorithms to deliver a short UV exposure treatment that polymerizes specific portions of the lens according to a predefined pattern of light, called a nomogram. Nomograms allow for adjustment of spherical and cylindrical refraction in 0.25 diopter increments, like the adjustment increments used to refract patients for glasses or contact lenses, as well as in other refractive procedures like LASIK, which has similar refractive accuracy. Designed for placement in the doctor's office, the LDD is a combination of a standard slit lamp and a digital light projector. The slit lamp portion allows the doctor to see inside the patient's eye and align the light beam with the LAL. The digital light projector portion projects an image onto the LAL using DLP technology that has approximately 250,000 micro mirrors that are electronically activated to represent an image stored in memory.

Each UV light treatment consumes only a portion of the macromers in the lens, allowing the LAL to be adjusted multiple times. This process can be repeated up to three times over a period of several weeks, until the patient and doctor are satisfied. The entire lens is then polymerized to provide a stable correction. After adjustment light treatments are completed, one or two lock-in light treatments are applied to consume all remaining macromers and photo-active compounds. After the final lock-in treatment, the lens power can no longer be adjusted.

Our approach

With the RxSight system, the surgeon performs a standard IOL implant procedure, replacing the patients' natural lens with the LAL. Two to three weeks following surgery, the patient visits the doctor's office for a standard postoperative refraction, which is similar to the eye test used to create a prescription for eye glasses. Using a traditional phoropter and vision chart, a clinician determines the refractive error and prescription required and inputs the information into the LDD's graphical user interface. The patient's eye is dilated and a contact lens is applied to the eye as the patient is seated in front of the LDD for a light treatment. Based on the prescription input, the LDD generates a programmed, predetermined exposure of UV light. For approximately 100 seconds, the light painlessly and non-invasively reshapes the implanted LAL to correct the measured refractive error. The entire treatment takes less than five minutes. The patient returns approximately three to five days later for additional light treatments to further adjust their vision, if desired, or to lock-in the lens. While patients can receive up to three adjustments, the average number of adjustments in our FDA clinical trial was 1.6.

The RxSight system enables a fully interactive and iterative process to optimize visual acuity with patients able to test drive their vision, comparing possible outcomes before selecting a final prescription for their LAL. In clinical practice since our FDA approval, roughly 60% of patients undergoing multiple adjustments have requested a change from their original spherical target, underscoring the value of adjustability and customization. From the time of surgery until 24 hours after the LAL is locked in, the patient wears UV light protective glasses as unprotected exposure to light can cause uncontrolled changes in the LAL. Since late 2021, we have included ActivShield technology on all LALs, which provides an extra layer of UV protection on the lens surface and reduces dependence on patient compliance with protective glasses.

Key benefits of RxSight system for patients

- **Superior vision outcomes.** In the pivotal study that formed the basis for our FDA approval, the observed rate of eyes with 20/20 or better uncorrected distance visual acuity for our LAL was 70.1%. This compares favorably to the results of pivotal studies with similar study designs and patient populations that supported FDA approval of Alcon's Acrysof Toric (38.4%) and J&J's Tecnis Toric (43.6%). Most LAL patients choose minor differences in the refractive correction of each eye, resulting in glasses-free vision across a full range of distances. In our most recent Phase IV commercial study data over 90% of LAL patients who chose to optimize vision with both eyes, achieved 20/20 distance vision and were also able to read 5-point font without glasses;
- **Postoperative customization.** Our RxSight system enables patients to preview and compare possible vision outcomes after surgery based on their unique preferences and lifestyle requirements before they select a final

prescription for their LAL. With up to three possible adjusting light treatments, patients can dial-in their optimal visual acuity through an interactive and iterative process;

- **No increase in glare and halo.** Our LALs do not induce higher rates of glare and halos compared to monofocal IOLs. In contrast, multifocal IOLs, generally relied upon to improve near vision, are associated with a higher incidence of unwanted side effects including reduced contrast sensitivity and increased glare and halos around bright lights. These problems can lead to explants, in which patients undergo another procedure to remove the multifocal IOL and replace it with another type of IOL. In FDA studies for the Alcon Panoptix, J&J Symfony and Alcon Vivity lenses, 48.8%, 59.2% and 17.0% of subjects, respectively, reported being bothered by halos postoperatively; and
- **Corrects residual refractive error.** The RxSight system can reduce the potential for secondary surgical procedures by correcting residual refractive error after surgery using our office based LDD to shape the LAL. With other premium IOLs, a separate LASIK procedure is generally the only way to correct for residual visual errors following the primary cataract procedure.

Key benefits of RxSight system for doctors

- **Clear value proposition for patients, helping doctors to build their premium cataract practices.** Rather than explaining the complicated trade-offs with respect to visual outcomes and predicting refraction before surgery, the surgeon may simply tell patients that their vision will be corrected postoperatively via a painless, in-office process similar to being prescribed glasses. The doctor can also share the LAL's clinical results with the patient to provide reassurance that the procedure will deliver desired results;
- **Increased confidence.** The clinical benefit of "dialing-in" to achieve superior visual outcomes postoperatively increases doctors' confidence that the LAL can meet patients' expectations. The doctor does not need to decide prior to surgery whether the patient will be particularly sensitive to suboptimal visual outcomes or side effects (such as glare, halo and loss of contrast). The patient is also unlikely to need a postoperative adjustment such as LASIK to improve their outcome;
- **Fewer intraoperative measurements.** With other premium IOLs, the lens power is fixed and cannot be changed after surgery, requiring doctors to spend considerable time on preoperative and intraoperative measurements to estimate the most suitable lens power to implant and lens position. With our RxSight system, surgeons are not as dependent on preoperative and intraoperative equipment for measurements. Instead, they can focus on the surgical procedure, knowing refractive error will be corrected postoperatively with the LDD, and with the patient's active involvement;
- **Broad application across different patients' needs.** We offer a single IOL that can address a broad range of patient types and needs, while providing a solution that doctors can trust to improve visual outcomes, eliminating the need for extensive preoperative discussions with patients about which IOL may best fit their lifestyle and visual preferences. Moreover, the superior outcomes and patient-centered approach of the RxSight system helps drive patient referrals and grow premium cataract volumes, which generally produce higher practice revenue and profit margin than conventional procedures; and
- **Economic benefits that drive practice growth.** A recent economic impact survey by Haffey & Company of almost 50 practices using the RxSight system revealed that LAL procedures were sourced from all other categories of other IOLs. For example, respondents indicated that approximately 40% of their LAL patients would have otherwise selected a conventional monofocal IOL, which is far less profitable for a practice than a LAL procedure. In addition, based on an average of 9 LALs implanted per month at these practices, doctors observed a payback period of approximately nine months for the LDD, based on the current list purchase price. Following this payback period, practices continue to reap the financial benefit of converting patients to the RxSight system.

Our growth strategies

We are leveraging the tangible and compelling benefits of our RxSight solution to achieve broad adoption of our technology and establish it as the standard of care for premium cataract surgery. Our growth strategies include:

- **Establishing new customers and growing our installed base of LDDs.** We believe our technology offers a differentiated value proposition to doctors and patients, providing us an opportunity to grow our share in the

premium IOL market and increase the penetration of premium IOLs in the broader cataract surgery market. To grow our installed base, we are focused primarily on converting high-volume premium cataract surgeons to the RxSight system by highlighting its clinical, economic and workflow benefits vs. competing premium IOL technologies. Secondarily, we are focused on the broader pool of cataract surgeons who may implant premium IOLs sparingly or not at all due to suboptimal visual outcomes, persistent side effects and uneven patient satisfaction sometimes associated with non-adjustable premium IOL offerings. Because our RxSight system is designed to overcome these shortcomings, we believe many of these doctors have the potential to be successful RxSight customers. We are also investing in professional education, additional clinical studies and registries that expand our evidence base, facilitating peer-to-peer dialogue and forums and communicating the benefits of our technology through marketing initiatives, tradeshows and podium presentations;

- **Increasing the utilization of our LALs by empowering doctors to grow their practices.** We work closely with every new customer to conduct a thorough training and onboarding process, providing a high level of service to help the practice succeed with the RxSight system. This support helps the practice confidently recommend the LAL to an increasing number of patients and, in turn, grow their practice. In a recent RxSight customer survey, 89% of doctors said they thought our RxSight system delivered the highest quality vision, 98% said they would recommend the LAL to others and 75% said they would select it for their own eyes. In addition to personnel support, we also provide practices with marketing materials, such as patient brochures, literature and digital content for website and social media promotions. We also provide ongoing training related to new technology features and developments, as well as education on the patient benefits of our solution;
- **Strategically expanding our commercial organization and marketing activities.** Since launching the RxSight system commercially in 2019, we have substantially increased the size and scope of our U.S. commercial organization. While we believe our current commercial organization is well built to reach our focused target of high-volume premium cataract surgeons, we will add highly qualified personnel for time to time, with a strategic mix of sales personnel and clinical specialists, to drive higher levels of awareness and penetration in certain regions. We also expect to accelerate marketing initiatives and professional education, including training on best practices and techniques;
- **Investing in RxSight system enhancements and expanding indications.** We continue to enhance our RxSight system to improve the patient and doctor experience, meet evolving customer needs and address the widest possible patient population. Since our initial FDA approval in November 2017 through December 31, 2022, we have received 20 supplemental approvals. Recent enhancements include increasing the range of available LAL powers, modifying the LAL to improve image quality, reducing the margin of residual refractive error, allowing an optional third refractive adjustment, developing new UV glasses with improved aesthetics and usability, and adding a photosensitive anterior layer (ActivShield™) to the LAL to help protect the lens from unwanted UV exposure. We believe these technological advancements help to drive increased adoption of our RxSight system;
- **Scaling our business to achieve cost and production efficiencies.** We expect to realize operating leverage through increased scale efficiencies as our commercial operations grow. We have executed a number of design and manufacturing process improvements to streamline both LAL and LDD production, and have developed a lower cost to manufacture LDD, which was approved by the FDA on January 31, 2023. We are also concurrently executing on our strategy to optimize our diverse supply chain and to develop second sources from less expensive suppliers. We anticipate that the combination of these strategies will drive margin improvement in the future when introduced into production and offered for sale; and
- **Growing our commercial operations in international markets.** While our current commercial focus is on the large opportunity within the United States, we believe the RxSight system offers compelling benefits for cataract doctors and patients in select international markets. According to the Market Scope 2022 Premium Report, over 70% of the premium IOL procedures in 2022 were outside the United States. Our RxSight system has approval in Mexico and Canada for improving uncorrected visual acuity by adjusting the LAL power to correct residual postoperative refractive error. We may selectively pursue commercial expansion outside the United States that accept these approvals in the future, with a priority on markets where we see significant potential growth opportunities. New approvals may also be sought in large cataract markets with more complex regulatory environments such as Asia.

FDA clinical studies

In July 2016, we completed our FDA Phase 3 pivotal randomized clinical study of 600 subjects, designed to evaluate the safety and effectiveness of performing light treatments to correct postoperative spherical and cylindrical refractive error. In this study, 391 subjects had the LAL implanted in one eye and the results were compared at the six-month postoperative visit against 193 subjects with a monofocal control IOL implanted in one eye. The LAL met all primary effectiveness endpoints and was approved by the FDA on November 22, 2017 as the first commercially available adjustable IOL. In the study, 70.1% of LAL subjects achieved monocular uncorrected distance visual acuity of 20/20 or better compared to 36.3% of the eyes implanted with the monofocal control IOL. In addition to being statistically significantly better than the control IOL, the observed rate of eyes with 20/20 or better uncorrected distance visual acuity was the highest reported for any approved intraocular lens and approximately twice what was observed by the two most popular astigmatism-correcting IOLs (38.4% by Alcon's Acrysof Toric, and 43.6% by J&J's Tecnis Toric) in similar patient populations in the pivotal studies that led to their approvals by the FDA. Additionally, LAL patients reported a low rate of glare or halo, visual side effects that are frequently reported with premium IOLs.

We are conducting a 500-eye prospective, randomized, controlled multicenter Post Approval Study, which was a requirement of our Premarket Approval ("PMA") approval. Subjects are randomized in a 2:1 ratio to receive either the LAL or a monofocal IOL. Study subjects will be followed for six months. The results will compare effectiveness and safety of the LAL and monofocal IOL. We anticipate completing enrollment in 2024.

Sales and marketing

We commenced commercial launch of our RxSight system in the United States in 2019 and are initially focused on the estimated 3,000 surgeons that perform 70%-80% of premium cataract surgery procedures. These surgeons are usually part of larger ophthalmology practices with multiple cataract surgeons. They typically have refractive surgery practices offering LASIK and are skilled at selling premium procedures based on delivery of better visual outcomes. Our U.S. commercial organization includes a direct sales team comprised of LDD sales personnel and LAL account managers, as well as clinical specialists and field service engineers and marketing personnel. While we believe we can effectively cover our concentrated target market with our focused commercial organization, we will add highly qualified personnel from time to time, with a strategic mix of sales personnel and clinical specialists, to drive further awareness and penetration among cataract surgeons.

Our commercial efforts are designed to create a "razor and razor blade" business model by building a sizable LDD installed base to drive ongoing growth in LAL procedure volumes. LDD sales personnel are responsible for establishing relationships with doctors and securing new customers. New customer contracts typically include sale of the LDD between approximately $115,000 - $120,000, sale of LALs for approximately $1,000 each and an LAL consignment agreement. Once the LDD is installed, our clinical specialists work closely with the practice's doctors, technicians and staff members to ensure that they are fully trained, proficient LAL providers. Our LAL account managers oversee this process and engage with practices on an ongoing basis to assist with patient awareness and education programs, development of efficient patient flow processes and other initiatives. To achieve broad awareness of the RxSight system among cataract surgeons, we also conduct various marketing programs, including promotions at industry and society conferences, podium presentations, social media, and educational webinars focused on the differentiated benefits of our RxSight system.

Our RxSight system has received regulatory approval in Mexico and Canada. We recently commenced limited sales activities in Canada through a distribution partner.

Research and development

Our research and development activities are focused on programs that improve clinical outcomes, improve customer experience, expand our indications for use, reduce manufacturing costs and lifecycle management. Since our initial FDA approval in November 2017 through December 31, 2022, we have received approximately 20 supplemental approvals that advance these objectives.

On January 31, 2023, the FDA approved our PMA supplement to our LDD for various modifications that are intended to reduce the cost to manufacture the device. We anticipate that this lower-cost-to-manufacture LDD will also require a submission for approval in countries outside the United States.

Research and development expenses were $26.0 million and $24.5 million for the years ended December 31, 2022 and 2021, respectively.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG RxSight, Inc. MDEG License # (if applicable) _____

Physical Address 100 Columbia, Suite 120

City Aliso Viejo State CA Zip 92656

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 949.521.7830 Website www.rxsight.com

Licensing Company Email pcullen@rxsight.com

Section 2: Personal Information

First Patrick Middle Morgan Last Cullen

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address 100 Columbia, Suite 120

City Aliso Viejo State CA Zip 92656

Telephone 949.521.7823 Email pcullen@rxsight.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Texas Southwestern Medical School		08/93 - 05/95	
Address	**City**	**State**	**Zip**
5323 Harry Hines Blvd	Dallas	TX	75390
Diploma/Degree obtained, if any			
Masters of Science in Biomedical Engineering			
School Name		From - To (MM/YY – MM/YY)	
University of Houston		08/89 - 05/93	
Address	**City**	**State**	**Zip**
4800 Calhoun Road	Houston	TX	77004
Diploma/Degree obtained, if any			
Bachelors of Science in Mechanical Engineering			
School Name		From - To (MM/YY – MM/YY)	
Plano Senior High School		08/87 - 05/89	
Address	**City**	**State**	**Zip**
2200 Independence Parkway	Plano	TX	75075
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/15 - Current	[redacted]Drilla Road	Dana Point	CA	92629
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
RxSight, Inc.			2/23 - Current	
Business Address		**City**	**State**	**Zip**
100 Columbia, Suite 120		Aliso Viejo	CA	92656
Phone	**Title**		**Number of Employed Hours**	
949.521.7830	Senior Vice President - Quality Assurance		1080	
Description of Duties				
Responsible for all quality system and quality operations for implantable medical device developer and manufacturer including quality system management representative and person responsible for regulatory compliance.				

Business Name			From - To (MM/YY – MM/YY)	
Intuitive Surgical			2/22 - 2/23	
Business Address		**City**	**State**	**Zip**
1020 Kifer Road		Sunnyvale	CA	94086
Phone	**Title**		**Number of Employed Hours**	
408.523.2100	Vice President - Product Quality		2080	
Description of Duties				
Responsible for all quality operations for minimally invasive surgical robotic system including deputy quality system management representative and deputy person responsible for regulatory compliance.				

Business Name			From - To (MM/YY – MM/YY)	
RxSight, Inc.			10/15 - 2/22	
Business Address		**City**	**State**	**Zip**
100 Columbia, Suite 120		Aliso Viejo	CA	92656
Phone	**Title**		**Number of Employed Hours**	
949.521.7830	Vice President - Quality Assurance		12608	
Description of Duties				
Responsible for all quality system and quality operations for implantable medical device developer and manufacturer including quality system management representative and person responsible for regulatory compliance.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

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Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) _____ Date _____

I, Patrick M. Cullen, **certify that as the MDEG Administrator for**

RxSight, Inc.,

that I (initial that you have read and meet the following requirements):

1. PMC Have a high school diploma or its equivalent;
2. PMC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. PMC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. PMC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Patrick Cullen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

August 29, 2023
Date

Board Use Only	Date Received:

List Containing Each Employee, Agent, Independent Contractor, Consultant, Guardian, Personal Representative, Lender or Holder of Indebtedness of the Applicant:

Wholesaler is providing a list for those located at the facility.

LAST NAME	FIRST NAME
Castillo	Kevin
De La Torre Bocanegra	Von S.
Duran	Elizabet
Garcia	Leonardo
Martin	Jacob
Martinez	Zully O
Negrete	Alejandro
Negron	Jose A.
Ortiz Ramirez	Erika
Reyes	Kevin
Robles	Maria G
Carbajal Hernandez	Jenny
De La Mora	Nathan
Gonzalez	Irvin Christopher
Ochoa	Miguel
Plotena	Migold
Nguyen	Ba Phat L
Nichols	William J
Ramos Vazquez	Clara E
Vargas	Carolina
Zedekiah	Kathleen
Figueroa	Abby M.
Reyes Ambrosio	Jorge
Mladosich	Anthony
Balbas	Ferdinand R.
Capdevielle	Alex A.
Dizon	Edison Navarro
Moala	Ofa T
Rodriguez	Alejandro
Villanueva	Oliver David
Tapia	Christopher
Clark	Benjamin
Elemen	Victoria
Sullivan	John
Lysik	Michael
Lee	Tyler J
Olivas	Ysidro
Robles	Roland B.
Walker	Sandra A
Cheung	Kimmy
Le	Joan
Stewart	Vivian A
Gillette	Dexter J
Ngam	Chenda C
Ruiz	Santiago
Arnett	Christopher J
Lauguico	Nicolo Marco Ferrariz
Olivas	Adrean P
Tocohua	Giovanny

Le	Joe
Kloos	Karl B
Diep	Chi
Gonzalez	Deyssy Yovana
Cervantes	Leslie
Gonzalez Cruz	Ana L.
Hua	Phat T
Lun	Savuth
Sandoval	Alfredo
Tellez	Alejandra
Dayrit	Vergel James P.
Duong	Phuc H.
Encineas	Amanda J
Ho	Calvin
Khader	Danielle
Lu	Tatiana
Nguyen	Justin
Nguyen	Matthew D
Sie	Darin
Yu	Tommy
Juan	Renato
Kanno	Charmaine
Young	Yi
Esslinger	Tracy A.
Nguyen	Katherine B.
Cullen	Patrick
Phiathep	Tino
Sefton	Cameron H.
Gonzalez	Lissette
Pham	Christopher
Radillo	Albert Rafael
Zhang	Zhouyuan
Goffredo	David B
Thompson	William J.
DeLuca	Carole J
Deck	Deborah
Ha	Jeffrey
O'Connell	Maureen
Hanna	Takla
Ahmadzai	Abdul
Bresson	Sebastian E.
Liang	Xiaojun
Nguyen	Jim
Meinke	Emma C
Sanchez	Daniel
Kondis	John
Nguyen	Hoang
Pelc	Matthew
Sandstedt	Christian
Hammoude	Mustapha A.

Haller	Matthew
Coleman	Richard W.
Govan	Akash D
Haynes	Susan A.
Kanemitsu	Kelly M.
Kardani	Shivam
Krykhtenko	Yana
Medina	Carlos A.
Mehra	Vikash
Peterson	Rod T
Calligori	David
Dong	Jeremy
Goldshleger	Ilya
Hong	Dong Gee
Hung	Hsin-Ling
Shultz	Bruce
Bloed	Charles J
Bui	Man Minh
Dibble	David Joshua
Nguyen	Kathy
Silantyeva	Elena A
Widdowson	George
Casarrubias	Francisco J
Ly	Thien T
Perekotiy	Vitaly V
Piunova	Victoria A.
Morales	Irene
Copado	Karen
Maniago	Riza
Cortes	Brianna I
Ortiz	Adan R
Nguyen	Shayla T
Ros	Sokla
Tran	Steven V.
Holt	Joshua A
Glick	Robert E
Frank	David M
Morris	Robert C
Velez	Janny
Lopez	Alejandro
Pozos	Maria E
Gomez Calderon	Juvenal
Cueva Vargas	Marco Vinicio
Leeds	Austin R
Shamsi	Wajeeha
Nguyen	Hannah
Villafan	Jessey R
Barnes	Alison
Brecht	Dorothy Llainna
Buysse	Dianna

Cassell	Loretta
Davis	Anthony C.
Franco	Melvic
Lehr	Joshua W.
Onufer	Barbara R
Parker	Ryan
Primeaux	Michael
Skelly	Jonathan
Smith	Joan
Smith	Karen M.
Tam	Joseph
Faass	Allen
Williston	Rebecca S
Phillips	Robert Ernest
Huang	Alexander
Kurtz	Ronald
Thunen	Shelley
Zimanyi	Gergely
Chaney	Karrington
Rodarte	Tayler M
Spiri	Heather M
Vitalone	Sherry L.
Garrett	Natalie
Vaughn	Caroline
Dang	Michael
Sudol	Shea L
Tran	Nick M.
Weinberg	Eric
Tham	Isabelle S.
Brown	Diane D.
Freeman	Roy
Nammar	Anisa C
Gaines	Scott
Mullowney	Amy M
Abebe	Elizabeth T.
Arakaki	Kimberly
DuCharme	Tina Michelle
Espiritu	Jamie K.
Fiscale	Lauren T
Hollenbaugh	Dawn M
McElroy	Amanda
Scott	Brittany Nicole
Sperber	Hayley
Stroh	Andrew Rolland
Walthall	Hayley
Zahn	Aaron Justin
Sadrnia	Naveed
To	Dangkhoa N
Ortiz	Melissa C
Lara	Michelle

Summers	Charles W
Ortega	Edsel E.
Nieto	Fernando J
Gardner	John L
McHugh	Colleen R.

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Facility Name: AKRON PHARMA INC

Physical Address: 415 OSER AVE, UNIT Q

City: HAUPPAUGE State: NY Zip: 11788

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 973-227-2000 Website: WWW.AKRONPHARMA.COM

Name of Designated Representative (DR): VINOD, VERA REDDY

Licensing Company Email: VINNY@AKRONPHARMA.COM DR Email: VINNY@AKRONPHARMA.COM

■ Pharmacies ☐ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	■ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical devices, equipment, supplies, gases ■ Others: OTC DIETARY SUPPLEMENTS	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ■ Warehouse ■ Retail pharmacy wholesale distributor ■ Others: VIRTUAL WHOLESALER

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Name: NV CONVEY HEALTH SOLUTION

Address: 7750 DEAN MARTIN DR City: LAS VEGAS State: NV Zip: 89139

Name: Cardinal Health

Address: 6640 Echo Ave City: Reno State: NV Zip: 89506

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

State of Incorporation/Organization:

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Owner's Name: KUMARSWAMY R MARURI

Business Name: AKRON PHARMA INC

Business Address: 415 OSER AVE, UNIT Q

City: HAUPPAUGE State: NY Zip: 11788

Telephone: 862-485-7389 Email: KREDDY@AKRONPHARMA.COM

Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

AKRON PHARMA INC

Facility Name

VINOD, VERA REDDY

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

06/12/2023

Date

Board Use Only	Date Received: 6.21.23	Amount: 1000.00 CK-1677

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

AKRON PHARMA INC.
0101029438

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on October 11, 2013.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey. Annual Reports are outstanding for the following year(s): 2021-2022

I further certify that the registered agent and office are:

RAMAMOHAN BOMMAREDDY
12 REGAN WAY
KINNELON, NJ 07405

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 11th day of April, 2023

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6142047186

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

STATE OF NEW YORK
DEPARTMENT OF STATE

I hereby certify that the annexed copy for AKRON PHARMA INC., File Number 221203000738 has been compared with the original document in the custody of the Secretary of State and that the same is true copy of said original.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on December 03, 2022.

Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100002587594 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

Application For Authority

of

AKRON PHARMA INC.

Pursuant to Section 1304 of the Business Corporation Law

FIRST The name of the corporation in the jurisdiction of its incorporation is:

AKRON PHARMA INC.

SECOND: The jurisdiction of its incorporation is the State of New Jersey and the date of its incorporation is: October 11, 2013.

THIRD: The business which the corporation proposes to do in the State of New York is, to wit:

Any lawful act or activity for which corporations may be organized under the Business Corporation Law of the State of New York. The corporation is not formed to engage in any act or activity requiring the consent or approval of any state official, department, board, agency or other body without such consent or approval first being obtained.

The aforesaid business is authorized in the jurisdiction of its incorporation.

FOURTH: The office of the corporation, within the State of New York, is to be located in the County of Suffolk.

FIFTH: The Secretary of State of the State of New York, is designated as agent of the corporation upon whom process against it may be served. The post office address to which the Secretary of State shall mail a copy of any process against the corporation is 47 Mall Dr., Unit 182, Commack, NY 11725.

SIXTH: The corporation has not since its incorporation or since its date its authority to do business in the State of New York was last surrendered, engaged in any activity in this state except as set forth in Section 1301(b) of the Business Corporation Law of the State of New York.

Dated: 12/01/2022

Kumaraswamy R Maruri, President

Filed with the NYS Department of State on 12/01/2022
Filing Number: 221203000738 DOS ID: 6659934

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2023-26

NAME OF SUPERVISOR
VINOD V. REDDY

THIS IS TO CERTIFY

AKRON PHARMA INC.
415 OSER AVE.
UNIT Q
HAUPPAUGE, NY 11788

is duly recorded as a

REGISTERED WHOLESALER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE TWENTY-SECOND DAY OF MARCH, 2023.
THIS CERTIFICATE EXPIRES ON THE TWENTY-EIGHTH DAY OF FEBRUARY, 2026.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
039900

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

1810

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. B150023786

Application/License No. _____

Akron Pharma Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
415 Oser Ave., Unit Q, Hauppauge, NY 11788, as
(Address of Applicant/Principal)
PRINCIPAL, and Old Republic Surety Company, a
(Surety Company)
corporation organized under the laws of the state of Wisconsin
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
18500 W Corporate Dr, Ste 170, Brookfield, WI 53045 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 5/30/2023.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 23rd day of May, 20 23.

APPLICANT/PRINCIPAL

COMPANY

x _____
Authorized Representative

Kumar Swamy Reddy Mamidi
print name

SIGNED and SEALED in the presence of:

x _____
Witness

x _____
Witness

SURETY

SEAL

_____
Surety Company's Representative

Lynn Derby, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

Countersigned by:

_____
Nevada Resident Agent

OLD REPUBLIC SURETY COMPANY

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That OLD REPUBLIC SURETY COMPANY, a Wisconsin stock insurance corporation, does make, constitute and appoint: Lynn S. Derby Of MINEOLA, New York

its true and lawful Attorney(s)-In-Fact, with full power and authority, not exceeding $10,000,000, for and on behalf of the company as surety, to execute and deliver and affix the seal of the company thereto (if a seal is required), bonds, undertakings, recognizances or other written obligations in the nature thereof, ***(other than bail bonds, bank depository bonds, mortgage deficiency bonds, mortgage guaranty bonds, guarantees of installment paper and note guaranty bonds, self-insurance workers compensation bonds guaranteeing payment of benefits, asbestos abatement contract bonds, waste management bonds, hazardous waste remediation bonds or black lung bonds)***, as follows: Effective Date of Change: 05/30/2023

Bond Number:	B150023786	Bond Amount:	One Hundred Thousand Dollars	$ 100,000.00
Principal Name:	Akron Pharma Inc.			
Obligee Name:	NV State Board of Pharmacy, Nevada			

and to bind OLD REPUBLIC SURETY COMPANY thereby, and all of the acts of said Attorneys-in-Fact, pursuant to these presents, are ratified and confirmed. This appointment is made under and by authority of the board of directors at a special meeting held on February 18, 1982.

This Power of Attorney is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the board of directors of the OLD REPUBLIC SURETY COMPANY on February 18,1982.

RESOLVED that the president, any vice president or assistant vice president, in conjunction with the secretary or any assistant secretary, may appoint attorneys-in-fact or agents with authority as defined or limited in the instrument evidencing the appointment in each case, for and on behalf of the company to execute and deliver and affix the seal of the company to bonds, undertakings, recognizances, and suretyship obligations of all kinds; and said officers may remove any such attorney-in-fact or agent and revoke any Power of Attorney previously granted to such person.

RESOLVED FURTHER that any bond, undertaking, recognizance, or suretyship obligation shall be valid and binding upon the Company

(i) when signed by the president, any vice president or assistant vice president, and attested and sealed (if a seal be required) by any secretary or assistant secretary; or

(ii) when signed by the president, any vice president or assistant vice president, secretary or assistant secretary, and countersigned and sealed (if a seal be required) by a duly authorized attorney-in-fact or agent; or

(iii) when duly executed and sealed (if a seal be required) by one or more attorneys-in-fact or agents pursuant to and within the limits of the authority evidenced by the Power of Attorney issued by the company to such person or persons.

RESOLVED FURTHER that the signature of any authorized officer and the seal of the company may be affixed by facsimile to any Power of Attorney or certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the company; and such signature and seal when so used shall have the same force and effect as though manually affixed.

IN WITNESS WHEREOF, OLD REPUBLIC SURETY COMPANY has caused these presents to be signed by its proper officer, and its corporate seal to be affixed this 23rd day of May, 2023.

OLD REPUBLIC SURETY COMPANY

Karen J. Haffner
Assistant Secretary

OLD REPUBLIC SURETY COMPANY CORPORATE SEAL 1981

Alan Pavlic
President

STATE OF WISCONSIN, COUNTY OF WAUKESHA - SS

On this 23rd day of May, 2023, personally came before me, Alan Pavlic and Karen J. Haffner, to me known to be the individuals and officers of the OLD REPUBLIC SURETY COMPANY who executed the above instrument, and they each acknowledged the execution of the same, and being by me duly sworn, did severally depose and say: that they are the said officers of the corporation aforesaid, and that the seal affixed to the above instrument is the seal of the corporation, and that said corporate seal and their signatures as such officers were duly affixed and subscribed to the said instrument by the authority of the board of directors of said corporation.

KATHRYN R. PEARSON NOTARY PUBLIC STATE OF WISCONSIN

Kathryn R. Pearson
Notary Public

My Commission Expires: 09/28/2026

(Expiration of notary's commission does not invalidate this instrument

CERTIFICATE

I, the undersigned, assistant secretary of the OLD REPUBLIC SURETY COMPANY, a Wisconsin corporation, CERTIFY that the foregoing and attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolutions of the board of directors set forth in the Power of Attorney, are now in force.

0725037

OLD REPUBLIC SURETY COMPANY CORPORATE SEAL 1981

Signed and sealed at the City of Brookfield, WI this 23rd day of May, 2023.

Karen J. Haffner
Assistant Secretary

ORSC 22282 (3-06)

ROSENZWEIG INS AGENCY INC

Vinod Vera Reddy

[redacted]Sunflower Ridge Rd,
South Setauket, NY- 11720
vinny@aumpharma.com
[redacted]

Experience

March 2023 – Present
Akron Pharma Inc., Hauppauge, NY

Supervisor/Designated Representative

Federal (DQSA & DSCSA&FDA) Regulation Compliance:

- Traceability of pedigree. Authentication to identify suspect and illegitimate products.
- Inventory control management performed inventory audits on regular basis.
- Manage and implement operational activities for DQSA & DSCSA
- Monitor daily opening and closing of the facility.

Distribution Operations:

- Responsible for day-to-day operations.
- Comply with all NYS Board of pharmacy regulations
- Maintain and comply all out of state wholesale distributor license.
- Maintain all company SOP logs including temperature, cleaning, pest control, security, product storage, employee receiving and shipping etc.
- Ensure proper storage of products in controlled environment
- Maintain customer and vendor files.
- Ensure that all paperwork is properly documented
- Comply with company policies and procedures.
- Supervise and train associates on a regular basis as per company SOPs.

Oct -2019 to Mar 23
Aum Pharmaceuticals, Hauppauge, NY
Operations Manager

- Responsible for smooth functioning of the plant as per the GMP Guidelines.
- Report Distribution Licensing using FDA CDER portal.
- Maintain all company SOP logs including temperature, cleaning, pest control, security, product storage, employee receiving and shipping etc.
- Monitor daily opening and closing of the facility.
- Inventory control management performs inventory audits on a regular basis.
- Manage and implement operational activities & Software for DQSA & DSCSA
- Traceability of pedigree. Authentication to identify suspect and illegitimate products.
- Manage and implemented operational activities & Software for DQSA & DSCSA

Aug 2017 – September 2019
Syon Pharmaceutical Inc., Brentwood, NY
Facility Supervisor

- Responsible for day-to-day operations.
- Complied with all NYS Board of pharmacy regulations.
- Maintained and comply all out of state wholesale distributor license.
- Ensured proper storage of products in controlled environment.
- Maintained customer and vendor files.
- Ensured that all paperwork is properly documented.
- Complied with company policies and procedures.
- Supervised and trained associates on a regular basis as per company SOPs.

MAY 2016-JULY 2017
GRAXCELL PHARMACEUTICALS,
Bohemia, NY
Operations Manager

- Organized shift schedule to meet production demands.
- Communicated production priorities and progress to team on a continuing basis.
- Ensured that the BMR (Batch Manufacturing Records) are completed on time and correctly.
- Maintained records and a clean environment to comply with regulatory requirements.
- Worked with the maintenance department to ensure that the process equipment and supporting machinery are properly maintained.
- Ensured weights, measures and raw materials are managed appropriately to assure batches manufactured contain proper ingredients and quantities.
- Initiated appropriate action when process deviations occur.
- Managed the performance of Production Associates and Leads
- Assisted with the operation and maintenance of production equipment.

February 2014 TO March 2016
Bactolac Pharmaceuticals Inc.,
Hauppauge, NY
Production Supervisor

- Read, Understood and Complied with Good Manufacturing Practices and Standard Operating Procedures
- Supervised the day-to-day activities of production associates.
- Assigned operators job responsibilities on daily basis.
- Ensured that necessary materials and supplies are available to facilitate the operator's completion of daily job responsibilities.
- Supervised production activities including Formulation, Filling, Inspection, Packaging, Labeling and Sanitization

August 2010 to December 2013
IT Objects LLC
Herndon, VA
Business Analyst

- Gather and organize information on problems or procedures.
- Analyze data gathered and develop solutions or alternative methods of proceeding. Confer with personnel concerned to ensure successful functioning of newly implemented systems or procedures.
- Interview personnel and conduct on-site observation to ascertain unit functions, work performed, and methods, equipment, and personnel used.
- Document findings of study and prepare recommendations for implementation of new systems, procedures, or organizational changes. Design, evaluate, recommend, and approve changes of forms and reports.
- Plan study of work problems and procedures, such as organizational change, communications, information flow, integrated production methods, inventory control, or cost analysis.
- Recruiting and staffing store team. Develops and recruits promotable candidates for store needs.
- Managing and directing training modules at all levels in store.
- Creating and maintaining a team environment.
- Implementing and leading all sales and training initiatives.
- Analyzing sales results and creating action plans to achieve desired results.
- Implementing and leading floor sets, inventory.
- Maintaining training modules, communication binder, bulletin boards, holds and damages, schedules and backroom organization.
- Managing and monitoring sales figures, payroll budgets, controllable expenses, inventory control

Education:
MAY2009
International Master of Business Administration
Stratford University, Falls Church, VA
JUNE2002
BS Hospitality Management
Intercollege, Nicosia, Cyprus

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Name of Pharmacy/Wholesaler AKRON PHARMA INC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 415 OSER AVE, UNIT Q

City HAUPPAUGE State NY Zip 11788

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 631-740-1439 Website WWW.AKRONPHARMA.COM

Licensing Company Email VINNY@AKRONPHARMA.COM

First VINOD Middle _____ Last VERA REDDY

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]SUNFLOWER RIDGE RD

City SOUTH SETAUKET State NY Zip 11720

Telephone [redacted] Email VINNY@AKRONPHARMA.COM

Are you a citizen of the United States? ☐ Yes ☒ No

1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

School Name		From - To (MM/YY – MM/YY)	
STRATFORD UNIVERSITY		2008-2010	
Address	**City**	**State**	**Zip**
7777 LEESBURG PIKE	FALLS CHURCH	VA	22043
Diploma/Degree obtained, if any			
MASTERS IN BUSINESS ADMINISTRATION& MASTERS IN INFORMATION SYSTEMS			

School Name		From - To (MM/YY – MM/YY)	
INTERCOLLEGE(UNIVERSITY OF NICOSIA)			
Address	**City**	**State**	**Zip**
46 MAKEDONITISSA AVE	NICOSIA, CYPRUS-2417	-	2417
Diploma/Degree obtained, if any			
BACHELORS IN HOSPITALITY MGMT			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/22-CURENT	[redacted]SUNFLOWER RIDGE RD	SOUTH SETAUKET	NY	11720
06/17-04/22	[redacted]BROADWAY	SMITHTOWN	NY	11787
06/15-06/17	[redacted] RIDGE RD	HAUPPAUGE	NY	11788
03/14-05/15	[redacted]ARDRA CT	SMITHTOWN	NY	11787
03/12-03/14	2[redacted]OAK STREET	CENTRAL ISLIP	NY	11722
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
AUM PHARMACEUTICALS			10/19-03/23
Business Address	**City**	**State**	**Zip**
320 OSER AVE	HAUPPAUGE	NY	11788
Phone	**Title**	**Number of Employed Hours**	
631-240-3250	OPERATIONS MANAGER	FULL TIME 6000+ BB	
Description of Duties			
PLEASE SEE ENCLOSED RESUME			

Business Name			From - To (MM/YY – MM/YY)
PLEASE SEE ENCLOSED RESUME			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
PLEASE SEE ENCLOSED RESUME			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
PLEASE SEE ENCLOSED RESUME			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, VINOD, VERA REDDY **, certify that as the designated representative for**

AKRON PHARMA INC ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VR I am at least 21 years of age;
3. VR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

VINOD, VERA REDDY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/12/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

VINOD, VERA REDDY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/20/2023

Date

Please have this section completed in the presence of a Notary Public.

State of NEW YORK, ss. County of SUFFOLK

I, VINOD, VERA REDDY, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/20/2023

Date

Subscribed and Sworn to before me this 20th day of JUNE 2023

Notary Public Signature

LISA A ROY
Notary Public - State of New York
NO. 01RO6204830
Qualified in Suffolk County
My Commission Expires Apr 27, 2025

(Seal)

28 June 2023

To Whom It May Concern

List of Current employees of the Akron Pharma facility:

1. **Kumarswamy Reddy Maruri:** Title: Owner-President- Sales& Marketing
2. **Vinod, Vera Reddy:** Title: Supervisor/Designated Representative
3. **Surindra Diaram:** Title: Quality Assurance/Regulatory Manager
4. **Nelly Sokhoo:** Title: Operations Manager
5. **Jose Lora:** Title: Warehouse Supervisor
6. **Juan Carlos:** Shipping & Receiving

Respectfully,

Vinod, Vera Reddy
Designated Representative
Akron Pharma Inc
415 Oser Ave, Unit Q
Hauppauge, New York-11788
Cell# +1 631-740-1439

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site AKRON PHARMA INC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 415 OSER AVE, UNIT Q

City HAUPPAUGE, NY-11788 State NY Zip 11788

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email VINNY@AKRONPHARMA.COM

First KUMARSWAMY Middle REDDY Last MARURI

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] EDGEWOOD AVE

City SAINT JAMES State NY Zip 11780

Telephone [redacted] Email KREDDY@AKRONPHARMA.COM

Are you a citizen of the United States? ☐ Yes ■ No

1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

School Name		From - To (MM/YY – MM/YY)	
Acharya Nagarjuna University			
Address	City	State	Zip
ANDHRA PRADESH, INDIA		---------	----------
Diploma/Degree obtained, if any			
PHARMA.D (Doctor of Pharmacy):			

School Name		From - To (MM/YY – MM/YY)	
Huron College			
Address	City	State	Zip
2023 Williams Parkway, East #4, Brampton	ONTARIO, CANADA	--------	----------
Diploma/Degree obtained, if any			
Post graduation in Industrial Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/22-PRESENT	[redacted]EDGEWOOD AVE	SAINT JAMES	NY	11720
08/11-06/22	[redacted]KISSENA BLVD, UNIT [redacted]	FLUSHING	NY	11355

Business Name		From - To (MM/YY – MM/YY)	
AKRON PHARMA INC		12/13-CURRENT	
Business Address	**City**	**State**	**Zip**
415 OSER AVE, UNIT Q	HAUPPAUGE	NY	11788
Phone	**Title**		
862-485-7389	OWNER & PRESIDENT		
Description of Duties			
SINGLE OWNER			

Business Name		From - To (MM/YY – MM/YY)	
SLV PHARMACEUTICALS LLC- DBA:AUM PHARMACEUTICALS		01/17-CURRENT	
Business Address	**City**	**State**	**Zip**
320 OSER AVE	HAUPPAUGE	NY	11788
Phone	**Title**		
862-485-7389	OWNER & PRESIDENT		
Description of Duties			
SINGLE OWNER			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KUMARSWAMY, R MARURI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/12/2023

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Suffolk

I, Kumarswamy Reddy maruri, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/20/2023

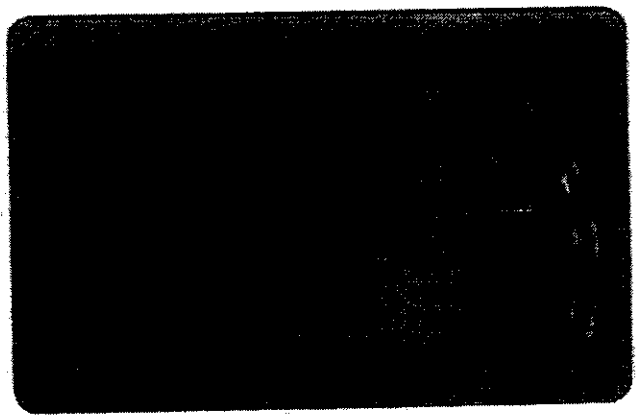
Date

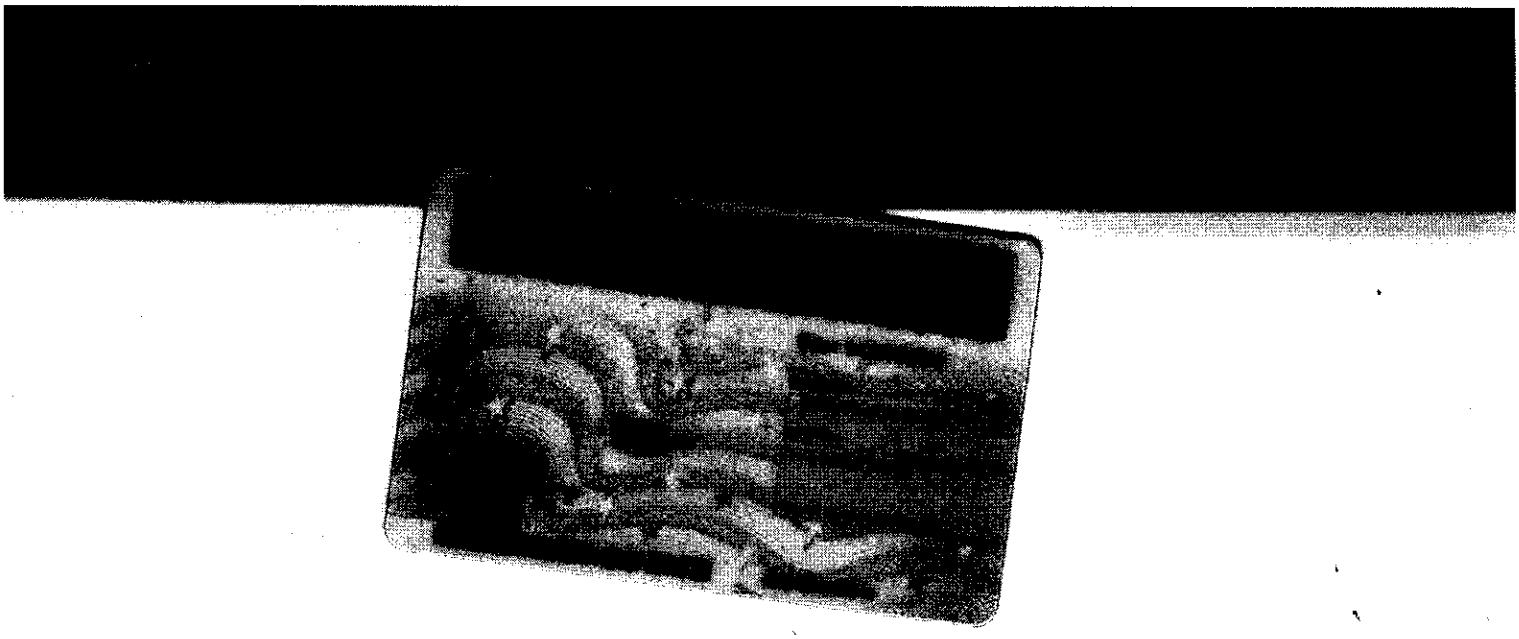
Subscribed and Sworn to before me this 20th day of June 2023

Notary Public Signature

LISA A ROY
Notary Public - State of New York
NO. 01RO6204830
Qualified in Suffolk County
My Commission Expires Apr 27, 2025

(Seal)





COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

Below are your electronic wallet cards to use as proof of your license. You can also print your license at any time by visiting www.colorado.gov/dora/DPO_Print_License and following the instructions listed.

If you would like a more durable wallet card option, you can order one for a fee by visiting www.nasbastore.org and selecting the "Colorado License Cards" link on the left hand side of the page. If you prefer, you can also contact NASBA by phone at 1-888-925-5237 or by email at nasbastore@nasba.org.

Should you have questions about your credential, or need other information please contact our Customer Service Team at 303-894-7800 or dora_dpo_licensing@state.co.us.

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy
Akron Pharma Inc
Wholesaler Out-of-State

WHO.0008694 — **Number**
Active — **Credential Status**
04/25/2023 — **Issue Date**
10/31/2024 — **Expire Date**
Verify this credential at: dpo.colorado.gov

1876

Acting Division Director: Karen McGovern Credential Holder Signature

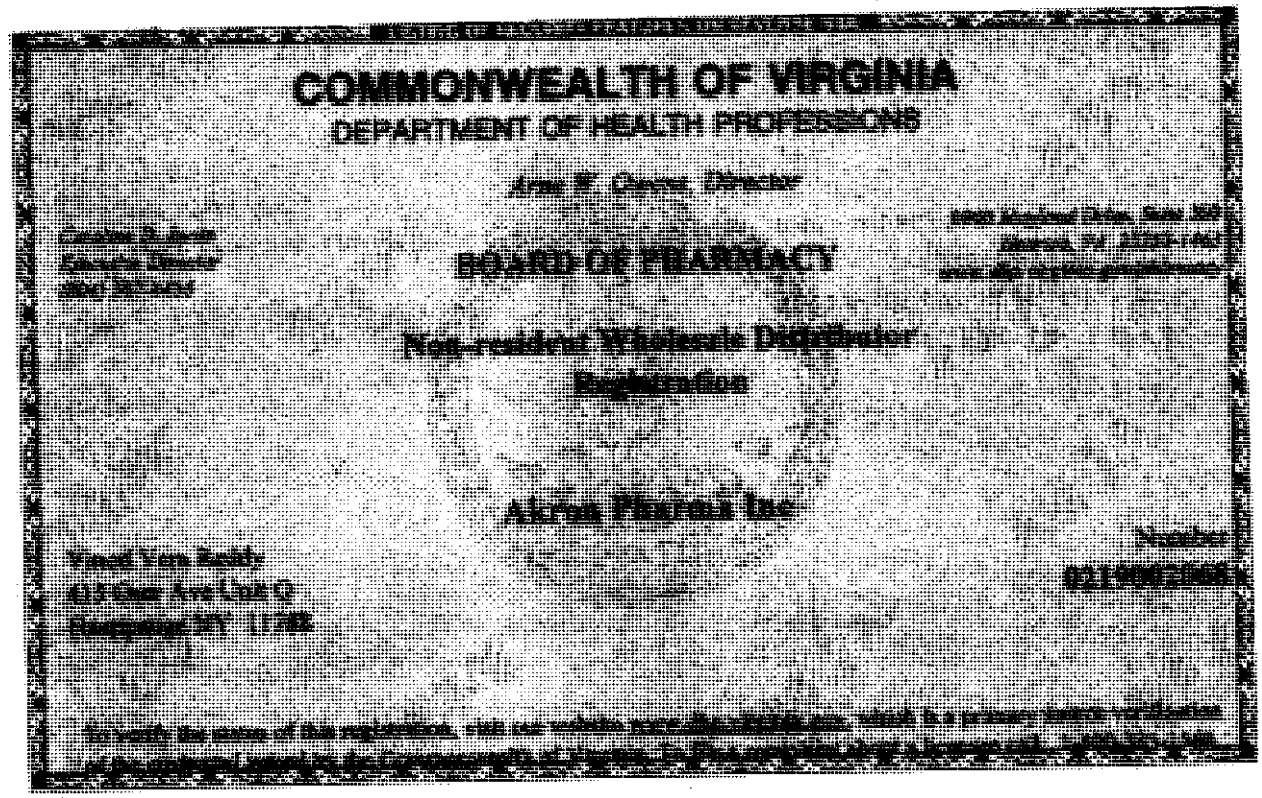
Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy
Akron Pharma Inc
Wholesaler Out-of-State

WHO.0008694 — **Number**
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04/25/2023 — **Issue Date**
10/31/2024 — **Expire Date**
Verify this credential at: dpo.colorado.gov

1876

Acting Division Director: Karen McGovern Credential Holder Signature



COMMONWEALTH OF VIRGINIA

DEPARTMENT OF HEALTH PROFESSIONS

BOARD OF PHARMACY

Non-resident Wholesale Distributor

Registration

Akron Pharma Inc

Number

MISSISSIPPI

Board of Pharmacy

Permit #:
16702 / 10 4AM

Drug Facility

Virtual Manufacturer (non-resident)

AKRON PHARMA INC

[redacted]

Permit Holder:
Vinod Vera Reddy

This permit is not transferable or assignable.

Issued: 05/24/2023
Renewed: 05/24/2023
Expires: 12/31/2023

Susan McCoy
Executive Director

Mississippi Board of Pharmacy | 6360 I-55 North | Suite 400 | Jackson, MS 39211
Phone: 601-899-8880 | Fax: 601-899-8851

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2025.

AKRON PHARMA INC

115 Oser Ave Ste C
Hauppauge, NY 11788-3978

License Number: 0130000588
Wholesaler - Category 2
Expiration Date: [illegible]

CLASS: Wholesaler - Category 2
BUSINESS TYPE: FS – Full Service

Responsible Person – Print, sign and post license in a public retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
VINOD VERA REDDY	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE

PHARMACY INSPECTION REPORT

☐ Pharmacy ☒ MW

Inspection # _____ conducted by
Investigator Ray Geraci
Date 3/13/23 Time In/Out _____ / _____

1. Routine
2. New Registration
3. Transfer Ownership
4. Discontinuance
5. Change of Name/Address
6. Medication Recall
7. Complaint Related
8. Follow-up to Previous Inspection
9. Special Project or Renovation

Reg. name AKRON PHARMA PNC
Trade name _____
No. and Street 415 OSER AVE UNIT Q
City Hauppauge County N.Y. Suffolk Zip 11788
Reg. # _____ Telephone 631 740-1439
Hours open per week 40 hrs # RXs daily _____

Pharmacists' Names	Hrs. Per Week	License Number	License Date	License Displayed	Registration Displayed
S.P. Supervisor Re Vinod Vera Reddy	50			Y N	Y N
Pharm.				Y N	Y N
Pharm.				Y N	Y N
Pharm.				Y N	Y N
Pharm.				Y N	Y N
Intern				Y N	Y N

Circle "S" if item is Satisfactory. Circle "N" if item is Not Satisfactory, and explain in Details of Inspection section below.
Be sure to include item number in explanation.

1. Registration name on exterior ..... S N
2. Licenses/current reg. displayed ..... S N
3. Registered pharmacist on duty ..... S N
4. Equip., facilities, and ref. items ..... S N
5. Price list available/current ..... S N
6. Drug stock current ..... S N
7. Stock properly branded ..... S N
8. Daily RX record ..... S N
9. Required RX fillings ..... S N
10. DEA records complete/available ..... S N NA
11. Safety/approp. closures/containers ..... S N NA

Whole sale distributer

12. RX labels required information ..... S N
13. Valid RX formats ..... S N
14. Substitution law compliance ..... S N
15. Required information on RXs ..... S N
16. Refill authorization/fill ..... S N
17. Refills in daily record ..... S N
18. Controlled substance compliance ..... S N
19. General sanitation ..... S N
20. Intern/unlicensed supervision ..... S N
21. Counseling offered/given/refusals documented ... S N
22. Types of pharmacy (circle those applicable): retail, hospital, skilled nursing, assisted living, compounding, sterile preparation, internet, home delivery, mail delivery, nuclear, veterinary

Details of Inspection On 3/13/23 manufacturing wholesaler Inspection of new reg was completed. Met with Supervisor Vinod Vera Reddy recieved permission to inspect pharmacy/d observed appropriate Signage on Front door. Observed that pharmacy is alarmed with sensors on front door, back door and recieving door which is a mechanical gate 3 cameras present in whs whse whse house and 3 ~~exterior back door~~ Cameras on the exterior of property including steel back door and.

Recommendation(completed in office)
Investigator Ray Geraci
Supervisor _____

I have received a copy of this inspection report.
Signature _____
Print name VINOD VERA REDDY
Title SUPERVISOR Date 03/13/23

This is page 1 of 2 page(s)

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE
ONE PARK AVENUE
NEW YORK, NEW YORK 10016

PHARMACY INSPECTION REPORT

Inspection # _____ conducted by
Investigator Ray Garcia
Date 3/13/23 Time _____

Reg. name AKRON PHARM. INC
Trade name _____
No. and Street 415 oser Ave unit Q, Hauppauge, NY 11788

Details of Inspection Front door as well. Door leading to wharehouse has a keypad for entry. Back door is secured and door leading to exterior exit doorway also has a keypad lock. There are two bathrooms one located in office area the other located in wharehouse. Front door and three front windows are reinforced so that if there was an attempt to break glass, the glass wouldnt fracture. ~~Wholesaler~~ will be facility will be wholesaling over the counter medications. SOPs were reviewed. Copy of packing slip and invoice will be emailed to this investigator as well as a list of officers, directors, manager and other persons in charge of wholesale drug distribution. Whole Sale distributer wharehouse appeared to be in satisfactory condition on day of inspection.

Recommendation (completed in office)
Investigator _____
Supervisor _____

I have received a copy of this inspection report.
Signature _____
Print name VINOD, VERA REDDY
Title SUPERVISOR Date 03/13/23

OPD234
continuation

4QQ

4

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Elanco US Inc.

Physical Address: 1411 Oak Street

City: Elwood State: KS Zip: 66024

Mailing Address (if different from physical address): 1411 Oak Street

City: Elwood State: KS Zip: 66024

Telephone: (902) 812-2445 Website: www.Elanco.com

Name of Designated Representative (DR): Chad Michalski

Licensing Company Email: Roxanne.Estela@Elancoah.com DR Email: chad.michalski@elancoah.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	▣ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
▣ Others: This site will ship to 3PL		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?	✓	
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01/18/2018	N/A	ID	Boise	Ada County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
BOP-18-018		Idaho Board of Pharmacy		
Reason/Charge				
Unlicensed in Idaho				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Elanco US Inc.			N/A	
Name of Business/Industry/Entity				
Elanco US Inc.				

Provide explanation below:

In June 2017, the Idaho State Board of Pharmacy changed the interpretation of their laws regarding Virtual Wholesalers and Virtual Manufacturers. Elanco US Inc. monitors all law changes from the Board of Pharmacies and is notified daily of changes. However, since the change was in interpretation rather than an actual language change we were not aware of the new requirements. When Elanco US Inc. Headquarters, located in Indiana, found this out we applied for a license right away and were issued a license, which we still hold .. However, since we had been shipping into the state using the old interpretation, which didn't require licensure for virtuals, we were out of compliance. Elanco paid a fee to the Idaho Board of Pharmacy to resolve this issue.

Original Signature (electronic, copies or stamps not accepted)

5/27/2023
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/05/21	N/A	AL	Birmingham	Shelby
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21-L-0042		Alabama Board of Pharmacy		
Reason/Charge				
Paperwork not reviewed before renewal end date.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Elanco US Inc.			N/A	
Name of Business/Industry/Entity				
Elanco US Inc.				

Provide explanation below:

Elanco US Inc. Shawnee, located in Kansas, turned in all applicable renewal documentation to the Alabama Board of Pharmacy by the deadline of 12/31/2021. As the documentation was not reviewed by the Regulator by January 1st Alabama considered our renewal expired. Once this was confirmed to Elanco on January 11th we stopped all shipments into the state until approval was received. We were fined $500.00. This wasn't considered a disciplinary action in Alabama. Elanco does not own this site anymore.

Original Signature (electronic, copies or stamps not accepted)

5/27/2022
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/4/2020	N/A	FL	Tallahassee	Leon
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2019-055050		Florida Department of Business and Professional Regulation		
Reason/Charge				
Sister State Fine				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Elanco US Inc.			N/A	
Name of Business/Industry/Entity				
Elanco US Inc.				

Provide explanation below:

Elanco US Inc. Headquarters, located in Indiana, received a violation in Florida in December 2020 for a fine we received in Idaho two years prior when Idaho changed their interpretation of the law. We notified Florida of this violation every year we renewed. We monitor all state laws using Porizo Compliance Digest to ensure we are registered correctly.

Original Signature (electronic, copies or stamps not accepted)

5/27/2023
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/21/2016	N/A	OH	Columbus	Franklin

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	Ohio Board of Pharmacy

Reason/Charge
License Denied

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Elanco US Inc.	N/A

Name of Business/Industry/Entity
Elanco US Inc.

Provide explanation below:

In July 2016, the Ohio State Board of Pharmacy changed its laws regarding Virtual Wholesalers and Virtual Manufacturers requiring either a VAWD Accreditation or a home state license. For our Elanco US Inc. Headquarters site located in Indiana, no home state license is required for veterinary wholesalers or manufacturers. Elanco was in the process of changing over Novartis Animal Health US, Inc. applications to Elanco US Inc. after the acquisition of Novartis Animal Health US, Inc. Since Novartis Animal Health US, Inc. never held a license in Ohio Elanco US Inc. did not get a grace period to comply with these new laws. Elanco US Inc. stopped sales into Ohio for 6 months. Elanco petitioned the Indiana Board of Pharmacy after submitting our VAWD application and an Indiana license was granted. We are now licensed to sell in Ohio.

Original Signature (electronic, copies or stamps not accepted)

5/27/2023
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year. This facility will only distribute to 3PLs. No product has been distributed yet.

Name: Integrated Commercialization Solutions, Inc.
Address: 420 INTERNATIONAL BLVD STE 500 City: Brooks State: KY Zip: 40109

Name: Integrated Commercialization Solutions, Inc.
Address: 6450 LASALLE DR STE D City: Lockbourne State: OH Zip: 43137

Name: DHL
Address: 1025 Sandhill Road City: Reno State: NV Zip: 89521

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: ~~Indiana~~
Parent Company (if any): ~~Elanco Animal Health Incorporated~~
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Indiana
Parent Company (if any): Elanco Animal Health Incorporated
Corporation/Organization Name: Elanco Us Inc.
Mailing Address: 2500 Innovation Way
City: Greenfield State: IN Zip: 46140
Telephone: 317-220-2913 Email: Roxanne.Estela@Elancoah.com
Contact Person Name: Roxanne Estela

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• ***Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing *Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Elanco US Inc.
Facility Name

Jose Correia de Simas
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

4-24-2023
Date

Board Use Only	Date Received: 5-30-23	Amount: 1000.00 CK- 186696

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See attached	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See ownership chart		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See attached	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See attached		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See attached	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See attached	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. See attached		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. See attached		✓	✓	✓

Top 5 Corporate Officers

Jeffrey Neil Simmons
President

Jose
Vice President

David Pugh
Treasurer

Catherine Powell
Secretary

Kathleen St. Louis
Assistant Treasurer

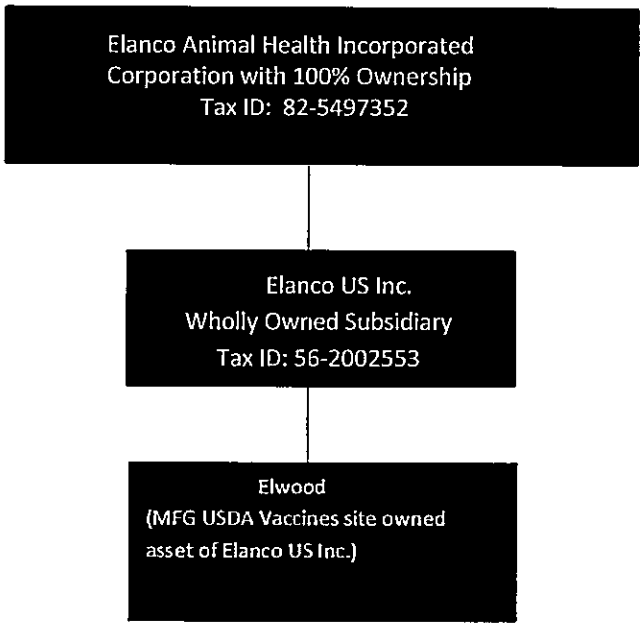
Other Corporate Officers:

Todd Sidney Young (CFO)
Marcela Adriana Kirberger (Corporate Secretary)
Timothy James Bettington (Vice President)
David Spencer Kinard (Vice President)
Rejeev Ashok Modi (Vice President)
Ramiro Martin Cabral (Vice President)
Beth Allison Haney (Assistant Treasurer)
James Micheael Meer (Assistant Treasurer)

Directors:

Jeffrey Neil Simmons
Todd Sidney Young
Marcela Adriana Kirberger
Timothy James Bettington
David Spencer Kinard

Ownership Chart



Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ELANCO US INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF APRIL, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ELANCO US INC." WAS INCORPORATED ON THE SIXTEENTH DAY OF DECEMBER, A.D. 1996.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2695209 8300

SR# 20231636606

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203218304

Date: 04-26-23

Kansas State Board of Pharmacy

800 SW Jackson St. Suite 1414
Topeka, Kansas 66612-1244
Phone (785) 296-4056
Fax (785) 296-8420

email pharmacy@pharmacy.ks.gov
www.pharmacy.ks.gov

4-120275
CHAD MICHALSKI
Elanco US Inc.
1411 Oak Street
Elwood, KS 66024

Schedules NPD

STATE OF KANSAS
STATE BOARD OF PHARMACY

N° 4-120275

CERTIFIES

This registration Must Be Renewed Annually by **June 30th.**

That **Elanco Animal Health Incorporated** *has complied with the Pharmacy Act of the State of Kansas providing for the registration of* ***Manufacturers*** *within the State of Kansas, and is hereby granted a PERMIT as defined in K.S.A. 65-1643 of the State of Kansas under the name of*

Elanco US Inc.

at **1411 OAK STREET** **ELWOOD** **KANSAS**

from this date until **6/30/2023** *, unless this registration is surrendered, or revoked or suspended by the Kansas State Board of Pharmacy.*

This registration issued **April 14, 2023.**

KANSAS STATE BOARD OF PHARMACY

By _____ Executive Secretary

THIS REGISTRATION MUST BE POSTED IN A CONSIPICUOUS PLACE - NOT TRANSFERABLE
DO NOT DESTROY - Return to Secretary for change in ownership, location or pharmacist in charge

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 9350331

Application/License No. _____

Elanco US Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1411 Oak Street, Elwood, KS 66024 (Address of Applicant/Principal), as PRINCIPAL, and Fidelity and Deposit Company of Maryland (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1299 Zurich Way, 5th Floor Schaumburg, IL 60196-1056 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 28, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 28 day of April, 2023.

APPLICANT/PRINCIPAL

Elanco US Inc.

Authorized Representative

SURETY COMPANY

Fidelity and Deposit Company of Maryland

Surety Company's Representative

Sandra L. Ham, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness JoAnn R. Frank

Witness Brittany D. Stuckel

Countersigned by:

N/A

Nevada Resident Agent

ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Illinois, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Illinois (herein collectively called the "Companies"), by **Robert D. Murray, Vice President**, in pursuance of authority granted by Article V, Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and appoint Sandra L. Ham, its true and lawful agent and Attorney-in-Fact, to make, execute, seal and deliver, for, and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings,** and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply, to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V, Section 8, of the By-Laws of said Companies, and is now in force.

IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said **ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND,** this 11th day of July, A.D. 2019.

ATTEST:
ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND

By: Robert D. Murray
Vice President

By: Dawn E. Brown
Secretary

State of Maryland
County of Baltimore

On this 11th day of July, A.D. 2019, before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **Robert D. Murray, Vice President and Dawn E. Brown, Secretary** of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, deposeth and saith, that he/she is the said officer of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.

Constance A. Dunn
Constance A. Dunn, Notary Public
My Commission Expires: July 9, 2023

EXTRACT FROM BY-LAWS OF THE COMPANIES

"Article V, Section 8, Attorneys-in-Fact. The Chief Executive Officer, the President, or any Executive Vice President or Vice President may, by written instrument under the attested corporate seal, appoint attorneys-in-fact with authority to execute bonds, policies, recognizances, stipulations, undertakings, or other like instruments on behalf of the Company, and may authorize any officer or any such attorney-in-fact to affix the corporate seal thereto; and may with or without cause modify of revoke any such appointment or authority at any time."

CERTIFICATE

I, the undersigned, Vice President of the ZURICH AMERICAN INSURANCE COMPANY, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing Power of Attorney is still in full force and effect on the date of this certificate; and I do further certify that Article V, Section 8, of the By-Laws of the Companies is still in force.

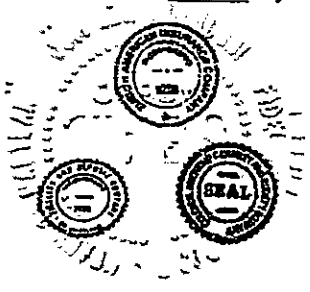
This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the ZURICH AMERICAN INSURANCE COMPANY at a meeting duly called and held on the 15th day of December 1998.

RESOLVED: "That the signature of the President or a Vice President and the attesting signature of a Secretary or an Assistant Secretary and the Seal of the Company may be affixed by facsimile on any Power of Attorney...Any such Power or any certificate thereof bearing such facsimile signature and seal shall be valid and binding on the Company."

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at a meeting duly called and held on the 5th day of May, 1994, and the following resolution of the Board of Directors of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at a meeting duly called and held on the 10th day of May, 1990.

RESOLVED: "That the facsimile or mechanically reproduced seal of the company and facsimile or mechanically reproduced signature of any Vice-President, Secretary, or Assistant Secretary of the Company, whether made heretofore or hereafter, wherever appearing upon a certified copy of any power of attorney issued by the Company, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seals of the said Companies, this 28th day of April, 2023.



Brian M. Hodges

Brian M. Hodges, Vice President

TO REPORT A CLAIM WITH REGARD TO A SURETY BOND, PLEASE SUBMIT A COMPLETE DESCRIPTION OF THE CLAIM INCLUDING THE PRINCIPAL ON THE BOND, THE BOND NUMBER, AND YOUR CONTACT INFORMATION TO:

Zurich Surety Claims
1299 Zurich Way
Schaumburg, IL 60196-1056
www.reportsfclaims@zurichna.com
800-626-4577

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Elanco US Inc.

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 1411 Oak Street

City Elwood State KS Zip 66024

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone (902) 812-2445 Website www.elanco.com

Licensing Company Email Roxanne.Estela@Elancoah.com

Section 2: Personal Information

First Chad Middle James Last Michalski

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 1411 Oak Street

City Elwood State KS Zip 66024

Telephone (902) 812-2445 Email chad.michalski@elancoah.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Western Ontario		09/99-03/07	
Address	City	State	Zip
1151 Richmond Street	London	ON	N6A 3K7
Diploma/Degree obtained, if any			
PhD			

School Name		From - To (MM/YY – MM/YY)	
University of Manitoba		09/95-/04/99	
Address	City	State	Zip
66 Chancellors Circle	Winnipeg	MB	R3T 2N2
Diploma/Degree obtained, if any			
BSc			

School Name		From - To (MM/YY – MM/YY)	
West Kildonan Collegiate		09/92-06/95	
Address	City	State	Zip
101 Ridgecrest Avenue	Winnipeg	MB	R2V 2A6
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/22-05/23	[redacted]Shannon Avenue	Smithville	MO	64089
From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/18-03/22	[redacted]Main Street	Cornwall	PE	C0A 1H0
From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/16-08/18	[redacted] Euston Street	Charlottetown	PE	C1A 1V8
From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/14-08/16	[redacted]Fitzroy Street	Charlottetown	PE	C1A 1S9
From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/13-07/14	[redacted] Water Street	Charlottetown	PE	C1A 0A8
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Elanco US Inc				From - To (MM/YY – MM/YY): 03/22-05/15
Business Address: 1411 Oak Street		City: Elwood	State: KS	Zip: 66024
Phone: 816-722-9448	Title: Sr. Director, Manufacturing | Site Head			Number of Employed Hours: 2368
Description of Duties: Overall accountability and oversight for all aspects of operations at the Elanco Elwood monocloal antibody manufacturing facility.				

Business Name: Elanco Canada Ltd				From - To (MM/YY – MM/YY): 08/18-03/22
Business Address: 37 McCarville Street		City: Charlottetown	State: PE	Zip: C1E 2A7
Phone: 902-566-4966	Title: Sr. Global Vaccine Manufacturing Advisor			Number of Employed Hours: 7128
Description of Duties: Lead global teams in execution of large/complex technical projects including development, capital, technology transfer, operational readiness and regulatory programs at the Elanco Charlottetown vaccine manufacturing facility.				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Chad Michalski, **certify that as the designated representative for**

Elanco US Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CM I am at least 21 years of age;
3. CM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Chad Michalski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

29May2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Chad Michalski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

29May2023

Date

Please have this section completed in the presence of a Notary Public.

State of Missouri, ss. County of Buchanan

I, Chad Michalski, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01 Jun 2023

Date

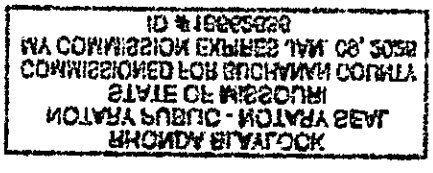
Subscribed and Sworn to before me this 1 day of June 2023.

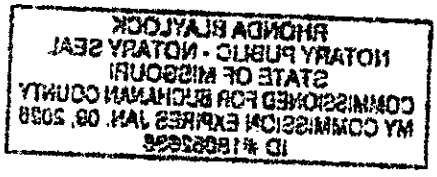
Rhonda Blaylock

Notary Public Signature

RHONDA BLAYLOCK
NOTARY PUBLIC - NOTARY SEAL
STATE OF MISSOURI
COMMISSIONED FOR BUCHANAN COUNTY
MY COMMISSION EXPIRES JAN. 09, 2026
ID #18662696

RHONDA BLAYLOCK
NOTARY PUBLIC - NOTARY SEAL
STATE OF MISSOURI
COMMISSIONED FOR BUCHANAN COUNTY
MY COMMISSION EXPIRES JAN. 09, 2026
ID #18662696





List of Elwood Employees

First Name	Last Name	Worker Type
Charley	Adams	Employee
Laura	Anderson	Employee
Samantha	Beloate	Employee
Amanda	Benefield	Employee
Angela	Billingsley	Employee
Briley	Blessing	Employee
Lynn	Browning	Employee
Bill	Burnich	Employee
Thomas	Docherty	Employee
Angelia	Dunbar	Employee
Diana	Garten	Employee
Caetlin	Girard	Employee
Brian	Gorrell	Employee
Iris	Guthmiller	Employee
Ellen	Henderson	Employee
LeErika	Hillen	Employee
Allyson	Kauth	Employee
Cody	Kirschner	Employee
Sarah	Krickeberg	Employee
Kosha	Kumar	Employee
Mark	Langemach	Employee
David	Lyons	Employee
Shana	Lyons	Employee
Gargi	Maity	Employee
Joseph	Maloney	Employee
Caleb	Mason	Employee
Jeremy	McClintock	Employee
Ken	McConnell	Employee

RICKY	MCCRARY	Employee
Sara	McCue	Employee
Chad	Michalski	Employee
Felicia	Nguyen	Employee
Chris	Parks	Employee
Larry	Payne	Employee
Courtney	Paz	Employee
Jay	Peterson	Employee
Jesica	Phelan	Employee
Robert	Pierce	Employee
Meera	Reiff	Employee
Shawna	Russell	Employee
Casey	Rutherford	Employee
Sammie	Shultz	Employee
Eric	Siegfreid	Employee
Alexander	Simon	Employee
Alan	Stewart	Employee
Margaret Rachel	Vandever	Employee
Ryan	Vandivert	Employee
Kristen	Vice	Employee
Adam	Workman	Employee

Elanco US Inc.
PO Box 708
2500 Innovation Way
Greenfield, IN 46140
317.276.2000

June 11, 2018

To Whom It May Concern:

In June 2017, the Idaho State Board of Pharmacy changed the interpretation of their laws regarding Virtual Wholesalers and Virtual Manufacturers. Elanco monitors all law changes from the Board of Pharmacies and is notified daily of changes. However, since the change was in interpretation rather than an actual language change we were not aware of the new requirements. When Elanco found this out we applied for a license right away and were issued a license, which we still hold.. However, since we had been shipping into the state using the old interpretation, which didn't require licensure for virtuals, we were out of compliance. Elanco paid a fee to the Idaho Board of Pharmacy to resolve this issue.

Please let me know if you have any further questions.

Roxanne P. Estela
Sr. Associate, Regulatory Affiars
Elanco US Inc.
Estela_Roxanne_P@elanco.com
(317) 220-2913

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

In the Matter of the License of: ELANCO US INC., Manufacturer License No. M46280, Respondent.	)	Case No. BOP 18-018 **STIPULATION AND CONSENT ORDER**

WHEREAS, information has been received by the Idaho Board of Pharmacy ("Board") that constitutes sufficient grounds for the initiation of an administrative action against Elanco US Inc. ("Respondent"); and

WHEREAS, the parties wish to expeditiously settle this matter in lieu of proceeding to an administrative hearing before the Board; now, therefore,

IT IS HEREBY STIPULATED AND AGREED between the undersigned parties that this matter shall be settled and resolved upon the following terms:

A. JURISDICTION OF THE BOARD

1. The Board may regulate the practice of pharmacy in the state of Idaho in accordance with title 54, chapter 17, Idaho Code. The Board is further empowered by title 37, chapter 27, Idaho Code, to administer the regulating provisions of the Uniform Controlled Substances Act in the state of Idaho.

2. Respondent is a licensee of the Board and holds Manufacturer License No. M46280. Respondent's license is subject to the provisions of title 54, chapter 17, Idaho Code, title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 27.01.01, *et seq.*

B. STIPULATED FACTS

1. Respondent is a corporation organized in the state of Indiana and is a manufacturer of drugs as defined by Idaho Code § 54-1705(24).

2. Respondent previously held Manufacturer Registration No. M21204, which expired June 30, 2016. The Board received the new Manufacturer Registration Application submitted by Respondent on July 10, 2017. In the course of reviewing the application, Board staff discovered they had a previous registration and contacted Respondent to request a list of medications shipped into Idaho for the time period of June 30, 2016, through the date of the application. Respondent provided Board Staff with a listing of the drug products shipped into the state of Idaho during the period of June 2016 through May 2017.

3. According to the list provided by Respondent, Respondent shipped 548 drug products to veterinary medical providers in the state of Idaho between June 2016 and May 2017. Each product shipped during the period in which Respondent was unlicensed in the state of Idaho is a violation of Idaho law and Board rules.

4. While Respondent's error may have been unintentional, Respondent acknowledges its actions constituted violations of the statutes and rules governing the practice of pharmacy in Idaho. More specifically, Respondent admits the violations are subject to the following statutes and rules:

a. Idaho Code § 54-1726(1)(f) (the Board may suspend, revoke or restrict the license or registration of any person, upon one or more of the following grounds. . .being found by the Board to be in violation of any of the provisions of this chapter, chapter 27, title 37, or rules adopted pursuant to either chapter);

b. Idaho Code § 54-1729(2)(c) (each drug or device outlet shall apply for a certificate of registration or a license in one of the following classifications . . . (c) manufacturer);

c. Idaho Code § 54-1728(1)(f) (upon the finding of the existence of grounds for discipline the Board may impose one or more of the following penalties . . . (f)

imposition of an administrative fine not to exceed two thousand dollars ($2,000) plus costs of prosecution and administrative costs);

d. Idaho Code § 54-1732(1) (no drug outlet designated in § 54-1729 shall be operated until a certificate of registration has been issued to said facility by the Board . . . upon the finding of a violation of this subsection, the Board may impose one or more of the penalties enumerated in § 54-1728, Idaho Code);

e. IDAPA 27.01.01.060 (a license or a certificate of registration, as applicable, is required for drug outlets doing business in or into Idaho); and

f. IDAPA 27.01.01.501 (the Board may suspend, revoke or restrict the registration of an individual on one or more of the grounds provided in Idaho Code § 54-1726);

5. Respondent, in lieu of proceeding with a formal disciplinary hearing, hereby agrees the Board may enter a final order against its license as set forth in Section C below.

C. STIPULATED PENALTIES

1. The parties agree that under the facts presented and the regulations that apply to such facts, the Board has the authority pursuant to Idaho Code § 54-1728(f) to impose an administrative fine of Two Thousand Dollars ($2,000) per occurrence for each drug product shipped into the state of Idaho during the time it was unlicensed. In the interests of efficiency and economy, it is agreed that Respondent shall pay a fine of Forty Thousand Dollars ($40,000) for the violations outlined above in Section B. This fine shall become due only after the Board approves and executes the Order incorporating this Stipulation and shall be paid to the Board within 180 days of the date the Order is executed.

2. Failure to comply with any of the terms of this Stipulation and Consent Order may result in additional action being taken against Respondent's manufacturer license.

3. All costs associated with Respondent's compliance with the terms of this Stipulation and Order shall be borne solely by Respondent.

D. COMPLIANCE WITH STIPULATION AND CONSENT ORDER

1. The Board has authority to enforce compliance with the terms and conditions of this Stipulation. By signing this Stipulation, Respondent waives its ability to challenge the Board's lack of authority to enforce compliance on appeal to a district court. If there is reason to believe Respondent has violated any of the terms or conditions of this Stipulation, the Executive Director of the Board shall file an administrative complaint, setting forth the allegations of non-compliance and notifying Respondent, and its attorney, if applicable, that Respondent may request a hearing regarding the allegations of non-compliance. If Respondent does not request a hearing on the administrative complaint, any allegations of non-compliance will be deemed admitted.

2. If Respondent fails to comply with this Stipulation, Respondent's license may be subject to further discipline, up to and including suspension or revocation. Therefore, the Board retains jurisdiction over this proceeding until all matters are finally resolved as set forth in this Stipulation. Any action taken by the Board to enforce compliance with this Stipulation shall be in accordance with this section.

3. Any additional costs and/or attorney fees incurred by the Board in any enforcement action shall be borne solely by Respondent.

E. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

Respondent, by signature of its authorized representative hereto, hereby acknowledges the following:

1. Respondent admits to the allegations stated above in Section B. Respondent understands these allegations constitute cause for disciplinary terms upon its license. Respondent agrees the Board has jurisdiction to proceed in this matter with its consent as indicated by signature

on its behalf hereto.

2. Respondent has read the above Stipulation fully and has had the opportunity to discuss it with legal counsel. Respondent understands and acknowledges that by its terms it is waiving certain rights provided under Idaho law.

3. Respondent understands that it has, among other rights, the right to a full and complete hearing; the right to confront and cross-examine witnesses; the right to present evidence or to call witnesses, or to so testify on its own behalf; the right to reconsideration; the right to appeal this matter to district court; and all rights provided by the Idaho Administrative Procedure Act and the laws and rules governing the practice of pharmacy in Idaho. Respondent hereby freely and voluntarily waives these rights, without further process, in order to enter into this Stipulation as a resolution of the allegations contained herein.

4. Respondent understands that in signing this Stipulation, it is enabling the Board to impose disciplinary terms upon its license as set forth in Section C without further process.

5. Respondent understands the Board may approve this Stipulation as proposed, approve it subject to specified changes, or reject it. Respondent understands that, if approved as proposed, the Board will execute and issue this Stipulation and Consent Order according to the aforementioned terms, and Respondent hereby agrees to the above Stipulation for settlement. If the Board approves this Stipulation subject to changes, and those changes are acceptable, Respondent acknowledges the Stipulation will take effect, and an order modifying the terms of the Stipulation will be issued. If the changes are unacceptable or the Board rejects this Stipulation, this Stipulation will be of no effect. Admissions in this Stipulation and negotiations preceding the signing of this Stipulation will not be admissible at any subsequent disciplinary hearing.

6. In the event this Stipulation is rejected by the Board or any changes proposed by the Board are not accepted, Respondent waives any right it may have to challenge the Board's

impartiality to hear the allegations in any subsequent administrative complaint based on the fact that the Board has considered and rejected this Stipulation.

7. Respondent understands the Board shall have the right to make full disclosure of this Stipulation and Consent Order to any state, agency or individual requesting information subject to any applicable provisions of the Idaho Public Records Act, title 9, chapter 3, Idaho Code.

8. Respondent understands this Stipulation and Consent Order is the resolution of a contested case and is a **public record**.

9. This Stipulation contains the entire agreement between the parties, and Respondent is not relying on any other agreement or representation of any kind, verbal or otherwise.

10. This Stipulation shall be presented to the Board with a recommendation for approval from the Executive Director of the Board and the Deputy Attorney General responsible for prosecution before the Board at the next regularly-scheduled meeting of the Board.

11. Except for Paragraph E.6., which becomes effective when Respondent signs this Stipulation, this Stipulation shall not become effective until it has been approved by a majority of the Board, and a Board member signs the attached Order.

DATED this 18 day of January, ~~2017.~~ 2018

ELANCO US INC.

By: _____

Its: Director and CFO
Authorized Representative for Respondent

I concur in this stipulation and order and recommend that the Board adopt the same.

DATED this 18 day of January, 2018.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

STEVEN L. OLSEN
Deputy Attorney General

I also concur in this stipulation and order and recommend the Board adopt the same.

DATED this 23rd day of January, 2018.

IDAHO BOARD OF PHARMACY

By: Alex J. Adams
Alex J. Adams, PharmD, MPH
Executive Director

ORDER

Pursuant to Idaho Code § 54-1728 and § 37-2718, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order, and it is hereby ordered that Respondent comply with said terms and conditions.

DATED this 8th day of February, 2018.

Nicole Chopski, PharmD
Board Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 31 day of February, 2018, I caused to be served a true and correct copy of the foregoing STIPULATION AND CONSENT ORDER by the following method to:

Roxanne Estela
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140-8767

☒ U.S. Mail
☐ Hand Delivery
☒ Certified Mail, Return Receipt Requested
☐ Overnight Mail
☐ Facsimile:

Steven L. Olsen
Deputy Attorney General
Civil Litigation Division
P. O. Box 83720
Boise, ID 83720-0010

☐ U.S. Mail
☐ Hand Delivery
☐ Overnight Mail
☐ Facsimile:
☒ Email: steven.olsen@ag.idaho.gov
colleen.funk@ag.idaho.gov

Ellen Mitchell
Investigations Support Coordinator

6/10/2022

To Whom it May concern:

Elanco turned in all applicable renewal documentation to the Alabama Board of Pharmacy by the deadline of 12/31/2022. As the documentation was not reviewed by the Regulator by January 1st Alabama considered our renewal expired. Once this was confirmed to Elanco on January 11th we stopped all shipments into the state until approval was received. We were fined $500.00

Roxanne P. Estela

Roxanne Estela
Advisor, State Licensing and Permits, North American Commercial Product Regulatory
Elanco US Inc.
2500 Innovation Way, Greenfield, IN 46140 USA
M + [redacted]
Roxanne.Estela@Elancoah.com

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
ELANCO US INC.	)	**BOARD OF PHARMACY**
	)	
Manufacturer	)	**CASE NO: 21-L-0042**
Permit No. 195965	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Elanco US, Inc. which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Elanco US, Inc. violated the applicable provisions of law based upon the conduct set out in Count One of the Statement.

2. Elanco US, Inc. shall pay to the Board an administrative fine in the amount of Five Hundred dollars ($500.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and Elanco US, Inc. shall not attempt to discharge the same in any bankruptcy proceeding.

3. That Elanco US, Inc. expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Elanco US, Inc. further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Elanco US, Inc. hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims; damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Elanco US, Inc. acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Elanco US, Inc.'s permit, including, but not limited to revocation.

6. That Elanco US, Inc. acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Elanco US, Inc. acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 24th day of September, 2021.

Elanco US, Inc.

By: José Simas
Its: Vice President, Jose Correia de Simas

DONE this the _____ day of _____, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Brenda Denson, PharmD, President

By: _____
James S. Ward
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
ELANCO US INC.	)	**BOARD OF PHARMACY**
	)	
Manufacturer	)	**CASE NO: 21-L-0042**
Permit No. 195965	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Elanco US Inc.
12809 Shawnee Mission Parkway
Shawnee Mission, Kansas 66216

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-92(12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on October 12, 2021 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Elanco US Inc. (Elanco) as a Manufacturer should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that Elanco has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

6. Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein.

COUNT ONE

Violating Code of Alabama (1975), § 34-23-32(2)(a), (d) and/or (f) by conducting business during 2021 without a current or valid permit to do so.

The Board alleges that each distribution is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 5th day of May, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

Alabama State Board of Pharmacy
111 Village Street
Birmingham, AL 35242

Your license/registration/permit has been delayed because you failed to complete your renewal before your license expired on **12/31/2020**. In order to continue processing your application, you must send us a written statement as to whether or not you have shipped/sold any drugs/devices/oxygen into Alabama or performed any drug/device/oxygen related duties in Alabama since your license/registration/permit lapsed.

Please sign, date, and return to the address above. Statement must be notarized

Sincerely,

Donna Yeatman R.Ph

All documentation was submitted to Alabama for license #195965 on December 31st, 2020 before the expiration of our license. Please find attached a copy of our submission, payment receipt for the license, and documents that were emailed to the board on December 31st, 2020. Elanco was in communication with the board on our license deficency, see attached emails, and received confirmation that our license was considered expired even though documents were sent to the board prior to the expiration date on 12/31/2021. On 1/11/2021 Elanco ordered a stop to all shipments into the state.

It is affirmed that all information provided herein is true and correct and it is recognized that providing false information may result in disciplinary action.

MUST BE SIGNED BY OWNER, OFFICER, OR CEO ONLY

Signature [signature] Date 1-12-2020

Printed Name Jose Correia de Simas Title Vice President

License/Registration/Permit # 195965

Subscribed and sworn to before me this_____day of_____20____.

_____

ALABAMA BOARD OF PHARMACY

MANUFACTURER DISTRIBUTOR RENEWAL

Instructions

You will need the following information for your renewal:

1. Owner, Officer & Designated Representative Details (Name, SSN, Date of Birth, Home Address, Phone Number, Email, Title)
2. Home State License or Home State Exemption
3. Verification of your home state license, if applicable (This can be a current online verification from the home state issuing agency)
4. Copy of DEA certificate, if applicable
5. Ownership Organizational Chart
6. List of all states licensed in
7. Copy of FDA inspection, FDA 483, warning letters, recalls, seizures, and response to any of these documents received since the last renewal.
8. Discipline received from any other state or regulatory organization since your last renewal

Note: You will have the opportunity to print your application and payment receipt after submission.

Facility/Business Data

Name of Business

Elanco US Inc.

Address1

12809 Shawnee Mission Parkway

Address2

1888

Products are shipped to: (Please mark all that apply)

- [x] Pharmacies
- [x] Wholesale Distributors
- [ ] Third Party Logistics Providers
- [ ] Repackagers
- [ ] Government Agencies
- [x] Hospitals/Clinics
- [ ] Licensed Prescribe rs
- [ ] Other

If other, please explain

Controlled Substance

Do you want to renew or add a controlled substance permit?

- [x] Yes
- [ ] No

Schedule:

- [ ] I
- [ ] II
- [ ] III
- [ ] IV
- [ ] V
- [x] AL State specific Controlled Substances

Contact Details

All official correspondence regarding this renewal application will be directed to this individual only.

Person to contact about this Renewal

Roxanne Estela

Phone Number

(131) 722-0291

1889

Pro

City

☑ Shawnee Mission

State

☐ KS

Phone Number

If o (913) 268-2000

FEIN Number

56-2002553

Business email

Conti Estela_Roxanne_P@Elanco.com

Do DEA number

RE0582002

Sch

Type of Operations

FDA Establishment Identification Number of each Manufacturing Facility that you distribute for:

1910953

Cont Type of Products Distributed: (Please mark all that apply)

All ☑ Controlled Substances ☐ Human Prescription Drugs ☑ Veterinary Prescription Drugs ☐ Prescription Devices ☐ Active Pharmaceutical Ingredient (API)

Per

R

Phc

(

Email

Estela_Roxanne_P@Elanco.com

Designated Representative

Full Name

Larry Geivett

Email

larry.geivett@bayer.com

Is this still the facility designated representative? ☑ Yes ☐ No

Owners/Officers

List all entities/people that own 10% or more

This submitted information does not constitute a notification of change of ownership. If you have a change of ownership, you must submit a facility change of ownership application; the application is available on our website.

☐ This applicant has individual owners

☑ This applicant has business entities as owners

☐ This business has both individual and business owners

☐ Publicly Traded or 501c3

Business Owner(s)

1891

Name : Elanco Animal Health Incorporated EIN/TIN/FEIN# : 82-5497352 % of Ownership : 100
Phone Number : (317) 220-2913 Address (Street, City, State, Zip Code) : 2500 Innovation Way City :
State : IN Zip :

Officer(s)

Full Name : Darlene Andrea Quashie Henry Title : Secretary Date Of Birth : 11/03/1971
Social Security Number : 099-84-7159 Email : Darlene.Henry@Elanco.com
Phone Number : (317) 276-2606
Home Address (Street, City, State, Zip Code) : 1997 Finchley Rd, Carmel, IN 46032

Full Name : William Shawn Mckee Title : President Date Of Birth : 01/09/1967
Social Security Number : 189-62-1185 Email : Mckee_William_Shawn@Elanco.com
Phone Number : (317) 797-1179
Home Address (Street, City, State, Zip Code) : 10816 Harbor Bay, Fishers, IN 46040

Full Name : Jose Manuel Correia de Simas Title : Vice President Date Of Birth : 08/20/1967
Social Security Number : 600-96-4297 Email : simas_jose@elanco.com
Phone Number : (317) 544-9063
Home Address (Street, City, State, Zip Code) : 13632 Kingston Dr, Fishers, IN 46055

Full Name : David Richard Pugh Title : Treasurer Date Of Birth : 07/28/1970
Social Security Number : 304-92-4976 Email : pughdr@elanco.com
Phone Number : (317) 361-9892
Home Address (Street, City, State, Zip Code) : 6210 Red Alder Drive, Avon IN 46123

Regulatory Questions (Since last renewal)

1893

1 Since the last renewal has applicant or any Owner, Officer, Member, Director, Manager or Partner thereof been arrested and/or convicted of a felony or misdemeanor , excluding minor traffic convictions?

☐ Yes ☑ No

2 Since the last renewal does applicant or any Owner, Officer, Member, Director, Manager or Partner thereof own, in whole or in part, any pharmacy, manufacturer, wholesaler, distributor, repackager, private label distributor, 503B Outsourcer and/or third-party logistics company?

☐ Yes ☑ No

3 Since the last renewal has any license or permit issued to any described entity (Owner, Officer, Member, Director, Manager, or Partner) been surrendered or subject to discipline in connection with the activities of any such entity or charged and/or convicted of any felony or misdemeanor excluding minor traffic violations?

☑ Yes ☐ No

4 Since the last renewal has applicant been denied or refused an application for a permit for a pharmacy, manufacturer, wholesaler, distributor, repackager, private label distributor, 503B Outsourcer and/or third-party logistics company?

☐ Yes ☑ No

5 Since the last renewal has applicant withdrawn an application for a permit or surrendered license once issued to any pharmacy, manufacturer, wholesaler, distributor, repackager, private label distributor, 503B Outsourcer and/or third-party logistic company?

☐ Yes ☑ No

6 Since the last renewal does Owner, Officer, Member, Director, Manager or Partner of the applicant own, in whole or inpart, or now own any entity that has been denied, refused or withdrawn an application for a permit or license of a pharmacy, manufacturer, distributor, repackager, private label distributor, 503B outsourcer and/or third-party logistics company?

☐ Yes ☑ No

7	Since the last renewal has Applicant or any Owner, Officer, Member, Director, Manager or Partner thereof been issued a license to practice pharmacy or as a pharmacy technician?	☐ Yes ☑ No
8	Since last renewal has an FDA 483 or Warning Letter been issued to Applicant or to any entity in which any Owner, Officer, Member, Director, Manager or Partner of the Applicant has been or is currently involved/affiliated?	☐ Yes ☑ No
9	Since the last renewal has any final judgement been entered or settlement reached resulting from a claim or action for damages caused by any error, omission, or negligence in the performance of any pharmacy or pharmaceutical professional services by the Applicant or any Owner, Officer, Member, Director, Manager or Partner.	☐ Yes ☑ No

Attachments

Please upload the proper documents listed in this section.

1	Home State License or Proof of Exemption ℹ	View/Download (https://albop.igovsolution.net/docs/albopdocuments/\2020\12\69bc51363cac4ddebaf2c2faf8a9c901.pdf)
2	Verification of Home State Permit <30 days old ℹ	View/Download (https://albop.igovsolution.net/docs/albopdocuments/\2020\12\710207c84c3a46378b51a9fa63b27637.pdf)
3	List of all states the applicant is currently permitted in ℹ	View/Download (https://albop.igovsolution.net/docs/albopdocuments/\2020\12\dfbd36a8aea4449380a5fd9e3fefd268.pdf)

1895

Ownership Organizational Chart

View/Download

(https://albop.igovsolution.net/docs/albopdocuments/\2020\12\fbea043f3f7d4464824350 74f747ce7c.pdf)

Question 3 Supporting Documents

View/Download

(https://albop.igovsolution.net/docs/albopdocuments/\2020\12\22bff60073734f539c0c10a45a5a032f.pdf)

Affirm And Submit

☑ It is affirmed that all information provided herein is true and correct and it is recognized that providing false information may result in disciplinary action. It is understood that there must be compliance with the provisions of the Alabama Pharmacy Act the Rules of the Board and all other applicable statutes and rules.

☑ All fees once submitted are non-refundable. Care should be taken to ensure all requested information and documentation is submitted/supplied. Failure to submit all requested deficient information or documentation within 30 days of issuance of notification will result in non-renewal of your permit and forfeiture of fees.

☑ It is acknowledged and agreed that the issuance of your renewal does not in any way waive or prevent the Board from initiating disciplinary charges based on your responses on this renewal application and/or any information obtained or discovered by the Board as a result of any such response.

Date

12/31/2020

E-Signature

Roxanne Estela

Email to send receipt

Estela_Roxanne_P@Elanco.com

1896

(Board of Pharmacy charge, including a convenience fee, will appear on your statement with a description including IGOVSOL*.)

Amount Due

1100.00

Transaction Fee

44.00

Total

1144.00

Payment Type

Credit Card

Person's Name on Card

Roxanne Estela

Card #

*****9914

Order ID

20201231000038412

Billing Zip Code

46220

Office: 111 Village Street, Birmingham, AL 35242. Tel: 205-981-2330, Fax: 205-981-2330, Office Hours: 8:00 AM – 4:00 PM CST

1897

1898

[EXTERNAL] ALBOP Renewal Receipt

From: ALBOP albop@igovsolution.net
To: Roxanne Estela ROXANNE.ESTELA@elancoah.com
Date: Thursday, December 31, 12:46 PM

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

Manufacturer Distributor Renewal

Your Renewal Order # : 20201231000038412

Name : Elanco US Inc.

License # : 195965

Submission Date : 12/31/2020

Renewal Fee : $500.00

CS Fee : $600.00

Convenience Fee : $44.00

Total Paid : $1144.00

Please click here to download your Renewal Application and Receipt.

:enewal 12809 Shawnee - License #196965

From: Roxanne Estela ROXANNE.ESTELA@elancoah.com
To: Kim Pickett kpickett@albop.com
Date: Thursday, December 31, 1:20 PM
12809 Current Licenses.pdf 105 KB
Elanco US Inc._Kansas 12809.pdf 1.1 MB
License Verification 12809.pdf 226 KB

li Kim,

ıpologies. I accidently attached documents for our 12707 license to the 12809 application.
'lease find the correct documents for 12809 attached.

}est,

Roxanne

:oxanne Estela (she/her/hers)
ıdvisor, Licenses and Permits
lorth American Regulatory Affairs, Commercial Products
:lanco US Inc.
:500 Innovation Way, Greenfield, IN 46140 USA
/ +1 317.220.2913
:stela_Roxanne_P@elanco.com
vww.elanco.com

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P **Please consider the environment before printing this email**

Ask me about how you can get involved in the Clothe-A-Child Feed-A-Family.

Alabama State Board of Pharmacy
Facility Renewal Deficiency Notice

Date Received
Office Use Only

Applicant Name: Elanco US Inc	Permit Number: 195965	Notification Date: 1/4/2021
Applicant Address: 12809 Shawnee Mission Parkway Shawnee Mission, KS 66216		

1. These items are needed to continue processing your application.

- A copy of your home state license for the permitted facility
- Provide a verification of your home state license. This can be from your states electronic verification but must not be more than 30 days old.

2. **Submit all required information at one time in a packet with this form as your cover page.**

3. Your renewal will be withdrawn if the deficiency packet is not received within **30 days** of the notification date above.

4. The deficiency response packet **cannot** be submitted by email. You must send it by US Mail or common carrier to the address below.

Alabama State Board of Pharmacy
111 Village Street
Birmingham, AL 35242

W: Alabama Permti#195965

From: Kim Pickett kpickett@albop.com
To: Roxanne Estela ROXANNE.ESTELA@elancoah.com
Date: Friday, January 8, 4:21 PM
Alabama Permit#195965.eml 226 KB
Revised Renewal Statement.docx 32 KB

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

he attached renewal deficiency email was sent to you on 1/4/2021. To date our office has not received the equired response. Permit#195965 expired on 12/31/2020 along with the renewal deficiency response you must omplete and submit the attached renewal statement.

hanks,

Kim Pickett
acilities Licensing Manager
labama State Board of Pharmacy
11 Village Street
irmingham, AL 35242
ax:205-803-6515
ww.albop.com

From: Roxanne Estela ROXANNE.ESTELA@elancoah.com
To: Kim Pickett kpickett@albop.com
Date: Friday, January 8, 4:38 PM

Hi Kim,

ust sent it off in the mail today it will arrive Monday.

est,

oxanne

oxanne Estela (she/her/hers)
dvisor, Licenses and Permits
orth American Regulatory Affairs, Commercial Products
lanco US Inc.
500 Innovation Way, Greenfield, IN 46140 USA
l +1 317.220.2913
stela_Roxanne_P@elanco.com
ww.elanco.com



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\sk me about how you can get involved in the Clothe-A-Child Feed-A-Family.

From: Roxanne Estela ROXANNE.ESTELA@elancoah.com
To: Kim Pickett kpickett@albop.com
Date: Friday, January 8, 5:21 PM
Renewal 12809 Shawnee - License #196965.pdf 1.5 MB

Kim,

As you can see in the attached email I also provided this information to you before the license expired via email stating I made a mistake in the online application.

Since this information was provided to the board before the license expired and before the deficiency notice was sent do you need the renewal statement?

oxanne

oxanne Estela (she/her/hers)
dvisor, Licenses and Permits
orth American Regulatory Affairs, Commercial Products
lanco US Inc.
500 Innovation Way, Greenfield, IN 46140 USA
l +1 317.220.2913
stela_Roxanne_P@elanco.com
ww.elanco.com



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Please consider the environment before printing this email

\sk me about how you can get involved in the Clothe-A-Child Feed-A-Family.

From: Kim Pickett kpickett@albop.com
To: Roxanne Estela ROXANNE.ESTELA@elancoah.com
Date: Monday, January 11, 12:00 PM

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

Not matter when you submitted the documents the renewal is not complete until it is reviewed and approved. This is why we open the renewal season on September 1, to allow adequate processing and review time. Your permit expired on 12/31/2020. The renewal has not been approved because the submission was incomplete. You need to submit the renewal statement and the items requested in the deficiency notice.

Thanks,
Kim Pickett

From: Roxanne Estela ROXANNE.ESTELA@elancoah.com
To: Kim Pickett kpickett@albop.com
Date: Monday, January 11, 4:58 PM

li Kim,

am working getting signatures for the renewal statement. The deficiency paperwork was delivered today at am.
n the meantime we have stopped shipments in to Alabama until you are able to process our registration.

Can you give us an idea of the application processing time once you have our renewal statement?

Thank you,

Roxanne

Roxanne Estela (she/her/hers)
Advisor, Licenses and Permits
North American Regulatory Affairs, Commercial Products
Elanco US Inc.
2500 Innovation Way, Greenfield, IN 46140 USA
M +1 317.220.2913
Estela_Roxanne_P@elanco.com
www.elanco.com

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Please consider the environment before printing this email

sk me about how you can get involved in the Clothe-A-Child Feed-A-Family.

From: Kim Pickett kpickett@albop.com
To: Roxanne Estela ROXANNE.ESTELA@elancoah.com
Date: Monday, January 11, 5:09 PM

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

-10 business days

hanks,
Kim Pickett

From: Roxanne Estela ROXANNE.ESTELA@elancoah.com
To: Kim Pickett kpickett@albop.com
Date: Monday, January 11, 5:24 PM

Thank you.

From: Roxanne Estela ROXANNE.ESTELA@elancoah.com
To: FERNANDO BERTAZZO FERNANDO.BERTAZZO@elancoah.com, GREGORY BUSSING GREGORY.BUSSING@elancoah.com
Date: Monday, January 11, 5:25 PM

Hello Greg and Fernando,

Please see the below email where Alabama confirms that processing will take 7-10 business days.

hank you,

.oxanne

Emails

To Whom it May Concern:

We received a violation in Florida in December 2020 for a fine we received in Idaho two years prior when Idaho changed their interpretation of the law. We notified Florida of this violation every year we renewed. We monitor all state laws using Porizo Compliance Digest to ensure we are registered correctly.

Sincerely,

Roxanne P. Estela

Roxanne Estela
Advisor, State Licensing and Permits
North American Commercial Product Regulatory
Elanco US Inc.
2500 Innovation Way, Greenfield, IN 46140 USA
M +[redacted]
Roxanne.Estela@Elancoah.com

FILED
Department of Business and Professional Regulation
Senior Deputy Agency Clerk
CLERK Brandon Nichols
Date 1/7/2021
File # 2021-00019

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

v. **Case Nos.: 2019-055050**

ELANCO US, INC.,

Respondent.
_____/

FINAL ORDER

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (Department), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Elanco US, Inc. and the Department, attached hereto and incorporated by reference. This Final Order resolves alleged violation of Section 499.0121(10), Florida Statutes (2018), failing to operate in compliance with applicable federal, state, and local laws and regulations.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department of Business & Professional Regulation as indicated on this Final Order.

DONE and ORDERED this 29th day of December, 2020 in Tallahassee, Florida.

HALSEY BESHEARS, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____
Walter Copeland
Division Director
Drugs, Devices, and Cosmetics

Prepared by:

Kathryn H. Price
DDC Chief Attorney
Division of Drugs, Devices, and Cosmetics

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the Notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by regular United States mail to: Elanco US, Inc., 2500 Innovation Way, Greenfield, Indiana 46140 this _____ day of December, 2020.

By: _____
Agency Clerk's Office

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

Case No.: 2019-055050

v.

ELANCO US, INC.,

Respondent.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (hereinafter, "this agreement") as disposition of the alleged violations described in the Notice of Violation in case number 2019-055050 (hereinafter, "the allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereinafter, "the Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. Elanco US, Inc. (hereinafter, "Respondent") is permitted as a non-resident prescription drug manufacturer by the Department, having been issued permit number 26:1837.

2. Respondent's address of record is 2500 Innovation Way, Greenfield, IN 46140.

3. Respondent was issued a Notice of Violation on December 4, 2020, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent, by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent neither admits nor denies the allegations in the Notice of Violation issued in case number 2019-055050, but enters into this agreement for the purpose of resolving the issues raised by the Department.

SETTLEMENT TERMS

6. Respondent affirms that it is currently in compliance with Chapter 499, Florida Statutes.

7. Respondent agrees to pay a settlement amount of five thousand dollars ($5,000.00). **Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047, Attention: Taya Orozco, Senior Legal Assistant**. Respondent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Respondent are absolute conditions precedent to the Department's execution of this agreement.

8. The acceptance of this agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes and Rule 61N-1.024, Florida Administrative Code.

STANDARD PROVISIONS

9. It is expressly understood that a violation of the terms of this agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

10. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. **The final order shall operate to close case number 2019-055050. The final order shall be the final disposition in this proceeding and shall constitute final agency action with respect thereto.**

11. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this agreement and the final order in which this agreement is incorporated, provided the final order does not conflict with this agreement.

12. Respondent waives the right to seek any attorney's fees or costs from the Department in connection with this proceeding.

13. This agreement may be executed in any number of counterparts including, without limitation, telecopies and facsimile transmission copies, all of which together shall constitute a single document.

14. The parties agree that this agreement represents a fair, appropriate, and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

15. The terms and provisions of this agreement are severable and, if any term or provision is declared or deemed void, invalid, illegal, or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

16. It is expressly understood that this agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts this agreement and adopts it in a final order.

17. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals and, as duly designated representatives, to fully bind such

principals.

ELANCO US, INC.,

By: Roxanne P. Estela

Name: Roxanne P. Estela

Title: Advisor, State Licenses

Date: 12/21/2020

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION DIVISION OF DRUGS, DEVICES, AND COSMETICS,

By: Walter Copeland

Name: Walter Copeland

Title: Division Director

Date: 12.29.2020

Prepared by:

Kathryn E. Price
DDC Chief Attorney
Division of Drugs, Devices, and Cosmetics

To Whom It May Concern:

In July 2016, the Ohio State Board of Pharmacy changed its laws regarding Virtual Wholesalers and Virtual Manufacturers requiring either a VAWD Accreditation or a home state license. In Indiana, no home state license is required for veterinary wholesalers or manufacturers. Elanco was in the process of changing over Novartis Animal Health US Inc. applications to Elanco US Inc. after the acquisition. Since Novartis Animal Health US Inc. never held a license in Ohio Elanco US Inc. did not get a grace period to comply with these new laws. Elanco US Inc. stopped sales into Ohio for 6 months. Elanco petitioned the Indiana Board of Pharmacy after submitting our VAWD application and an Indiana license was granted. We are now licensed to sell in Ohio.

Please let me know if you have any further questions.

Sincerely,

Roxanne P Estela

Roxanne Estela
Sr. Regulatory Associate
Elanco US Inc.
[redacted]
Estela_Roxanne_P@Elanco.com

Steven W. Schierholt, Esq.
Executive Director

John R. Kasich
Governor

STATE OF OHIO BOARD OF PHARMACY

October 21, 2016

Elanco Animal Health
ATTN: Roxanne Estela
PO Box 708
Greenfield, IN 46140

Re: Application for Virtual Wholesale Distributor of Dangerous Drugs Licensing

Ms. Estela,

We are in receipt of your application for an Ohio Wholesale Distributor of Dangerous Drugs license as a Virtual Manufacturer/Broker. Your application is incomplete because you have not submitted your state license verification where the facility is physically located and/or proof of Verified-Accredited Wholesale Distributors (VAWD) accreditation pursuant to rule 4729-9-28 of the Ohio Administrative Code.

The State of Ohio Board of Pharmacy recognizes that virtual distributors/brokers do not store drugs onsite; however, virtual distributors/brokers are responsible for proper record keeping of wholesale transactions and for ensuring that the dangerous drugs are legitimate, FDA approved drugs. Therefore, the wholesale distributor of dangerous drugs shall possess a current, valid license in the state in which they are physically located and must be in good standing. If the home state does not license virtual wholesale distributors/brokers, one of the requirements for Ohio licensure is that the facility must obtain/maintain VAWD accreditation from the National Association of Boards of Pharmacy (NABP).

Please resubmit your application with your home state license verification or VAWD accreditation with a copy of this letter within thirty (30) days. If the requested documents are not received within this time frame, the application will be considered abandoned and the application fee forfeited.

We appreciate your concern regarding this matter. If you need any additional assistance or have any additional questions, please do not hesitate to contact me directly.

Thank you,

Chandra Galante, RPh

Chandra Galante, RPh
Director of Licensing
State of Ohio Board of Pharmacy

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Facility Name: Independent Pharmacy Distributor, LLC DBA MFG TPL

Physical Address: 518 Old Thomasville Road

City: High Point State: NC Zip: 27260

Mailing Address (if different from physical address): Same

City: _____ State: _____ Zip: _____

Telephone: 336-296-1444 Website: www.mfgtpl.com

Name of Designated Representative (DR): Amanda Fleming

Licensing Company Email: licensing@ipdpharma.com DR Email: afleming@mfgtpl.com

■ Pharmacies ■ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	☐ Dangerous Drugs ■ Controlled Substances ☐ [a]Medical devices, equipment, supplies, gases ■ Others: Legend Pharmaceuticals	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ■ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Name: Home Aide Diagnostics, Inc.

Address: 1072 South Powerline Road City: Deerfield Beach State: FL Zip: 33442

Name:

Address: City: State: Zip:

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

State of Incorporation/Organization: NC

Parent Company (if any):

Corporation/Organization Name: Independent Pharmacy Distributor, LLC DBA MFG TPL

Mailing Address: 518 Old Thomasville Road

City: High Point State: NC Zip: 27260

Telephone: 336-296-1444 Email: afleming@mfgtpl.com

Contact Person Name: Amanda Fleming

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: Applied For		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Independent Pharmacy Distributor, LLC DBA MFG TPL
Facility Name

Russell Warren Patterson
Print Name of Authorized Person Submitting Application

Russell Patterson
Original signature of Authorized Person (copies or stamps not accepted)

6/14/23
Date

Board Use Only	Date Received: 7/26/23	Amount: 1000 -CK -1006

Corporate Officers

Russell Warren Patterson
President
DOB - [redacted]
[redacted] West Market Center Drive
High Point, NC 27260

Amanda Simerson Fleming
General Manager
DOB – [redacted]
[redacted] Old Thomasville Road
High Point, NC 27260

100% Owner

Russell Warren Patterson
President
DOB - [redacted]
[redacted] West Market Center Drive
High Point, NC 27260

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF EXISTENCE
(Limited Liability Company)

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

INDEPENDENT PHARMACY DISTRIBUTOR, LLC

is a limited liability company duly formed, and existing under the laws of the State of North Carolina, having been formed on 15th day of July, 2015

I FURTHER certify that, as of the date of this certificate, (i) the said limited liability company is not dissolved under the terms of its articles of organization, (ii) the said limited liability company's articles of organization are not suspended for failure to comply with the Revenue Act of the State of North Carolina, (iii) that said limited liability company is not administratively dissolved for failure to comply with the provisions of the North Carolina Limited Liability Company Act, (iv) that this office has not filed any decree of judicial dissolution, articles of dissolution, articles of merger, or articles of conversion for said limited liability company.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 23rd day of June, 2023.

Elaine F. Marshall

Secretary of State

Scan to verify online.

Certification# 117186233-1 Reference# 20258524- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

BK: R 8612
PG: 1977-1977
RECORDED:
05-05-2022
04:17:04 PM
BY: MARY MORGAN
DEPUTY-HP

2022029517
GUILFORD COUNTY, NC
JEFF L. THIGPEN
REGISTER OF DEEDS

NC FEE $26 00

ASSUMED BUSINESS NAME CERTIFICATE (NCGS §66-71.5)

Please print legibly.

1. The assumed business name is:
   MFG TPL

   (You may include no more than five (5) assumed business names on this form.)

2. The real name of the person or entity engaging in business under the assumed business name is:
   Independent Pharmacy Distributor, LLC
   1458071

   (Corporations, LLC's, limited partnerships must provide the exact name registered with the NC Secretary of State's office and the SOSID number assigned at the time of formation. Go to www.sosnc.gov/br/search to look up your information.)

3. The nature/type of the business is: Third Party Logistics/Wholesale Drug Distributor

4. The street address of the principal place of business is: (PO Boxes are not acceptable)
   Return to: 1107 West Market Center Drive, High Point, NC 27260

5. The mailing address, if different from the street address, is:
   518 Old Thomasville Road, High Point, NC 27260

6. The counties where the assumed business name will be used to engage in business are:
   ■ All 100 North Carolina counties

This certificate is signed by the owner/legal representative of the person or entity named above, this 26 day of April, 2022.

Signature: Russell Patt

Printed/Typed Name: Russell Patterson

Title: President

(See instructions for who must sign for various business entity types.)

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF EXISTENCE
(Limited Liability Company)

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

INDEPENDENT PHARMACY DISTRIBUTOR, LLC

is a limited liability company duly formed, and existing under the laws of the State of North Carolina, having been formed on 15th day of July, 2015

I FURTHER certify that, as of the date of this certificate, (i) the said limited liability company is not dissolved under the terms of its articles of organization, (ii) the said limited liability company's articles of organization are not suspended for failure to comply with the Revenue Act of the State of North Carolina, (iii) that said limited liability company is not administratively dissolved for failure to comply with the provisions of the North Carolina Limited Liability Company Act, (iv) that this office has not filed any decree of judicial dissolution, articles of dissolution, articles of merger, or articles of conversion for said limited liability company.

Scan to verify online.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 23rd day of June, 2023.

Elaine F. Marshall

Secretary of State

Certification# 117186233-1 Reference# 20258524- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

1927

2023

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
557

LICENSE/CERTIFICATE: Distributor

TYPE PRESCRIPTION DRUG LICENSE

Expiration Date 12/31/2023

LICENSEE OR CERTIFICATOR

INDEPENDENT PHARMACY DISTRIBUTOR LLC DBA
MFG TPL
518 OLD THOMASVILLE ROAD
HIGH POINT NC 27260

LICENSED 2023 NORTH CAROLINA

Steven W. Troxler

STEVE TROXLER, COMMISSIONER

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

NORTH CAROLINA CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE

Department of Health and Human Services
Raleigh, North Carolina

THE N.C. Controlled Substances Act of 1971 reads in part as follows:

90-103(a): A registration under G.S. 90-102 to manufacture, distribute, or dispense a controlled substance, may be suspended or revoked by the Commission upon a finding that the registrant:

(1) has furnished false or fraudulent information in any application filed under this Article;

(2) has been convicted of a felony under any State or federal law relating to any controlled substance; or

(3) has had his federal registration suspended or revoked to manufacure, distribute or dispose controlled substances.

DHHS Registration Number		This Registration Expires
NC-DHHS-1003968		10/31/2023
Schedules	**Business Activity**	**Date Issued**
2, 2N, 3, 3N, 4, 5	Distributor	8/29/2022

Form DHHS-222

Department of Health and Human Services

Independent Pharmacy Distributor, LLC DBA MFG TPL

518 Old Thomasville Road
High Point NC 27260

This registration is not transferable on change of ownership, control, location or business activity

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RI0634128	11-30-2023	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	09-19-2022

INDEPENDENT PHARMACY DISTRIBUTOR, LLC
MFG TPL
518 OLD THOMASVILLE RD
HIGH POINT, NC 272608431

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RI0634128	11-30-2023	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	09-19-2022

INDEPENDENT PHARMACY DISTRIBUTOR, LLC
MFG TPL
518 OLD THOMASVILLE RD
HIGH POINT, NC 272608431

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RI0634128	11-30-2023	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	09-19-2022

INDEPENDENT PHARMACY DISTRIBUTOR, LLC
MFG TPL
518 OLD THOMASVILLE RD
HIGH POINT, NC 272608431

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

**This bond replaces and supersedes any and all bonds with LEXINGTON NATIONAL INSURANCE CORPORATION bond number L265860-2113 **

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. L265860-2113

Application/License No. _____

Independent Pharmacy Distributor LLC dba MFG TPL (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 518 Old Thomasville Road, High Point, NC 27260 (Address of Applicant/Principal), as PRINCIPAL, and LEXINGTON NATIONAL INSURANCE CORPORATION (Surety Company), a corporation organized under the laws of the state of Florida (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is P.O. BOX 6098, LUTHERVILLE, MD 21094 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 06/20/2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of June, 2023.

APPLICANT/PRINCIPAL

COMPANY

Russell Pitt
Authorized Representative

SURETY

Surety Company's Representative

Jeremy Crawford, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Amanda Fleming
Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent Jeremy Crawford

Posted February 20, 2020

IMPORTANT NOTICE – THIS POWER OF ATTORNEY IS VOID IF "LNIC Original" WATERMARK IS NOT PRESENT

POWER OF ATTORNEY
Lexington National Insurance Corporation

Lexington National Insurance Corporation, a corporation duly organized under the laws of the State of Florida and having its principal administrative office in Baltimore County, Maryland, does hereby make, constitute and appoint:

Jeremy Crawford, Michael Williams, Michelle Anderson, Allison Lemke

as its true and lawful attorney-in-fact, each in their separate capacity, with full power and authority to execute, acknowledge, seal and deliver on its behalf as surety any bond or undertaking of $1,500,000 or less. This Power of Attorney is void if used for any bond over that amount.

This Power of Attorney is granted under and by authority of the following resolutions adopted by the Board of Directors of the Company on February 15, 2018:

Be it Resolved, that the President or any Vice-President shall be and is hereby vested with full power and authority to appoint suitable persons as Attorney-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and on the behalf of the Company, to execute, acknowledge and deliver any and all bonds, contracts, or indemnity and other conditional or obligatory undertakings, including any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts, and any all notices and documents cancelling or terminating the Company's liability thereunder and any such instruments so executed by any Attorney-in Fact shall be binding upon the Company as if signed by the President and sealed by the Corporate Secretary.

RESOLVED further, that the signature of the President or any Vice-President of LEXINGTON NATIONAL INSURANCE CORPORATION may be affixed by facsimile to any power of attorney, and the signature of the Secretary or any Assistant Secretary and the seal of the Company may be affixed by facsimile to any certificate of such power, or any such power or certificate bearing such facsimile signature or seal shall be valid and binding on the Company. Any such power so executed and sealed and certified by certificate so executed and sealed with respect to any bond to which it is attached continue to be valid and binding upon the Company.

IN WITNESS WHEREOF, the Company have caused this instrument to be signed and their corporate seal to be hereto affixed.

LEXINGTON NATIONAL INSURANCE CORP INCORPORATED 1989 FLORIDA

Ronald A. Frank, President

State of Maryland
County of Harford County, SS:

Before me, a notary public, personally appeared, Ronald A. Frank, President of Lexington National Insurance Corporation, who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under the PENALTY of PERJURY under the laws of the State of Maryland that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Commission Expires: 05/23/24

Notary

ALYSSA BARNES NOTARY PUBLIC HARFORD COUNTY MD

I, Lisa R. Slater, Secretary of Lexington National Insurance Corporation, do hereby certify that the above and foregoing is true and correct copy of a Power of Attorney, executed by said company, which is still in full force and effect; furthermore, the resolutions of the Boards of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said Company at Baltimore, Maryland this 26th day of June, 2023

Corporate Seal: LEXINGTON NATIONAL INSURANCE CORP INCORPORATED 1989 FLORIDA

Lisa R. Slater, Secretary

F:\Unic\Power of Attorney form CS 2021 with Watermark Seal

Acknowledgment of Surety

State of Minnesota
County of Ramsey

On this 26th day of June, 2023 before me personally appeared **Jeremy Crawford** who acknowledged that he or she is the attorney in fact who is authorized to sign on behalf of **Lexington National Insurance Corporation** (surety company), the foregoing instrument, and he thereupon duly acknowledged to me that he executed the same.

Madelyn Van Hollen
Notary Public

MADELYN ROSE VAN HOLLEN
Notary Public-Minnesota
My Commission Expires Jan. 31, 2027

AMANDA FLEMING

[redacted]Horseshoe Neck Road [redacted]
afleming@mfgtpl.com

EXPERIENCE

MARCH 2022 – PRESENT

GENERAL MANAGER/DESIGNATED REPRESENTATIVE, MFG TPL

Oversee and manage all operations, performance and development of the business including: budget planning, licensing, compliance, and staff training.

JUNE 2021 – MARCH 2022

CHIEF OPERATIONS OFFICER, PRESIDENTIAL LIFE INSURANCE COMPANY

Designed and implemented a Medicare Prescription Drug Plan to include: plan benefits and formulary design, Medication Therapy Maintenance (MTM) program design and maintenance, Fraud, Waste and Abuse Program, Call Center operations, verification of pharmacy credentials, beneficiary eligibility verification, setup connectivity between CMS and Third Party Administrator, credentialed Medicare agents, implemented policies and procedures established by Federal programs, developed and implemented training programs, managed federal contracts and relationships, supervised customer service functions, ensured timely reporting requirements were met

JANUARY 2019– JUNE 2021

CHIEF EXECUTIVE OFFICER, EXEMPLAR, THE HEALTHCARE PARTNERSHIP ORGANIZATION

Maintained and grew partnerships between pharmacies, insurance agents, providers and insurance companies to include over 7000 partners. Developed and implemented policies and procedures and training programs.

AUGUST 2009-JANUARY 2019

MANAGER, PHARMACY MANAGEMENT COMPANY

District Manager- Responsible for the financial growth of seven pharmacies. Maintained Human Resources Department, Payroll Department and managed 50+ associates. Developed and maintained training programs. Managed inventory, pricing and purchasing.

Lead Pharmacy Technician- Responsible for the growth and success of the pharmacy. Trained and lead staff, ensured proper inventory maintenance, maintained customer relationships and production standards.

Certified Pharmacy Technician- Responsible for processing prescriptions, accurate prescription filling, maintain patient profiles, mastered customer service relationships, maintained proper recordkeeping.

Inventory Purchaser- Reduced inventory cost, maintained adequate inventory, and established and retained relationships with drug wholesale representatives.

EDUCATION

2008

BACHELOR OF SCIENCE IN CRIMINAL JUSTICE, APPALACHIAN STATE UNIVERSITY

LICENSES

- Certified Pharmacy Technician
- Licensed Insurance Agent

AMANDA FLEMING

[redacted] Horseshoe Neck Road · [redacted]
afleming@mfgtpl.com

EXPERIENCE

MARCH 2022 – PRESENT

GENERAL MANAGER/DESIGNATED REPRESENTATIVE, MFG TPL

Oversee and manage all operations, performance and development of the business including: budget planning, licensing, compliance, and staff training.

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JANUARY 2019– JUNE 2021

CHIEF EXECUTIVE OFFICER, EXEMPLAR, THE HEALTHCARE PARTNERSHIP ORGANIZATION

Maintained and grew partnerships between pharmacies, insurance agents, providers and insurance companies to include over 7000 partners. Developed and implemented policies and procedures and training programs.

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MANAGER, PHARMACY MANAGEMENT COMPANY

District Manager- Responsible for the financial growth of seven pharmacies. Maintained Human Resources Department, Payroll Department and managed 50+ associates. Developed and maintained training programs. Managed inventory, pricing and purchasing.

Lead Pharmacy Technician- Responsible for the growth and success of the pharmacy. Trained and lead staff, ensured proper inventory maintenance, maintained customer relationships and production standards.

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Inventory Purchaser- Reduced inventory cost, maintained adequate inventory, and established and retained relationships with drug wholesale representatives.

EDUCATION

2008

BACHELOR OF SCIENCE IN CRIMINAL JUSTICE, APPALACHIAN STATE UNIVERSITY

LICENSES

- Certified Pharmacy Technician
- Licensed Insurance Agent

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler INDEPENDENT PHARMACY DISTRIBUTOR, LLC DBA MFG TPL

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 518 OLD THOMASVILLE ROAD

City HIGH POINT State NC Zip 27260

Mailing Address (if different from physical address) N/A

City _____ State _____ Zip _____

Telephone 336-296-1444 Website _____

Licensing Company Email LICENSING@IPDPHARMA.COM

Section 2: Personal Information

First AMANDA Middle SIMERSON Last FLEMING

Alias(es, nicknames, name changes, etc.) AMANDA JEANETTE SIMERSON

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address [redacted]HORSESHOE NECK ROAD

City LEXINGTON State NC Zip 27295

Telephone [redacted] Email AFLEMING@MFGTPL.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
APPALACHIAN STATE UNIVERSITY		08/05-12/08	
Address	City	State	Zip
287 RIVERS STREET	BOONE	NC	28608
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE IN CRIMINAL JUSTICE			

School Name		From - To (MM/YY – MM/YY)	
WEST DAVIDSON HIGH SCHOOL		08/00-05/04	
Address	City	State	Zip
200 DRAGON DRIVE	LEXINGTON	NC	27295
Diploma/Degree obtained, if any			
DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/86-05/23	[redacted]HORSESHOE NECK ROAD	LEXINGTON	NC	27295
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
MFG TPL			03/22-PRESENT	
Business Address		City	State	Zip
518 OLD THOMASVILLE ROAD		HIGH POINT	NC	27260
Phone	Title		Number of Employed Hours	
336-296-1444	GENERAL MANAGER/DESIGNATED REP		2400 ,	
Description of Duties				
SEE ATTACHED				

Business Name			From - To (MM/YY – MM/YY)	
INDEPENDENT PHARMACY DISTRIBUTOR, LLC			12/22-03/22	
Business Address		City	State	Zip
1107 W. MARKET CENTER DRIVE		HIGH POINT	NC	27260
Phone	Title		Number of Employed Hours	
336-817-6794	OPERATIONAL EFFICIENCY MANAGER		480 ,	
Description of Duties				
REVIEWED POLICIES AND PROCEDURES TO DEVELOP TRAINING PLANS FOR ALL ASSOCIATES.				

Business Name			From - To (MM/YY – MM/YY)	
PRESIDENTIAL LIFE INSURANCE COMPANY			06/20-12/22	
Business Address		City	State	Zip
1107 W. MARKET CENTER DR		HIGH POINT	NC	27260
Phone	Title		Number of Employed Hours	
3362961444	CHIEF OPERATIONS OFFICER		5200 ,	
Description of Duties				
IMPLEMENTATION OF POLICIES AND PROCEDURES ESTABLISHED BY FEDERAL PROGRAMS, DEVELOPED AND IMPLEMENTED TRAINING PROGRAMS, MANAGED FEDERAL CONTRACTS AND RELATIONSHIPS				

Business Name			From - To (MM/YY – MM/YY)	
EXEMPLAR, THE HEALTHCARE PARTNERSHIP ORGANIZATION			01/20-06/20	
Business Address		City	State	Zip
1107 W. MARKET CENTER DRIVE		HIGH POINT	NC	27260
Phone	Title		Number of Employed Hours	
3362961444	CHIEF EXECUTIVE OFFICER		800 ,	
Description of Duties				
MAINTAINED AND GREW PARTNERSHIPS BETWEEN PHARMACIES, INSURANCE AGENTS, PROVIDERS AND INSURANCE COMPANIES TO INCLUDE OVER 7000 PARTNERS. DEVELOPED AND IMPLEMENTED P&P AND TRAI				

Business Name			From - To (MM/YY – MM/YY)	
PHARMACY MANAGEMENT COMPANY			08/09-01/20	
Business Address		City	State	Zip
1107 W. MARKET CENTER DRIVE		HIGH POINT	NC	27260
Phone	Title		Number of Employed Hours	
336-817-6794	DISTRICT MANAGER		21440 ,	
Description of Duties				
RESPONSIBLE FOR THE FINANCIAL GROWTH OF 7 PHARMACIES. MAINTAINED HR DEPT, PAYROLL DEPT, AND 50+ ASSOC. DEVELOPED,MAINTAINED TRAINING PROGRAMS,MANAGED INVENTORY, PRICING, PURCHAS				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, AMANDA SIMERSON FLEMING, **certify that as the designated representative for**

INDEPENDENT PHARMACY DISTRIBUTOR, LLC DBA MFG TPL,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AF I am at least 21 years of age;
3. AF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

AMANDA FLEMING

Print Name (First, Last)

Amanda Fleming

Original Signature (electronic, copies or stamps not accepted)

5/12/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

AMANDA FLEMING

Print Name (First, Last)

Amanda Fleming

Original Signature (electronic, copies or stamps not accepted)

5/12/2023

Date

Please have this section completed in the presence of a Notary Public.

State of NC, ss. County of Guilford

I, Amanda Fleming, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Amanda Fleming

Original Signature

5/12/23

Date

Subscribed and Sworn to before me this 12 day of May, 2023.

P Renee Robbins

Notary Public Signature

P. RENEE ROBBINS
Notary Public - North Carolina
Randolph County
My Commission Expires Nov 11, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

100% Owner

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: INDEPENDENT PHARMACY DISTRIBUTOR, LLC DBA MFG TPL

Pharmacy/MDEG/Wholesaler License # (if applicable): N/A

Physical Address: 518 OLD THOMASVILLE ROAD

City: HIGH POINT State: NC Zip: 27260

Mailing Address (if different from physical address): SAME

City: N/A State: N/A Zip: N/A

Telephone: 336-296-1444 Website: WWW.MFGTPL.COM

Licensing Company Email: LICENSING@IPDPHARMA.COM

Section 2: Personal Information

First: RUSSELL Middle: WARREN Last: PATTERSON

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] SALEM GLEN BLVD

City: CLEMMONS State: NC Zip: 27012

Telephone: [redacted] Email: RPATTERSON@MFGTPL.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
SEE ATTACHED RESUME			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/08-PRESENT	[redacted]SALEM GLEN BLVD	CLEMMONS	NC	27012
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SEE ATTACHED RESUME			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

RUSSELL PATTERSON

Print Name (First, Last)

Russell Patt

Original Signature (electronic, copies or stamps not accepted)

5/12/2023

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Guilford

I, Russell Patterson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Russell Patt

Original Signature

05-24-2023

Date

Subscribed and Sworn to before me this 24 day of May 2023

Lindsay Bess

Notary Public Signature

LINDSAY BESS
NOTARY
My Commission Expires
3-11-2025
PUBLIC
DAVIDSON COUNTY, NC

(Seal)

Russell Warren Patterson
Curriculum Vita

Education

Pharm D.	2003, Doctor of Pharmacy, Auburn University – Auburn, Alabama Graduated, Magna Cum Ladue
M.S.	1994, Material Science Engineering, Auburn University – Auburn, Alabama Graduated, Magna Cum Ladue
B.S.	1992, Applied Physics, Auburn University – Auburn, Alabama Graduated, Cum Ladue

Russell Patterson Pharm D.,

- 2009 – Present **Clinical Director and Business Owner**
    - Independent Pharmacy Owner – 9 Stores (Tyro Family Pharmacy, Monroe Family Pharmacy, Thomasville Family Pharmacy, South Park Family Pharmacy, Lexington Family Pharmacy, Greensboro Family Pharmacy, High Point Family Pharmacy, Family Pharmacy of NC, Lexington Drug)
        - Eight Pharmacies selected for Community Care of North Carolina's (CCNC) Community Pharmacy Enhanced Services Network Program (CPESN)
    - Pharmacy Management Company (PMC) – Owner
        - PMC manages Independent Pharmacies in 8 states.
        - PMC offers management in all areas of Independent Pharmacy including inventory management, auditing, purchasing, process development and clinical management.
    - Carolina Clinical Health Services (CCHS) - Clinical Director and Owner
        - CCHS is a Medical Service Organization.
        - CCHS manages all aspects of Physician Clinics from Credentialing, Contracting, Billing, Billing Optimization, Accreditation and Quality Metrics.
        - CCHS manages Physician Clinics in 8 states.
    - Independent Pharmacy Distributor (IPD) – Owner/Manager/Compliance Officer
        - Responsibilities Include: Management of all departments from Inventory, recording keeping, Warehouse operations, Shipping, Receiving, Storage and compliance from the start of the company (2015) to present. Personally oversee policy and procedure development and training of personnel.
        - IPD is VAWD accredited wholesale drug distribution company.
        - Licensed in 48 States.
        - Direct Authorized Distributor for 68 Manufactures.
        - Over 4000 Pharmacies nationwide.
    - Family Primary Care – Owner

        - Primary Care clinical Practice
    - National Insurance Associates (NIA) – Owner
        - NIA is a Insurance Marketing Organization.
        - NIA focused on group health Insurance.
        - Distribution on national scale with brokers and captive agents.
    - ProRxSolutions – Owner
        - ProRxSolutions is a Pharmacy Benefits Management Company.
        - National presence contracted with 67,000 pharmacies nationwide.
    - Exemplar Network – Owner
        - Network of 23,000 Independent Pharmacy Owners
        - Network of 76,000 Independent Physicians.
        - Development of Exemplar's five core business elements:
            - Pharmacy Management Services
            - Physician Clinical Management Services
            - Pharmacy Benefits Management
            - Health Insurance
                - Health Benefits Administrator
            - Sourcing/Wholesale Services
    - Exemplar Health Benefits Administrator (EHBA) – Owner
        - EHBA is a Third Party Administrator.

- 2003 – 2009 **Walmart Pharmacies**, NC
    - Pharmacy Manager
    - District Manager

- 1997 – 1999 **Process Engineer, Siecor, Hickory, NC**

- 1987 - 1997 **Army Officer, United States Army**

- Professional Credentials and Certifications
  State of North Carolina Pharmacist License (current)

MFG TPL

MFG TPL Company Employee List

Name	Title	Address	Telephone	Email
Russell Warren Patterson	Owner/President	[redacted] Salem Glen Blvd, Clemmons NC 27012	[redacted]	rpatterson@mfgtpl.com
Melody Davis Patterson	Supervisor of the Designated Representative	[redacted] Salem Glen Blvd, Clemmons NC 27012		mpatterson@mfgtpl.com
Amanda Simerson Fleming	General Manager & Designated Representative	[redacted] Horseshoe Neck Road, Lexington, NC 27295		afleming@mfgtpl.com

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: MR Unlimited LLC

Physical Address: 2505 Stone Hollow Dr Ste 300

City: Brenham State: TX Zip: 77833

Mailing Address (if different from physical address): same as physical

City: _____ State: _____ Zip: _____

Telephone: 979-921-6141 Website: _____

Name of Designated Representative (DR): Darryl W. McNabb

Licensing Company Email: darryl.mcnabb@mrunlimitedllc.com DR Email: darryl.mcnabb@mrunlimitedllc.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Pharmaceuticals

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Smart Source (AmeriSource Bergen)
Address: PO Box 978740 City: Dallas State: TX Zip: 75397

Name: McKesson Medical Surgical
Address: PO Box 933027 City: Atlanta State: GA Zip: 31193

Name: Anda, Inc
Address: PO Box 930219 City: Atlanta State: GA Zip: 31193

Name: Medline Industries, Inc
Address: PO Box 121800 City: Dallas State: TX Zip: 75312

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: Darryl W. McNabb
Business Name: MR Unlimited, LLC
Business Address: 2505 Stone Hollow Dr Ste 300
City: Brenham State: TX Zip: 77833
Telephone: 979-921-6141 Email: darryl.mcnabb@mrunlimitedllc.com

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

MR Unlimited, LLC

Facility Name

Darryl W. Merlob

~~Print~~ Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

06/21/2023

Date

Board Use Only	Date Received: 7/7/23	Amount: 1000.00 CK. 8845

MR Unlimited, LLC Officer List

Darryl McNabb – Sole Owner

No other officers to provide.

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for MR UNLIMITED, LLC (file number 801149069), a Domestic Limited Liability Company (LLC), was filed in this office on July 21, 2009.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on June 23, 2023.

Jane Nelson
Secretary of State

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

MR UNLIMITED LLC
2505 STONE HOLLOW DR STE 300
BRENHAM TX 77833

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

MR UNLIMITED LLC
2505 STONE HOLLOW DR STE 300
BRENHAM, TX 77833

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1000185
Expires: May 25, 2025

NON-TRANSFERABLE

Commissioner

516910

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: MR Unlimitied LLC

Address: 2505 Stone Hollow Dr, Suite 300

City: Brenham State: TX Zip: 77833

I hereby authorize the Texas Dept of State Health Services to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant _____

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
1000185	Current	10/19/2021	05/25/2023

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☒ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☒ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☒ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☒ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☒ Yes ☐ No

Signature of State Official	Title	State	Date	State Seal
Justin Arnold	Medical Research Specialist	TX	04/12/2023	

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 5328091

Application/License No. _____

Mr. Unlimited, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2505 Stone Hollow, Suite 300 Brenham, TX 77833 (Address of Applicant/Principal), as PRINCIPAL, and SureTec Insurance Company (Surety Company), a corporation organized under the laws of the state of Texas (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 2103 CityWest Boulevard, Suite 1300 Houston, TX 77042 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 19, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

POA #: 5328091

SureTec Insurance Company
LIMITED POWER OF ATTORNEY

Know All Men by These Presents, That SURETEC INSURANCE COMPANY (the "Company"), a corporation duly organized and existing under the laws of the State of Texas, and having its principal office in Houston, Harris County, Texas, does by these presents make, constitute and appoint

Davor Mimica

its true and lawful Attorney-in-fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver any and all bonds, recognizances, undertakings or other instruments or contracts of suretyship to include waivers to the conditions of contracts and consents of surety for:

Principal: Mr. Unlimited, LLC
Obligee: Nevada State Board of Pharmacy
Amount: $ 100,000.00

and to bind the Company thereby as fully and to the same extent as if such bond were signed by the President, sealed with the corporate seal of the Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolutions of the Board of Directors of the SureTec Insurance Company:

Be it Resolved, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and of behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached. *(Adopted at a meeting held on 20th of April, 1999.)*

In Witness Whereof, SURETEC INSURANCE COMPANY has caused these presents to be signed by its President, and its corporate seal to be hereto affixed this 3rd day of February, A.D. 2023.

SURETEC INSURANCE COMPANY

By: _____
Michael C. Keimig, President

State of Texas ss:
County of Harris

On this 3rd day of February, A.D. 2023 before me personally came Michael C. Keimig, to me known, who, being by me duly swom, did depose and say, that he resides in Houston, Texas, that he is President of SURETEC INSURANCE COMPANY, the company described in and which executed the above instrument; that he knows the seal of said Company; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said Company; and that he signed his name thereto by like order.

TANYA SNEED
Notary Public State of Texas
Commission # 128571231
Commission Expires 03/30/2027

_____
Tanya Sneed, Notary Public
My commission expires March 30, 2027

I, M. Brent Beaty, Assistant Secretary of SURETEC INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Company, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

Given under my hand and the seal of said Company at Houston, Texas this 19th day of June, 2023, A.D.

_____
M. Brent Beaty, Assistant Secretary

Any instrument issued in excess of the penalty stated above is totally void and without any validity.
For verification of the authority of this power you may call (713) 812-0800 any business day between 8:30 am and 5:00 pm CST.

Bond No. 5328091

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 19th day of June, 2023.

APPLICANT/PRINCIPAL

Mr. Unlimited, LLC

Authorized Representative

SURETY COMPANY

SureTec Insurance Company

Surety Company's Representative

Davor Mimica, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident/Non-Res Agent
Davor Mimica

Posted February 20, 2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler MR Unlimited, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2505 Stone Hollow Dr Ste 300

City Brenham State Texas Zip 77833

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 979-921-6141 Website _____

Licensing Company Email darryl.mcnabb@mrunlimitedllc.com

Section 2: Personal Information

First Darryl Middle Wayne Last McNabb

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Addres[redacted] Possum Trot

City Brenham State Texas Zip 77833

Telephone [redacted] Email darryl.mcnabb@mrunlimitedllc.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
LeTourneau University, Houston Campus		09/94 – 12/96	
Address	City	State	Zip
P.O. Box 7668	Longview	TX	75607
Diploma/Degree obtained, if any			
BS in Business Management			

School Name		From - To (MM/YY – MM/YY)	
Prairie View A&M University		08/93 – 12/93	
Address	City	State	Zip
P.O. Box 2610	Prairie View	TX	77446
Diploma/Degree obtained, if any			
NA			

School Name		From - To (MM/YY – MM/YY)	
Anne Arundel Community College		09/88 – 12/90	
Address	City	State	Zip
101 College Parkway	Arnold	MD	21012
Diploma/Degree obtained, if any			
Associate of Arts in Architectural Design			

School Name		From - To (MM/YY – MM/YY)	
Glen Burnie High School		12/86 – 06/88	
Address	City	State	Zip
7550 B&A Blvd	Glen Burnie	Md	21060
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
N/A			
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/04 - Present	[redacted] Possum Trot	Brenham	TX	77833
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: MR Unlimited, LLC			From - To (MM/YY – MM/YY): 08/09 – Present
Business Address: 2505 Stone Hollow Drive, ste 300	City: Brenham	State: TX	Zip: 77833
Phone: 979-924-6141	Title: Owner/Operations Manager		Number of Employed Hours:
Description of Duties: See attached Resume' and Work History sheets. ~~XXX~~			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes*	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I, Darryl Wayne McNabb, **certify that as the designated representative for**

MR Unlimited, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DWM I am at least 21 years of age;
3. DWM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DWM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DWM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DWM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DWM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Darryl McNabb

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-5-2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Darryl McNabb
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2023-6-5
Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Washington

I, Darryl W McNabb, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/5/2023
Date

Subscribed and Sworn to before me this 5 day of June '23

Carrie L. Little
Notary Public Signature

CARRIE LYNN LITTLE
Notary Public, State of Texas
Comm. Expires 05-06-2025
Notary ID 1170226-8

XXXX 1979

DARRYL W. McNABB
[redacted]ossum Trot
Brenham, TX 77833
[redacted]

POBJECTIVE

Obtain a position of increasing responsibility that will allow me to use my learned skills from both civilian and military occupations; to facilitate the directives of the company and my department of assignment while making a significant contribution to the success of the organization.

SUMMARY

Experienced in Production; Scheduling; Procurement, Order Processing and Shipping; emphasizing in Administration, Supervisory and Financial Skills; Inventory Control with experience in QA/QC; Inspection Procedures. Legal Compliance; Strategic Planning; Leadership; Motivating Others; Persuasion; Supports Innovation; Problem Solving; Analyzing Information; Dealing with Complexity; Decision Making; Developing Budgets; Statistical Analysis; Presentation Skills; Information Security Policies.

QUALIFACTIONS

Business Operations and Material Management: Review purchase and sales history along with manufacture and industry released shortages to ensure availability of needed products. Develop and maintain business sourcing and procurement activities, to ensure coordination of strategic sourcing initiatives. Determine market conditions within the "Supply Chain" including primary and secondary procurement, including market forecasting, world events and sale trends. **Sales/Contracts:** Generate new sales leads in all available markets, Review customer requirements, including State and Federal Invitation for Bids (IFB's) to determine accuracy of required product and/or generic/alternate availability. Submit quotes and/or alternate item review for approval. **Marketing:** Create sales advertisements and establish a market presence within various industry buying groups, establishing a market edge, credibility and product diversity. **Accounting**: Reconciliation of business software regarding Purchase Orders, Invoices, Receivables, Collections, **Shipping**: Performed all aspects of Shipping/Receiving with local freight carriers. **Quality Assurance/Control**: Established protocol to ensure condition of product upon receipt, storage and delivery, maintaining accuracy of Order Picking/Packing. Review engineering codes, specifications, drawings and change notices to reflect customer specification. Perform inspections and review manufacturing "mic" sheets to ensure compliance with drawings and specified manufacturing codes. Maintain corrective action system to identify, evaluate and prevent quality issues and assure appropriate steps are taken to prevent the reoccurrence. **Risk Management:** Provide professional risk management services in the areas of risk control consultation and education, property/casualty insurance, health care claims adjudication and personal risk services. **Compliance**: State and Federal Licensing and Pedigree Laws and they pertain to Pharmaceuticals and Medical Supplies.

EXPERIENCE

08/2009-Present	MR UNLIMITED, LLC, Brenham, TX
07/2003-08/2009	Regional Manager, PMP Health Services, Inc., Waller, TX
1996-2003	Manufacturing Expeditor, Instomet, Inc., Houston, Texas
1995-1996	Drafter/Designer, Daniel Industry, Flow Products Division, Houston, Texas
1994-1995	Material Handler, Compaq Computer Corp., Houston, Texas
1990-1993	Box Line Supervisor, United Parcel Service, Laurel, Maryland
1990-Present	United States Air Force Reserves, 433d MOS, Alamo Wing, Lackland AFB, Texas

EDUCATION

Discovering Individual Styles of Communication, Administaff University Program, February 2000

Basic Principles for a Collaborative Workplace, Administaff University Program, March 2000

Bachelor of Science, Business Management, LeTouneau University, Houston Campus, 1996

Total Quality Management Cascade Training, United States Air Force, April 1994

Management by Commitment, United Parcel Service, May 1993

Peoples Workshop, United Parcel Service, May 1993

COPY

WORK HISTORY

MR UNLIMITED, LLC.
2505 Stone Hollow Drive, Ste 300
Brenham, TX 77833

(old address,
2015-2021, 105 E. Main Street, Ste 200B
Brenham, TX 77833

2009-2015, 1205 S. Austin, Ste 1
Brenham, TX 77833)
979-921-6141
Supervisor: N/A

08-15-2009 to **PRESENT**

$80,000.00
Owner/Operations Manager - **Chief Operations Officer**
Business Operations and Material Management: Review purchase and sales history along with manufacture and industry released shortages to ensure availability of needed products. Develop and maintain business sourcing and procurement activities, to ensure coordination of strategic sourcing initiatives. Determine market conditions within the "Supply Chain" including primary and secondary procurement, including market forecasting, world events and sale trends. **Sales/Contracts:** Generate new sales leads in all available markets, Review customer requirements, including State and Federal Invitation for Bids (IFB's) to determine accuracy of required product and/or generic/alternate availability. Submit quotes and/or alternate item review for approval. **Marketing:** Create sales advertisements and establish a market presence within various industry buying groups, establishing a market edge, credibility and product diversity. **Accounting**: Reconciliation of business software regarding Purchase Orders, Invoices, Receivables, Collections, **Shipping**: Performed all aspects of Shipping/Receiving with local freight carriers. **Quality Assurance/Control**: Established protocol to ensure condition of product upon receipt, storage and delivery, maintaining accuracy of Order Picking/Packing. Review engineering codes, specifications, drawings and change notices to reflect customer specification. Perform inspections and review manufacturing "mic" sheets to ensure compliance with drawings and specified manufacturing codes. Maintain corrective action system to identify, evaluate and prevent quality issues and assure appropriate steps are taken to prevent the reoccurrence. **Risk Management:** Provide professional risk management services in the areas of risk control consultation and education, property/casualty insurance, health care claims adjudication and personal risk services. **Compliance**: State and Federal Licensing and Pedigree Laws and they pertain to Pharmaceuticals and Medical Supplies.

PMP Health Services, Inc.
2611 Washington Street, Ste D
Waller, TX 77383
1201 S. Austin
Brenham, TX 77833
979-277-9595
Supervisor: N/A

07-04 to 08-14-2009

$22,490.00/year plus commission
Regional Manager
Business Operations of the Texas office, including: **Material Management**: Review purchase and sales history along with manufacture and industry released shortages to ensure availability of needed products. Develop and maintain business sourcing and procurement activities, to ensure coordination of strategic sourcing initiatives. Determine market conditions within the "Supply Chain" including primary and secondary procurement.
Sales: Generate new sales leads in all available markets, Review customer requirements, including State and Federal bids to determine accuracy of required product and/or generic/alternate availability. **Marketing:** Create sales ads and establish a market presence within various buying groups. **Accounting**: Reconciliation of business software regarding Purchase Orders, Invoices, Receivables, Collections, **Shipping**: Performed all aspects of packaging, Receiving/Shipping with local and freight carriers. **Quality Assurance/Control**: Established protocol to ensure accuracy of Order Picking/Packing
Compliance: State and Federal Licensing and Pedigree Laws.

Instromet, Inc.
12650 Directors Drive, Suite 100
Houston, TX 77477
281-491-5252
Supervisor: Pat Barnes

06-96 to 07-04

$41,080.00/year
Manufacturing Expeditor: Coordinate customer specifications with inside sales, engineering and manufacturing. Initiate and track Engineering Change Notice's (ECN's), release and distribute drawings for manufacturing.

Production/Scheduling. Plan, schedule, coordinate and control daily evaluation of projects and track jobs with subcontractors. Coordinate timelines and schedules with customer need dates, engineering, drafting, manufacturing, measurement/inspection, assembly, dry calibration and flow calibration dates and resolve conflicts as they arise. Create and assign Part Numbers, Bill of Materials, Purchase Orders inquiries and Work Orders. Provide weekly status reports to upper management, sales and engineering on each outstanding project. Monitor and record daily performance of employee's in work center and design performance standards and incentive programs.

Engineering and Design. Lead designer using AutoCAD to create working layouts for product designs, manufacturing and

assembly drawings of Ultrasonic gas flow meters and meter runs. Check and approve drawings and engineering change notices. Working knowledge of design codes and industry standards.

Quality Assurance /Quality Control and Inspection. Review engineering codes, specifications, drawings and change notices to reflect customer specification. Perform inspections and review manufacturing "mic" sheets to ensure compliance with drawings and specified manufacturing codes. Maintain corrective action system to identify, evaluate and prevent quality issues and assure appropriate steps are taken to prevent the reoccurrence.

Risk Management. Provide professional risk management services in the areas of risk control consultation and education, property/casualty insurance, health care claims adjudication and personal risk services.

Daniel Industry, Flow Products Division
9720 Old Katy Road
Houston, TX 77055-6209
713-467-6000
Supervisor: Bill Lindsey

02-95 to 06-96 Advancement

$25,000.00/year
Drafter/Designer: Initiate and track Engineering Change Notice (ECN's), Manufacturing liaison, Distribution of drawings and ECN's.

Engineering and Design. Lead designer using AutoCAD to create working layouts for product designs, manufacturing and assembly drawings of Ultrasonic gas flow meters and meter runs. Coordinate drafting requests with inside sales and Engineering on multiple product lines. Check and approve drawings and Engineering Change Notice (ECN's),. Working knowledge of design codes and industry standards

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Compaq Computer Corp.
20555 State Hwy 249
Houston, TX 77070
281-370-0670
Supervisor: Dennis

07-94 to 02-95 Full Time employment

$7.00/hour
Material Handler: Process customers' orders, via pick n pack operations, shipping and receiving. Included the use of isle rangers, forklifts and motorized pallet jacks.

Kroger
28597 Tomball Pkwy
Tomball, TX 77375
713-351-6131
Supervisor: Mr. Hutchins

10-94 to 02-95 Monetary hourly increase

$4.35/hour
Trainer/Sacker: Trained employees in store policies, customer service and grocery distribution

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United Parcel Service
14841 Swiezter Lane
Laurel, MD 20707
410-604-4633
Supervisor: Les Austin

08-90 to 08-94 College/Relocation

$20,000.00/year
Box Line Supervisor: Coordinated personnel scheduling between other work centers. Monitored and recorded daily performance of employee's in work center.

Chi Chis Mexican Restraunt
8030 Ritchie Hwy
Pasadena, MS 21122
410-761-8833
Supervisor: Harry Ritter

12-87 to 04-92 College

$2.50/hour + Tips
Waiter/Service Asst./Host: Facilitate customer orders, clear tables, greet customers and allocate seating.

Alcap Construction Inc.
8009 Jumpers Hole Road
Pasadena, MD 21122
410-761-8710
Supervisor: Tim Collins

06-88 to 12-90 Military enlistment

$10.00/hour per job
Designer/Draftsman: Coordinated design and construction between insurance companies, owners and contractors. Facilitated field surveys and drawing design.

Mistral Inc.
7222 Parkway Drive
Dorsey, MD 21076
410-712-4755
410-646-255
Supervisor: Leonard Brownlee

08-88 to 09-89 College

$5.50/hour

COPY

1982

Warehouse: Shipping and receiving, inventory control, filling customer orders.

USAFR
433 Maintenance Operations Center
Lackland AFB, Texas 78236
Comm: (210) 925-1457
Comm Fax: 210-925-0261

Supervisor: SMSgt David Salazar
E-mail: david.salazar@us.af.mil
06-90 to 10-2014

E-6 Rank
Maintenance Operations Center (MOC) Controller:
Maintains present & projected status of three C-5A aircraft - Oversight of scheduled/unscheduled maintenance planning & flying schedule execution of 16 C-5A aircraft.
- Utilized radio, telephone, verbal communications, e-mail & computer management information systems
- Established workload requirements based on available resources to meet optimum production deadlines

Maintains both a present and projected comprehensive status of forms and maintenance on assigned aircraft. **Utilizes** radio, telephone and verbal communications and computer management information systems to establish priority workload requirements based on available resources. Through daily/weekly coordination with Command Post, Plans and Scheduling, base and local supply liaisons, and supervision and technicians, maintains a variety of essential information to maintain optimum production and meet pre-established deadlines. Responsible for the control and monitoring of condition tags in accordance with technical manuals and local operating instructions. **Utilizes** maintenance data collection computer programs to manage aircraft forms, documentation and completion of discrepancies and assigns maintenance operational checks to completed discrepancies to ensure aircraft systems function properly. **Assigns** priorities on aircraft parts.

Aerospace Maintenance Journeyman:
Troubleshoots and maintains aircraft structures, systems, components and support equipment. Adjusts, aligns, rigs and calibrates aircraft systems. Jack, tows and services aircraft. Inspects aircraft structures, systems, components and support equipment. Inspects and checks components for clearance, tolerances, proper installation and operation. Inspects and operates powered and non-powered aerospace equipment. Reviews maintenance forms, aircraft records and reports to ensure complete documentation. Inventories and maintains alternate mission equipment.

General Conference, Transportation Division
6620 Amberton Drive
Baltimore, MD 21227
410-796-8484

Supervisor: John Sasz

06-88 to 08-88 Summer help

$6.00/hour
Warehouse: Shipping and receiving, inventory missionary goods, build crates for overseas deployment.

Unaccounted time:

08-94 to 10-94 Recently moved from Maryland to Texas.

EDUCATION

LeTourneau University, Houston Campus
P.O. Box 7668
Longview, TX 75607-7668

09-94 to 12-96 Bachelor of Science in Business Management

Prairie View A&M University
P.O. Box 2610
Prairie View, TX 77446-2610

08-93 to 12-93 N/A – Architectural Design

Anne Arundel Community College
101 College Parkway
Arnold, MD 21012

09-88 to 12-90 Associates of Arts in Architectural Design

Glen Burnie High School
7550 B&A Blvd.
Glen Burnie, MD 21060

12-86 to 06-88 Graduated with Diploma, study in Architectural Design

REFERENCES

David Jantzi – Personal/Business Reference
[redacted] W. Briarwood Drive
Brenham, Tx 77833
Ph: [redacted]
Pratice Administrator for Brazos Valley Allergy & Asthma Clinics
Years Known: 2004
[redacted]

Charles Garcia – Personal Reference
[redacted] Gentle Grove Drive
San Antonio, Tx
Ph: [redacted]
USAF – 433 AW
Years Known: 1993
[redacted]

COPY

XXXX
1983

Edward A. Gutierrez – Personal Reference
[redacted] S. Chambers St.
Giddings, Tx 78942
Ph[redacted]
Police Officer, Elgin Police Department
Work Ph: (512)285-5757
Years known: 1997
[redacted]

Linda Montellano – Personal Reference
[redacted] Summer Wind
San Antonio, Tx
Ph: [redacted]3
Constituent Services – Senator Menendez
[redacted]

Dave Essary – Business Reference
davee08@live.com

Sean Shaffer – Business Reference
The Compounding Center Pharmacy, Inc.
[redacted] E Bell Rd #163
Phoenix, AZ 85032
[redacted]

Brandt Harner – Business Reference
[redacted]

AFFILIATIONS

ADDITIONAL INFORMATION

Designated Representative for California Board of Pharmacy – MR Unlimited, LLC.

Self-Inspection Monitor, Primary, 433d MOS/CC, 20101020

Award & Decoration Monitor, Primary, 433d MOS, 20110211

Personal Wireless Communication System (PWCS) Manager, Alternate, 433d MOS, 20110301

Motorcycle Safety Monitor, 433d MOS

RECOGNITIONS

2001 Adult CPR; Workplace Training Standards First Aid; Forklift Certification

2000
- (February 01) Certificate of Completion, Discovering Individual Styles of Communication
- (February) Discovering Individual Styles of Communication, Administaff University Program
- (March) Basic Principles for a Collaborative Workplace, Administaff University Program
- (March 21) Certificate of Completion, Basic Principles of a Collaborative Workplace
- (October 24) Certificate of Completion, MAS90 for Windows Inventory Management for Manufacturing
- (October 25) Certificate of Completion, MAS90 for Windows Work Order

1997 Letter of Appreciation, George A. Ebert, Lt. Col, Commander, USAFR

1996 Bachelor of Science, Business Management, LeTouneau University, Houston Campus

1994
- Certificate for Outstanding Achievement, USAFR; Promotion to Staff Sergeant; Total Quality Management Cascade Training
- (April)Total Quality Management Cascade Training, United States Air Force
- (May) Management by Commitment, United Parcel Service
- (May) Peoples Workshop, United Parcel Service

1993
- Outstanding Reserve Associate Maintenance Award, USAFR
- Certificate For Outstanding Achievement
- Management By Commitment and Peoples Workshop

1992 Nominee for the Outstanding Reserve Associate Maintenance Airman Award as Outstanding Airman of the Year of the 21st Air Force, USAFR

1991 Honor Graduate from Quality Training Program (QTP), Commander – Weapons Drill Team: Shepphard AFB

1988 Drafting Award – Glen Burnie High School

BMTS LMABM990000

Apprentice Airlift Acft Maint. Spl. J3ABR45732B 000

Quality Training Program (QTP)

NCO prep school, correspondence 9307

COPY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: MR Unlimited, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 2505 Stone Hollow Dr Ste 300

City: Brenham State: Texas Zip: 77833

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 979-921-6141 x1 Website:

Licensing Company Email: darryl.mcnabb@mrunlimitedllc.com

Section 2: Personal Information

First: Darryl Middle: Wayne Last: McNabb

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Possum Trot

City: Brenham State: Texas Zip: 77833

Telephone: [redacted] Email: darryl.mcnabb@mrunlimitedllc.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
LeTourneau University, Houston Campus		09/94 - 12/96	
Address	City	State	Zip
P.O Box 7668	Longview	TX	75607
Diploma/Degree obtained, if any			
BS in Business Management			
School Name		From - To (MM/YY – MM/YY)	
Prairie View A&M University		08/93 - 12/93	
Address	City	State	Zip
P.O. Box 2610	Prairie View	TX	77446
Diploma/Degree obtained, if any			
N/A			
School Name		From - To (MM/YY – MM/YY)	
Anne Arundel Community College		09/88 - 12/90	
Address	City	State	Zip
101 College Parkway	Arnold	MD	21012
Diploma/Degree obtained, if any			
Associate of Arts in Architectural Design			
School Name		From - To (MM/YY – MM/YY)	
Glen Burnie High School		12/86 - 06/88	
Address	City	State	Zip
7550 B:A Blvd	Glen Burnie	MD	21060
Diploma/Degree obtained, if any			
Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
N/A			
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/04 - Present	[redacted] Possum Trot	Brenham	TX	77833
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
MR Unlimited, LLC			08/09 - Present
Business Address	**City**	**State**	**Zip**
2505 Stone Hollow Drive, STE 300	Brenham	TX	77833
Phone	**Title**		
979-921-6141	Owner / Operations Manager		
Description of Duties			
See attached Resume' and Work History Sheets ~~XXXX~~			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Darryl McNabb
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2023-6-5
Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Washington

I, Darryl W McNabb, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/5/23
Date

Subscribed and Sworn to before me this 5 day of June '23.

Carrie L. Little
Notary Public Signature

CARRIE LYNN LITTLE
Notary Public, State of Texas
Comm. Expires 05-06-2025
Notary ID 1170226-8
(Seal)

***
1991

DARRYL W. McNABB
[redacted] Possum Trot
Brenham, TX 77833
[redacted]

POBJECTIVE

Obtain a position of increasing responsibility that will allow me to use my learned skills from both civilian and military occupations; to facilitate the directives of the company and my department of assignment while making a significant contribution to the success of the organization.

SUMMARY

Experienced in Production; Scheduling; Procurement, Order Processing and Shipping; emphasizing in Administration, Supervisory and Financial Skills; Inventory Control with experience in QA/QC; Inspection Procedures. Legal Compliance; Strategic Planning; Leadership; Motivating Others; Persuasion; Supports Innovation; Problem Solving; Analyzing Information; Dealing with Complexity; Decision Making; Developing Budgets; Statistical Analysis; Presentation Skills; Information Security Policies.

QUALIFACTIONS

Business Operations and Material Management: Review purchase and sales history along with manufacture and industry released shortages to ensure availability of needed products. Develop and maintain business sourcing and procurement activities, to ensure coordination of strategic sourcing initiatives. Determine market conditions within the "Supply Chain" including primary and secondary procurement, including market forecasting, world events and sale trends. **Sales/Contracts:** Generate new sales leads in all available markets, Review customer requirements, including State and Federal Invitation for Bids (IFB's) to determine accuracy of required product and/or generic/alternate availability. Submit quotes and/or alternate item review for approval. **Marketing:** Create sales advertisements and establish a market presence within various industry buying groups, establishing a market edge, credibility and product diversity. **Accounting**: Reconciliation of business software regarding Purchase Orders, Invoices, Receivables, Collections, **Shipping**: Performed all aspects of Shipping/Receiving with local freight carriers. **Quality Assurance/Control**: Established protocol to ensure condition of product upon receipt, storage and delivery, maintaining accuracy of Order Picking/Packing. Review engineering codes, specifications, drawings and change notices to reflect customer specification. Perform inspections and review manufacturing "mic" sheets to ensure compliance with drawings and specified manufacturing codes. Maintain corrective action system to identify, evaluate and prevent quality issues and assure appropriate steps are taken to prevent the reoccurrence. **Risk Management:** Provide professional risk management services in the areas of risk control consultation and education, property/casualty insurance, health care claims adjudication and personal risk services. **Compliance**: State and Federal Licensing and Pedigree Laws and they pertain to Pharmaceuticals and Medical Supplies.

EXPERIENCE

08/2009-Present	MR UNLIMITED, LLC, Brenham, TX
07/2003-08/2009	Regional Manager, PMP Health Services, Inc., Waller, TX
1996-2003	Manufacturing Expeditor, Instomet, Inc., Houston, Texas
1995-1996	Drafter/Designer, Daniel Industry, Flow Products Division, Houston, Texas
1994-1995	Material Handler, Compaq Computer Corp., Houston, Texas
1990-1993	Box Line Supervisor, United Parcel Service, Laurel, Maryland
1990-Present	United States Air Force Reserves, 433d MOS, Alamo Wing, Lackland AFB, Texas

EDUCATION

Discovering Individual Styles of Communication, Administaff University Program, February 2000

Basic Principles for a Collaborative Workplace, Administaff University Program, March 2000

Bachelor of Science, Business Management, LeTouneau University, Houston Campus, 1996

Total Quality Management Cascade Training, United States Air Force, April 1994

Management by Commitment, United Parcel Service, May 1993

Peoples Workshop, United Parcel Service, May 1993

COPY

WORK HISTORY

MR UNLIMITED, LLC.
2505 Stone Hollow Drive, Ste 300
Brenham, TX 77833

(old address,
2015-2021, 105 E. Main Street, Ste 200B
Brenham, TX 77833

2009-2015, 1205 S. Austin, Ste 1
Brenham, TX 77833)
979-921-6141
Supervisor: N/A

08-15-2009 to **PRESENT**

$80,000.00
Owner/Operations Manager - **Chief Operations Officer**
Business Operations and Material Management: Review purchase and sales history along with manufacture and industry released shortages to ensure availability of needed products. Develop and maintain business sourcing and procurement activities, to ensure coordination of strategic sourcing initiatives. Determine market conditions within the "Supply Chain" including primary and secondary procurement, including market forecasting, world events and sale trends. **Sales/Contracts:** Generate new sales leads in all available markets, Review customer requirements, including State and Federal Invitation for Bids (IFB's) to determine accuracy of required product and/or generic/alternate availability. Submit quotes and/or alternate item review for approval. **Marketing:** Create sales advertisements and establish a market presence within various industry buying groups, establishing a market edge, credibility and product diversity. **Accounting**: Reconciliation of business software regarding Purchase Orders, Invoices, Receivables, Collections, **Shipping**: Performed all aspects of Shipping/Receiving with local freight carriers. **Quality Assurance/Control**: Established protocol to ensure condition of product upon receipt, storage and delivery, maintaining accuracy of Order Picking/Packing. Review engineering codes, specifications, drawings and change notices to reflect customer specification. Perform inspections and review manufacturing "mic" sheets to ensure compliance with drawings and specified manufacturing codes. Maintain corrective action system to identify, evaluate and prevent quality issues and assure appropriate steps are taken to prevent the reoccurrence. **Risk Management:** Provide professional risk management services in the areas of risk control consultation and education, property/casualty insurance, health care claims adjudication and personal risk services. **Compliance**: State and Federal Licensing and Pedigree Laws and they pertain to Pharmaceuticals and Medical Supplies.

PMP Health Services, Inc.
2611 Washington Street, Ste D
Waller, TX 77383
1201 S. Austin
Brenham, TX 77833
979-277-9595
Supervisor: N/A

07-04 to 08-14-2009

$22,490.00/year plus commission
Regional Manager
Business Operations of the Texas office, including: **Material Management**: Review purchase and sales history along with manufacture and industry released shortages to ensure availability of needed products. Develop and maintain business sourcing and procurement activities, to ensure coordination of strategic sourcing initiatives. Determine market conditions within the "Supply Chain" including primary and secondary procurement.
Sales: Generate new sales leads in all available markets, Review customer requirements, including State and Federal bids to determine accuracy of required product and/or generic/alternate availability. **Marketing:** Create sales ads and establish a market presence within various buying groups. **Accounting**: Reconciliation of business software regarding Purchase Orders, Invoices, Receivables, Collections, **Shipping**: Performed all aspects of packaging, Receiving/Shipping with local and freight carriers. **Quality Assurance/Control**: Established protocol to ensure accuracy of Order Picking/Packing
Compliance: State and Federal Licensing and Pedigree Laws.

Instromet, Inc.
12650 Directors Drive, Suite 100
Houston, TX 77477
281-491-5252
Supervisor: Pat Barnes

06-96 to 07-04

$41,080.00/year
Manufacturing Expeditor: Coordinate customer specifications with inside sales, engineering and manufacturing. Initiate and track Engineering Change Notice's (ECN's), release and distribute drawings for manufacturing.

Production/Scheduling. Plan, schedule, coordinate and control daily evaluation of projects and track jobs with subcontractors. Coordinate timelines and schedules with customer need dates, engineering, drafting, manufacturing, measurement/inspection, assembly, dry calibration and flow calibration dates and resolve conflicts as they arise. Create and assign Part Numbers, Bill of Materials, Purchase Orders inquiries and Work Orders. Provide weekly status reports to upper management, sales and engineering on each outstanding project. Monitor and record daily performance of employee's in work center and design performance standards and incentive programs.

COPY

Engineering and Design. Lead designer using AutoCAD to create working layouts for product designs, manufacturing and

assembly drawings of Ultrasonic gas flow meters and meter runs. Check and approve drawings and engineering change notices. Working knowledge of design codes and industry standards.

Quality Assurance /Quality Control and Inspection. Review engineering codes, specifications, drawings and change notices to reflect customer specification. Perform inspections and review manufacturing "mic" sheets to ensure compliance with drawings and specified manufacturing codes. Maintain corrective action system to identify, evaluate and prevent quality issues and assure appropriate steps are taken to prevent the reoccurrence.

Risk Management. Provide professional risk management services in the areas of risk control consultation and education, property/casualty insurance, health care claims adjudication and personal risk services.

Daniel Industry, Flow Products Division
9720 Old Katy Road
Houston, TX 77055-6209
713-467-6000
Supervisor: Bill Lindsey

02-95 to 06-96 Advancement

$25,000.00/year
Drafter/Designer: Initiate and track Engineering Change Notice (ECN's), Manufacturing liaison, Distribution of drawings and ECN's.

Engineering and Design. Lead designer using AutoCAD to create working layouts for product designs, manufacturing and assembly drawings of Ultrasonic gas flow meters and meter runs. Coordinate drafting requests with inside sales and Engineering on multiple product lines. Check and approve drawings and Engineering Change Notice (ECN's),. Working knowledge of design codes and industry standards

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Compaq Computer Corp.
20555 State Hwy 249
Houston, TX 77070
281-370-0670
Supervisor: Dennis

07-94 to 02-95 Full Time employment

$7.00/hour
Material Handler: Process customers' orders, via pick n pack operations, shipping and receiving. Included the use of isle rangers, forklifts and motorized pallet jacks.

Kroger
28597 Tomball Pkwy
Tomball, TX 77375
713-351-6131
Supervisor: Mr. Hutchins

10-94 to 02-95 Monetary hourly increase

$4.35/hour
Trainer/Sacker: Trained employees in store policies, customer service and grocery distribution

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United Parcel Service
14841 Swiezter Lane
Laurel, MD 20707
410-604-4633
Supervisor: Les Austin

08-90 to 08-94 College/Relocation

$20,000.00/year
Box Line Supervisor: Coordinated personnel scheduling between other work centers. Monitored and recorded daily performance of employee's in work center.

Chi Chis Mexican Restraunt
8030 Ritchie Hwy
Pasadena, MS 21122
410-761-8833
Supervisor: Harry Ritter

12-87 to 04-92 College

$2.50/hour + Tips
Waiter/Service Asst./Host: Facilitate customer orders, clear tables, greet customers and allocate seating.

Alcap Construction Inc.
8009 Jumpers Hole Road
Pasadena, MD 21122
410-761-8710
Supervisor: Tim Collins

06-88 to 12-90 Military enlistment

$10.00/hour per job
Designer/Draftsman: Coordinated design and construction between insurance companies, owners and contractors. Facilitated field surveys and drawing design.

Mistral Inc.
7222 Parkway Drive
Dorsey, MD 21076
410-712-4755
410-646-255
Supervisor: Leonard Brownlee

COPY

08-88 to 09-89 College

$5.50/hour

Warehouse: Shipping and receiving, inventory control, filling customer orders.

USAFR
433 Maintenance Operations Center
Lackland AFB, Texas 78236
Comm: (210) 925-1457
Comm Fax: 210-925-0261

Supervisor: SMSgt David Salazar
E-mail: david.salazar@us.af.mil
06-90 to 10-2014

E-6 Rank
Maintenance Operations Center (MOC) Controller:
Maintains present & projected status of three C-5A aircraft - Oversight of scheduled/unscheduled maintenance planning & flying schedule execution of 16 C-5A aircraft.
- Utilized radio, telephone, verbal communications, e-mail & computer management information systems
- Established workload requirements based on available resources to meet optimum production deadlines

Maintains both a present and projected comprehensive status of forms and maintenance on assigned aircraft. **Utilizes** radio, telephone and verbal communications and computer management information systems to establish priority workload requirements based on available resources. Through daily/weekly coordination with Command Post, Plans and Scheduling, base and local supply liaisons, and supervision and technicians, maintains a variety of essential information to maintain optimum production and meet pre-established deadlines. Responsible for the control and monitoring of condition tags in accordance with technical manuals and local operating instructions. **Utilizes** maintenance data collection computer programs to manage aircraft forms, documentation and completion of discrepancies and assigns maintenance operational checks to completed discrepancies to ensure aircraft systems function properly. **Assigns** priorities on aircraft parts.

Aerospace Maintenance Journeyman:
Troubleshoots and maintains aircraft structures, systems, components and support equipment. Adjusts, aligns, rigs and calibrates aircraft systems. Jack, tows and services aircraft. Inspects aircraft structures, systems, components and support equipment. Inspects and checks components for clearance, tolerances, proper installation and operation. Inspects and operates powered and non-powered aerospace equipment. Reviews maintenance forms, aircraft records and reports to ensure complete documentation. Inventories and maintains alternate mission equipment.

General Conference, Transportation Division
6620 Amberton Drive
Baltimore, MD 21227
410-796-8484

Supervisor: John Sasz

06-88 to 08-88 Summer help

$6.00/hour
Warehouse: Shipping and receiving, inventory missionary goods, build crates for overseas deployment.

Unaccounted time:

08-94 to 10-94 Recently moved from Maryland to Texas.

EDUCATION

LeTourneau University, Houston Campus
P.O. Box 7668
Longview, TX 75607-7668

09-94 to 12-96 Bachelor of Science in Business Management

Prairie View A&M University
P.O. Box 2610
Prairie View, TX 77446-2610

08-93 to 12-93 N/A – Architectural Design

Anne Arundel Community College
101 College Parkway
Arnold, MD 21012

09-88 to 12-90 Associates of Arts in Architectural Design

Glen Burnie High School
7550 B&A Blvd.
Glen Burnie, MD 21060

12-86 to 06-88 Graduated with Diploma, study in Architectural Design

REFERENCES

David Jantzi – Personal/Business Reference
[redacted]V. Briarwood Drive
Brenham, Tx 77833
Ph: [redacted]
Pratice Administrator for Brazos Valley Allergy & Asthma Clinics
Years Known: 2004
[redacted]

Charles Garcia – Personal Reference
[redacted]Gentle Grove Drive
San Antonio, Tx
Ph: [redacted]
USAF – 433 AW
Years Known: 1993
[redacted]

COPY

Edward A. Gutierrez – Personal Reference
[redacted] S. Chambers St.
Giddings, Tx 78942
Ph: [redacted]
Police Officer, Elgin Police Department
Work Ph: (512)285-5757
Years known: 1997
[redacted]

Linda Montellano – Personal Reference
[redacted] Summer Wind
San Antonio, Tx
Ph: [redacted]
Constituent Services – Senator Menendez
[redacted]

Dave Essary – Business Reference
[redacted]

Sean Shaffer – Business Reference
The Compounding Center Pharmacy, Inc.
[redacted] E Bell Rd [redacted]
Phoenix, AZ 85032
[redacted]

Brandt Harner – Business Reference
[redacted]

AFFILIATIONS

ADDITIONAL INFORMATION

Designated Representative for California Board of Pharmacy – MR Unlimited, LLC.

Self-Inspection Monitor, Primary, 433d MOS/CC, 20101020

Award & Decoration Monitor, Primary, 433d MOS, 20110211

Personal Wireless Communication System (PWCS) Manager, Alternate, 433d MOS, 20110301

Motorcycle Safety Monitor, 433d MOS

RECOGNITIONS

2001 Adult CPR; Workplace Training Standards First Aid; Forklift Certification

2000
- (February 01) Certificate of Completion, Discovering Individual Styles of Communication
- (February) Discovering Individual Styles of Communication, Administaff University Program
- (March) Basic Principles for a Collaborative Workplace, Administaff University Program
- (March 21) Certificate of Completion, Basic Principles of a Collaborative Workplace
- (October 24) Certificate of Completion, MAS90 for Windows Inventory Management for Manufacturing
- (October 25) Certificate of Completion, MAS90 for Windows Work Order

1997 Letter of Appreciation, George A. Ebert, Lt. Col, Commander, USAFR

1996 Bachelor of Science, Business Management, LeTouneau University, Houston Campus

1994
- Certificate for Outstanding Achievement, USAFR; Promotion to Staff Sergeant; Total Quality Management Cascade Training
- (April)Total Quality Management Cascade Training, United States Air Force
- (May) Management by Commitment, United Parcel Service
- (May) Peoples Workshop, United Parcel Service

1993
- Outstanding Reserve Associate Maintenance Award, USAFR
- Certificate For Outstanding Achievement
- Management By Commitment and Peoples Workshop

1992 Nominee for the Outstanding Reserve Associate Maintenance Airman Award as Outstanding Airman of the Year of the 21st Air Force, USAFR

1991 Honor Graduate from Quality Training Program (QTP), Commander – Weapons Drill Team: Shepphard AFB

1988 Drafting Award – Glen Burnie High School

BMTS LMABM990000

Apprentice Airlift Acft Maint. Spl. J3ABR45732B 000

Quality Training Program (QTP)

NCO prep school, correspondence 9307

COPY

MR Unlimited, LLC Employees List

Darryl McNabb – Owner-Operations Manager

Carrie Little – AR/Payroll

Cheslea Garbs - Shipping

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
Consumer Protection Division
PO Box 149347, Austin, TX 78714
(512) 834-6660

Name	MR UNLIMITED LLC MR UNLIMITED LLC	License Type	Prescription Drugs
Address	2505 STONE HOLLOW DR STE 300 BRENHAM TX 77833	License Number	1000185
Inspection Type	Periodic/Routine	Inspection Number	246330
Inspector	SMITH, AMBER N	Inspection Date	01/27/2023

NOTICE OF INSPECTIONAL OBSERVATIONS

This notice is to acknowledge that the Texas Department of State Health Services (DSHS) conducted an inspection of your business on the date listed above. The information that has been gathered is subject to further department review and you may receive additional correspondence as a result.

There is no deficiency/violation cited or noted within the scope of this inspection/visit.

Inspector:

SMITH, AMBER N

Date: 01/27/2023

Firm Representative:

Darryl McNabb

Date: 01/27/2023

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-State	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Non-sterile Compounding
	☐ Location Change *	☐ Internet	☐ Sterile Compounding
	☐ Name Change*	☐ Nuclear	☐ Mail-Order Service
		☐ Other:	☐ Off-site Cognitive Services
	* If making a change, provide license #:		☒ Long Term Care
			☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: All westCare Pharmacy LLC

Physical Address: 2401 S. Eastern Ave STE 241

City: Las Vegas State: NV Zip: 89104

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 714-924-2800 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: N/A Contact Email: Allwestcarepharmacy@gmail.com

Website: N/A

Nevada Business License # (if applicable) E33760992023-0

Supervising/Managing Pharmacist Name (NRS 639.220): Soheila Baghbanbashi

Supervising/Managing Pharmacist NV Pharmacist Registration #: NV 11821

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Soheila Baghbanbashi	NV Pharmacist Registration #: NV 11821
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name: NA	Credentials:	%:
Name: NA	Credentials:	%:
Name: NA	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Tahsin Shanan

Mailing Address: 4572 Avery Rock St.

City: Las Vegas State: NV Zip: 89147

Telephone: 714-924-2800 Email: Allwestcarepharmacy@gmail.com

Contact Person Name: Tahsin Shanan

Please check type of partnership (NAC 639.214) ☐ General ☒ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Member (title) for Allwestcare Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Tahsin Shanan

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8-2-2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Tahsin Shanan hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manging Member (title) for All westCare Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 14th day of August, 2023

Notary Public

EDWIN LUNA CARRENO
Notary Public - State of Nevada
County of Clark
APPT. NO. 21-2857-01
My App. Expires Apr. 26, 2025

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: SOHEILA BAGHBANBASHI Pharmacist Registration #: NV 11821

Pharmacy Name: All westcare Pharmacy LLC

Initial each statement below to indicate you have read and agree with the following:

SB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

SB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

SB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

SB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

SB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Soheila Baghbanbashi
Original signature of Managing Pharmacist (copies or stamps not accepted)

8/9/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tahsin Shaven

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

8-2-2023

Date

Board Use Only	Date Received: 8/17/23	Amount: 500-CC

ALL WESTCARE PHARMACY LLC PARTNERSHIP LIST		
NAME	**TITLE**	**%**
TAHSIN SHANAN	MANAGING MEMBER	60 %
SALWA NAIM	MANAGING MEMBER	40 %

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **ALL WESTCARE PHARMACY LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 07/27/2023, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/02/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202308023851732
You may verify this certificate online at http://www.nvsos.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler All westCare Pharmacy LLC

Physical Address 2401 S. Eastern Ave STE 2411

City Las Vegas State NV Zip 89104

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 714-924-2800 Website _____

Licensing Company Email Allwestcare Pharmacy@gmail.com

Section 2: Personal Information

First Tahsin Middle Hassan Mohamed Last Shanan

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Avery Rock St

City Las Vegas State NV Zip 89147

Telephone [redacted] Email Allwestcare Pharmacy@gmail.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		NA

Applicant's initials TS

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)		
6th october university	09-2001 / 06-2006		
Address	**City**	**State**	**Zip**
6th october city, Giza, Egypt	Giza	cairo	
Diploma/Degree obtained, if any			
Pharmacist			

School Name	From - To (MM/YY – MM/YY)		
Elsedik high school	09-1996 / 06-2001		
Address	**City**	**State**	**Zip**
Al Haram st	Giza	Cairo	
Diploma/Degree obtained, if any			
High school diploma			

School Name	From - To (MM/YY – MM/YY)		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name	From - To (MM/YY – MM/YY)		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name	From - To (MM/YY – MM/YY)		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/23 / Now	[redacted] Avery Rock st	Las Vegas	NV	89147
01/22 / 01-23	[redacted] S. Hualapai way	Las Vegas	NV	89147
01/21 / 01-22	[redacted] walking view CT	Las Vegas	NV	89135
02/2020-01/22	[redacted] Coyote cub ave.	Las Vegas	NV	89129
06/2016-01/2020	[redacted] N Chrisdect st #202	Anaheim	CA	92807
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
TMS Pharmacy LLC			02/22 – Now
Business Address	**City**	**State**	**Zip**
580 E windmill lane STE 135	Las Vegas	NV	89123
Phone	**Title**		
725-204-9605	Pharmacist		
Description of Duties			
Recive, verify, fill and approve prescription. Patients Consultations.			

Business Name			From - To (MM/YY – MM/YY)
Walmart Pharmacy			09/21 – 02/22
Business Address	**City**	**State**	**Zip**
5200 S. Fort Apache Rd	Las Vegas	NV	89148
Phone	**Title**		
702-367-4001	Pharmacist		
Description of Duties			
Recive Verify, fill and approve Prescriptions Patients Consultations.			

Business Name			From - To (MM/YY – MM/YY)
CVS Pharmacy			
Business Address	**City**	**State**	**Zip**
8116 S. Las Vegas Blvd	Las Vegas	NV	89123
Phone	**Title**		
702-467-7063	Pharmacist		
Description of Duties			
Recive, Verify, fill and approve Prescriptions Patients Consultations			

Business Name			From - To (MM/YY – MM/YY)
Credo Pharmacy			2-2020 / 3-2021
Business Address	**City**	**State**	**Zip**
8995 W. Flamingo RD STE 120	Las Vegas	NV	89147
Phone	**Title**		
702-800-4000	Intern Pharmacist		
Description of Duties			
Typing and filling Prescriptions – under Pharmacist Supervision Consult patients.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials TS

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		NA
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Applicant's initials TS

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

T

Original Signature (electronic, copies or stamps not accepted)

8-3-2023

Date

Applicant's initials TJ

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tahsin Shanan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-14-2023
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Tahsin Hassan Mohamed Shanan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-14-2023
Date

Subscribed and Sworn to before me this 14th day of August, 2023.

Notary Public Signature

EDWIN LUNA CARRENO
Notary Public - State of Nevada
County of Clark
APPT. NO. 21-2857-01
My App. Expires Apr. 26, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler All Westcare Pharmacy

Physical Address 2401 S. Eastern Ave, Ste 2401

City Las Vegas State NV Zip 89104

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (702) 785-3773 Website _____

Licensing Company Email Allwestcare@gmail.com

Section 2: Personal Information

First SALWA Middle _____ Last NAIM

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] SILVER BIT CT

City NLV State NV Zip 89032

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☑ No PERMANENT RESIDENT

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Applicant's initials _____

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)
ROSEMAN UNIVERSITY		8/15 - 6/18
Address	**City**	**State** **Zip**
11 Sunset Way	LAS VEGAS	NV 89014
Diploma/Degree obtained, if any		
PHARM D.		
School Name		**From - To (MM/YY – MM/YY)**
UNLV		8/05 - 5/09
Address	**City**	**State** **Zip**
4505 S. Maryland Pkwy	Las Vegas	NV 89154
Diploma/Degree obtained, if any		
Biological Sciences/Chemistry BoS		
School Name		**From - To (MM/YY – MM/YY)**
Community College High School - West		8/2004 - 6/04
Address	**City**	**State** **Zip**
6375 W. Charleston Blvd	Las Vegas	NV 89146
Diploma/Degree obtained, if any		
Advanced HS. Diploma		
School Name		**From - To (MM/YY – MM/YY)**
Cimmeron High School		8/02 - 8/04
Address	**City**	**State** **Zip**
2301 N. Tenaya Wy	Las Vegas	NV 89129
Diploma/Degree obtained, if any		
Transfered to CCSN-West High to seek advanced degree		
School Name		**From - To (MM/YY – MM/YY)**
Address	**City**	**State** **Zip**
Diploma/Degree obtained, if any		

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/2020 - present	[redacted] SILVER BIT CT	NLV	NV	89032
10/2018 - 6/2020	[redacted] ~~W. Holly~~ Fountain Ave	W. Hollywood	CA	90046
6/2018 - 10/2018	[redacted] Crystal Ct.	Beaumont	CA	92223
8/12 - 6/18	[redacted] Silver Bit Ct	NLV	NV	89032
From - To (MM/YY – MM/YY)	Address		State	Zip
From - To (MM/YY – MM/YY)	Address		State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: TMS Pharmacy LLC. | From - To (MM/YY – MM/YY): 2/22 - present
Business Address: 580 E. Windmill Lane, Ste 135 | City: Las Vegas | State: NV | Zip: 89123
Phone: (725) 204-9605 | Title:
Description of Duties: UNDER SUPERVISION OF RPH - Counseling pts, filling + verifying Rx's, Admin duties

Business Name: Desert Oasis Healthcare | From - To (MM/YY – MM/YY): 6/18 - 5/19
Business Address: 275 E. Hills Rd | City: | State: CA | Zip: 92262
Phone: 760-320-8814 | Title: Pharmacy Resident
Description of Duties: MTM, managed pts under collaborative practice in managing pts within various clinics, workshop lead, preceptorships of IPPE & APPE students, teaching LLL, poster presentation, residency technology project development.

Business Name: Savon Pharmacy | From - To (MM/YY – MM/YY): 8/15 - 7/19
Business Address: 7075 W. Ann Rd | City: Las Vegas | State: NV | Zip: 89130
Phone: (702) 395-6912 | Title: Intern
Description of Duties: Pt. profile assessment, pt counseling, fill Rx's, inventory tracking, pt & medical personnel outreach

Business Name | From - To (MM/YY – MM/YY)
Business Address | City | State | Zip
Phone | Title
Description of Duties

Business Name | From - To (MM/YY – MM/YY)
Business Address | City | State | Zip
Phone | Title
Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8/4/23
Date

Applicant's initials

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SALWA NAIM
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/14/23
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Salwa Naim, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/14/23
Date

Subscribed and Sworn to before me this 14th day of August, 2023.

Notary Public Signature

EDWIN LUNA CARRENO
Notary Public - State of Nevada
County of Clark
APPT. NO. 21-2857-01
My App. Expires Apr. 26, 2025

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler TMV PHARMACY

Physical Address 580 E. WINDMILL LANE, STE 125

City LAS VEGAS State NV Zip 89123

Mailing Address (if different from physical address) SAME AS ABOVE

City State Zip

Telephone (725) 204-9605 Website

Licensing Company Email INFO@TMVPHARMACY.US.COM

Section 2: Personal Information

First JAZWA Middle Last NAIM

Alias(es, nicknames, name changes, etc.) NONE

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address 580 E. WINDMILL LANE, STE 125

City LAS VEGAS State NV Zip 89123

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☑ No RESIDENT OF USA.

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		.

Applicant's initials _____

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ROSEMAN UNIVERSITY		8/15 - 6/18	
Address	**City**	**State**	**Zip**
11 SUNSET WAY,	LAS VEGAS	NV	89014
Diploma/Degree obtained, if any			
PHARM D.			

School Name		From - To (MM/YY – MM/YY)	
UNLV		8/2005 - 2009	
Address	**City**	**State**	**Zip**
4505 S. MARYLAND PKWY	LAS VEGAS	NV	89154
Diploma/Degree obtained, if any			
BIOLOGICAL SCIENCES / CHEMISTRY BS			

School Name		From - To (MM/YY – MM/YY)	
COMMUNITY COLLEGE HIGH SCHOOL - WEST		8/2004 - 6/2004	
Address	**City**	**State**	**Zip**
6375 W. CHARLESTON Blvd	LAS VEGAS	NV	89146
Diploma/Degree obtained, if any			
ADVANCED HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
CIMARRON HIGH		8/2002 - 8/2004	
Address	**City**	**State**	**Zip**
2301 N. TENAYA WAY	LAS VEGAS	NV	89128
Diploma/Degree obtained, if any			
TRANSFERRED TO CCSN - WEST HIGH			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/20 - present	[redacted] Silver Bit Ct	NLV	NV	89023
10/18 - 6/20	[redacted] Fountain Ave	W. Hollywood	CA	90046
6/18 - 10/18	[redacted] Crystal Ct.	Beaumont	CA	92223
8/12 - 6/18	[redacted] Silver Bit Ct.	NLV	NV	89032
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
TMS PHARMACY LLC			2/22 - PRESENT
Business Address	**City**	**State**	**Zip**
580 E. WINOMILL LANE, Ste 135	LV	NV	89128
Phone	**Title**	**Number of Employed Hours**	
(702)(725)204-9605	GRAD INTERN	2736	
Description of Duties			
Under Supervision of Rph - consulting pts, filling + verifying Rx's, Admin duties			

Business Name			From - To (MM/YY – MM/YY)
DESERT OASIS HEALTHCARE			6/18 - 5/19
Business Address	**City**	**State**	**Zip**
275 El Cielo Rd	Palm Springs	CA	92262
Phone	**Title**	**Number of Employed Hours**	
760-320-8814	PHARMACY RESIDENT	1760	
Description of Duties			
MTM, managed pts in the COPD, DM, ID, Antiviral Clinics, workshop lead, teach, poster presentation, IPPE/APPE preceptorship.			

Business Name			From - To (MM/YY – MM/YY)
SAHARA PHARMACY			8/15 - 7/19
Business Address	**City**	**State**	**Zip**
7075 W. ANN Rd	LV	NV	89130
Phone	**Title**	**Number of Employed Hours**	
702-395-6912	INTERN	2160	
Description of Duties			
Assessment & pt profiles, fill Rx's, pt. counseling, communication w/ pts, and medical personnel, inventory taking			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Applicant's initials _____

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date 8/1/23

Applicant's initials _____

I, SHAWA NAIM, **certify that as the designated representative for**

ALL WESTLAKE PHARMACY,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

SHAWA NAIM

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/1/23

Date

Applicant's initials

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SALWA NAIM
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/14/23
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Salwa Naim, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/14/23
Date

Subscribed and Sworn to before me this 14th day of August, 2023.

Notary Public Signature

EDWIN LUNA CARRENO
Notary Public - State of Nevada
County of Clark
APPT. NO. 21-2857-01
My App. Expires Apr. 26, 2025
[Seal]

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☐ Out-of-State	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Freestanding Emergency Department	☐ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Pyxis Automated Dispensing Cabinet

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ER at North LasVegas, an Extension of Valley Hospital

Physical Address: 6625 N. 5th St

City: North Las Vegas State: NV Zip: 89084

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 702-545-2800 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-545-28010 Contact Email: zephanye.sistrunk@uhsinc.com

Website: _____

Nevada Business License # (if applicable) NV19981003340

Supervising/Managing Pharmacist Name (NRS 639.220): Talia Jespersen

Supervising/Managing Pharmacist NV Pharmacist Registration #: 19077

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015). (Use a separate piece of paper if additional space is needed.)

Name: Zephanye Sistrunk	NV Pharmacist Registration #: 17084
Name: Jennifer Rogers	NV Pharmacist Registration #: 18277
Name: Selina Dang	NV Pharmacist Registration #: 20280
Name: Himani Mehta	NV Pharmacist Registration #: 17834
Name: Talia Jespersen	NV Pharmacist Registration #: 19077
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: DELAWARE

Parent Company (if any): UNIVERSAL HEALTH SERVICES, INC. (ultimate parent company)

Corporation Name: VALLEY HEALTH SYSTEM LLC

Mailing Address: 367 S. GULPH ROAD

City: KING OF PRUSSIA State: PA Zip: 19406-3121

Telephone: 610-768-3300 Email: uhscorpfilings@uhsinc.com

Contact Person Name: STEVE FILTON

Date of SEC Registration: 09/08/1981 | SEC Registration Number: 1-1-765 | Stock Exchange Symbol: UHS

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☒ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the MANAGING PHARMACIST (title) for ER at North Las Vegas, an Extension of Valley (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Talia Jespersen

Print Name of Authorized Person

Talia Jespersen

Original signature of Authorized Person (copies or stamps not accepted)

5/17/23

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Talia Jespersen hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the MANAGING PHARMACIST (title) for ER at North Las Vegas, an Extension of Valley (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Talia Jespersen
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 17 day of August, 2023

Janice Marie Schwab
Notary Public

JANICE MARIE SCHWAB
Notary Public, State of Nevada
Appointment No. 14-12761-1
My Appt. Expires Feb 20, 2026

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Talia Jespersen Pharmacist Registration #: 19077

Pharmacy Name: ER at North Las Vegas, an Extension of Valley Hospital

Initial each statement below to indicate you have read and agree with the following:

TJ I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

TJ I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

TJ I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

TJ I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

TJ I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Talia Jespersen — Original signature of Managing Pharmacist (copies or stamps not accepted)

8/17/23 — Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Talia Jespersen

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Talia Jespersen — 8/17/23

Original signature of Authorized Person (copies or stamps not accepted) — Date

Board Use Only	Date Received: 8/21/23	Amount: 500 - cc

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

VALLEY HEALTH SYSTEM LLC

Nevada Business Identification # NV19981003340
Expiration Date: 01/31/2024

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/09/2023.

Certificate Number: B202301093294239
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VALLEY HEALTH SYSTEM LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF AUGUST, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "VALLEY HEALTH SYSTEM LLC" WAS FORMED ON THE SIXTEENTH DAY OF JANUARY, A.D. 1998.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2847793 8300

SR# 20233236298

Authentication: 203953874

Date: 08-14-23

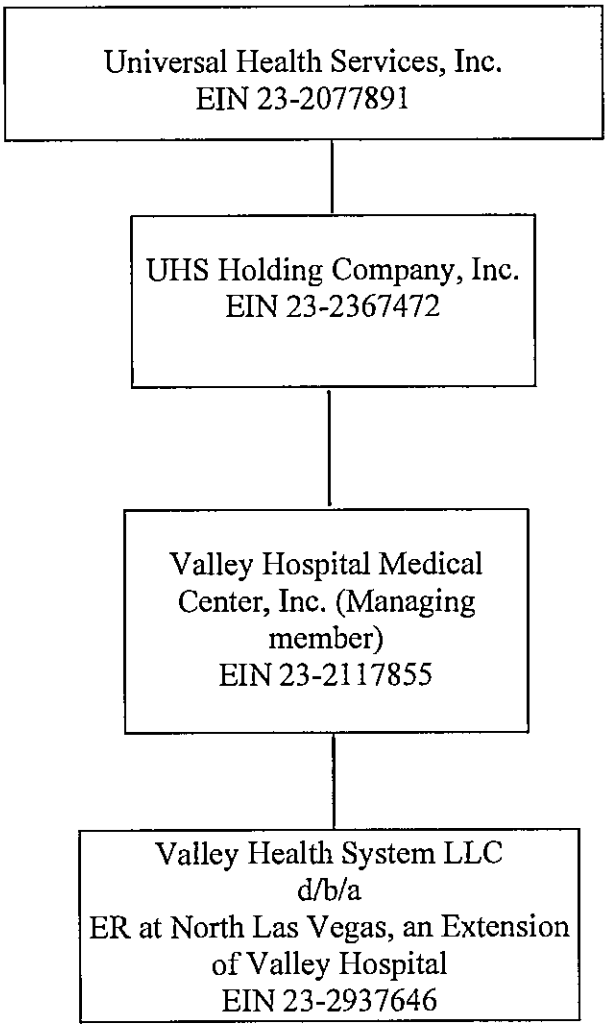
You may verify this certificate online at corp.delaware.gov/authver.shtml

- **List all Officers and Directors: NRS 639.231(2)(b), NAC 639.214(5)(a)**
  - Edward Sim – President (Director)
  - Steve Filton – Vice President (Director)
  - Matthew Klein – Vice President, Secretary (Director)
  - George H. Brunner, Jr. – Assistant Secretary
  - Cheryl K. Ramagano – Treasurer
  - Robert Zurad – Assistant Treasurer

- **List the top four stockholders and their percent ownership. NRS 639.231(3)**

  For UHS, Inc.: Alan B. Miller – 11.9%; The Vanguard Group – 11.5%; FMR LLC – 8.1%; BlackRock, Inc. – 7.3%

VALLEY HEALTH SYSTEM, LLC
CORPORATE STRUCTURE



Notes-

Management Agreement between UHS of Delaware, Inc., and Valley Health System LLC.

Detailed Ownership Information

Valley Hospital Medical Center, owns and operates Valley Health System, LLC

Valley Hospital Medical Center, Inc. is the Sole Member of Valley Health System, LLC

Valley Hospital Medical Center, Inc. is owned by UHS Holding Company, Inc.

UHS Holding Company, Inc. is owned by Universal Health Services, Inc. (the ultimate parent company)

FRANCISCO V. AGUILAR
Secretary of State

GABRIEL DI CHIARA
Chief Deputy

STATE OF NEVADA

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings & Notary Division
202 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

UHS of Delaware
367 S. Gulph Road
King of Prussia, PA 19406, USA

Work Order #: W2023010900369
January 9, 2023
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 40412

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Annual List	Fees	20232868150	1/9/2023 8:43:08 AM	Approved	1	$150.00	$150.00
Annual List	Business License Fee	20232868150	1/9/2023 8:43:08 AM	Approved	1	$200.00	$200.00
Total							$350.00

Payments

Type	Description	Payment Status	Amount
Credit Card	6732825726656707003058	Success	$350.00
Total			$350.00

Credit Balance: $0.00

UHS of Delaware
367 S. Gulph Road
King of Prussia, PA 19406, USA

FRANCISCO V. AGUILAR
Secretary of State

GABRIEL DI CHIARA
Chief Deputy

STATE OF NEVADA

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings Division
202 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

01/09/2023

Work Order Item Number:	W2023010900369 - 2620014
Filing Number:	20232868150
Filing Type:	Annual List
Filing Date/Time:	01/09/2023 08:43:08 AM
Filing Page(s):	2

Indexed Entity Information:

Entity ID: LLC295-1998

Entity Name: VALLEY HEALTH SYSTEM LLC

Entity Status: Active

Expiration Date: 01/21/2498

Commercial Registered Agent
CORPORATION SERVICE COMPANY
112 NORTH CURRY STREET, Carson City, NV 89703, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

FRANCISCO V. AGUILAR
Secretary of State

STATE OF NEVADA

FRANCISCO V. AGUILAR
Secretary of State

GABRIEL DI CHIARA
Chief Deputy

OFFICE OF THE
SECRETARY OF STATE

Commercial Recordings & Notary Division
202 N. Carson Street
Carson City, NV 89701
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North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

UHS of Delaware
367 S. Gulph Road
King of Prussia, PA 19406, USA

Work Order #: W2023011201373
January 12, 2023
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 40412

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Certificates	Fees	20232878063	1/12/2023 12:45:25 PM	Approved	1	$50.00	$50.00
Total							$50.00

Payments

Type	Description	Payment Status	Amount
Credit Card	6735563074476134703280	Success	$50.00
Total			$50.00

Credit Balance: $0.00

UHS of Delaware
367 S. Gulph Road
King of Prussia, PA 19406, USA

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **VALLEY HEALTH SYSTEM LLC**, as a FOREIGN LIMITED-LIABILITY COMPANY duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 01/21/1998, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/12/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202301123306118
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application

☑ ANNUAL ☐ AMENDED (check one)

List of Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

VALLEY HEALTH SYSTEM LLC	NV19981003340
NAME OF ENTITY	Entity or Nevada Business Identification Number (NVID)

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☐ Corporation
- ☐ This corporation is publicly traded, the Central Index Key number is: ____

☐ Nonprofit Corporation (see nonprofit sections below)

☑ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership

☐ Business Trust

☐ Corporation Sole

Filed in the Office of	Business Number
F V Aguilar	LLC295-1998
	Filing Number
	20232868150
Secretary of State	Filed On
State Of Nevada	01/09/2023 08:43:08 AM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

☐ 001 - Governmental Entity

☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number ____

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming an exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

☐ No - no additional form is required

☐ Yes - the "Charitable Solicitation Registration Statement" is required.

☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

FRANCISCO V. AGUILAR
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

CORPORATION, INDICATE THE MANAGING MEMBER:

Name	Country
VALLEY HOSPITAL MEDICAL CENTER INC	

Address	City	State	Zip/Postal Code
367 SOUTH GULPH ROAD	KING OF PRUSSIA	PA	19406-0958

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

X Steve Filton
Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Subscriber, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Title	Date
Authorized Signer	01/09/2023

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-State	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Non-sterile Compounding
	☐ Location Change *	☐ Internet	☐ Sterile Compounding
	☐ Name Change*	☐ Nuclear	☐ Mail-Order Service
		☐ Other:	☐ Off-site Cognitive Services
	* If making a change, provide license #:		☐ Long Term Care
			☐ Hospital
	PH _____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Genoa Healthcare LLC

Physical Address: 6039 Eldora Ave, Suite E

City: Las Vegas State: NV Zip: 89146

Mailing Address (if different from physical address): 11000 Optum Circle, Suite 100

City: Eden Prairie State: MN Zip: 55344

Telephone: 725-279-2999 Toll Free # (NAC 639.708, NRS 639.23286): 1-800-519-1139

Fax: Pending Contact Email: genpharmlic@optum.com

Website: www.genoahealthcare.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Jodie Becker

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23472

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Jodie Becker	NV Pharmacist Registration #: 23472
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: PA

Parent Company (if any): Specialized Pharmaceutical, Inc

Corporation/Organization Name: _____

Mailing Address: 707 S Grady Way, Suite 700

City: Renton State: WA Zip: 98057

Telephone: 253-218-0830 Email: genpharmlic@optum.com

Contact Person Name: Karen Bohmer

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: PA

Parent Company (if any): Specialize Pharmaceutical, Inc

Corporation/Organization Name: _____

Mailing Address: 707 S Grady Way, Suite 700

City: Renton State: WA Zip: 98057

Telephone: 253-218-0830 Email: genpharmlic@optum.com

Contact Person Name: Karen Bohmer

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Secretary (title) for Genoa Healthcare LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Karen Bohmer

Print Name of Authorized Person

Karen E Bohmer

Original signature of Authorized Person (copies or stamps not accepted)

5/12/23

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Jodie Becker Pharmacist Registration #: 23472

Pharmacy Name: Genoa Healthcare LLC

Initial each statement below to indicate you have read and agree with the following:

JB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

JB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

JB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

JB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

JB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:
N/A	N/A	N/A	N/A

Criminal Action:	State:	Date:	Case #:	County:	Court:
Driving under influence/alcohol	CA	03/07/2000	1004711	Stanislaus	Stanislaus

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

05/03/2023
Date

Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)	✓	✓		
• List the top four stockholders and their percent ownership. NRS 639.231(3)	✓	✓		
• List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)		✓		
• For General Partnerships, list the name of each partner. NAC 639.214(2) • For Limited Partnerships, list the names of (NAC 639.214(3)): o All General Partners; o All Limited Partners who hold 10% or more of the interest.			✓	
• Certificate of Corporate Status or Certificate of Good Standing from the Secretary of State's Office where the business is domiciled, dated within the last 6 months.	✓	✓	✓	✓
• Designated Representative Form http://bop.nv.gov/Services/newapps/Business/ must be completed by the Designated Representative. NAC 639.5005. The requirement does not apply to: a. An applicant or a licensee that is a publicly traded corporation; b. An applicant or licensee whose pharmacy is determined by the Board to be located within a large retail store, including, without limitation, a grocery store, variety store or department store under common ownership; or c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• Personal History Record Application http://bop.nv.gov/Services/newapps/Business/ must be completed by: a. For Non-publicly traded - The top 4 shareholder/stockholders. b. For Partnerships - All general partners; all limited partners who hold 10% or more of the interest. c. For Sole Owner - The owner.		✓	✓	✓
• Sterile Compounding Questionnaire must be completed if the pharmacy will provide sterile compounded drugs. Access form at http://bop.nv.gov/Services/newapps/Business/.	✓	✓	✓	✓
• Submit a copy of your most recent pharmacy inspection from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. (REQUIRED FOR NON-NEVADA PHARMACIES ONLY) NRS 639.2328(2)(f)	✓	✓	✓	✓
• Submit a copy of your license, certification, permit or registration issued to your pharmacy from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. (REQUIRED FOR NON-NEVADA PHARMACIES ONLY) NRS 639.2328(2)(a)	✓	✓	✓	✓
• License Verification by the regulatory board or licensing authority of the state or territory in which the pharmacy is located. You may use the License Verification form here: http://bop.nv.gov/Services/newapps/Business/. (REQUIRED FOR NON-NEVADA PHARMACIES ONLY) NRS 639.2238(2)(g)	✓	✓	✓	✓
• Copy of DEA Registration if handling controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)	✓	✓	✓	✓
• Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)	✓	✓	✓	✓
• Transmit Controlled Substance Prescription Data- Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Karen Bohmer

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Karen Bohmer

Original signature of Authorized Person (copies or stamps not accepted)

5/12/23

Date

Board Use Only	Date Received: _____	Amount: 500.00 # 12889411

On March 7th 2000 I violated a very important California law by driving under the influence of alcohol with a blood alcohol level of between .10 and .11. My charges were the following: VC 23152: (a) It is unlawful for any person who is under the influence of any alcoholic beverage or drug, or under the combined influence of any alcoholic beverage and drug, to drive a vehicle. (b) It is unlawful for any person who has 0.08 percent or more, by weight, of alcohol in his or her blood to drive a vehicle. For purposes of this article and Section 34501.16, percent, by weight, of alcohol in a person's blood is based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath.

In this case I paid a heavy fine of over eleven hundred dollars, in addition to this, my driver's license was suspended and I had to attend a weekly education program for three months.

The location of this situation took place in Modesto, California. The circumstances surrounding this situation, was in part work-related. At this time I worked at a local restaurant where I was a server. After work I stayed to have some food and a drink with co-workers and before I knew it one of our co-workers ended up drinking more than her fair share of alcoholic beverages. Therefore I miss judged my body weight per alcohol consumption and offered to drive her home. It was on my way to her house that I was pulled over and given this citation. By no way am I denying my lack of judgment but I am merely providing an explanation to a very embarrassing situation of my past.

In addition to this violation, on October 10, 2002 I fell in violation of VC 23103 (BAC .10-.08). This being a similar situation, of working at a restaurant in Sacramento, California, were we would frequently be asked by management to do wine pairing tests with wine and food. This particular evening I received a phone call from a friend in distress that needed me to come pick her up downtown Sacramento, California. At this time, I didn't feel impaired to drive my vehicle and being shaken up by my friend's phone call, I quickly left without thinking about the alcohol that I had just consumed.

In this particular situation I felt that my alcohol content was well within the limits of the law, therefore I hired an attorney to help me with this case. My attorney and I found numerous mistakes within the arresting officer's documentation and therefore the court drastically reduced my fine. In addition, DMV dismissed this charge and my license was not suspended, due to reasonable doubt on being over the legal limit. Likewise with the court, I received a fine of eight hundred dollars and community service of five days.

This situation was very upsetting, embarrassing, and disturbing for myself, which invoked major changes to my life. I quit my place of employment, of working in a restaurant, and started pursuing my education full-time with work in a screen printing shop on a part-time bases. I can honestly say without a doubt that this situation scared me to never drink and drive again. These two horrible choices of drinking and driving and the circumstances surrounding the outcome of doing such a thing, has made me the person I am today. I am strong, determined, educated on the facts of drinking and driving, and motivated in making my life successful. In addition, when I get the chance

05/02/2023

of watching a person who is thinking about getting in the car after a few alcoholic beverages I strongly advise them not to do something so stupid, and I follow up with discussion about my situations of the past.

If this letter requires any further information please feel free in contacting me at [redacted] Also my attorney stated that if need be he could provide any assistance on this matter with letters or conversations (phone: 916-457-0132).

05/03/2023

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Karen Bohmer hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary (title) for Genoa Healthcare LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Karen A Bohmer
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 20th day of MARCH, 2023

Aileen M Warren
Notary Public

AILEEN M WARREN
Official Seal
Notary Public - State of Illinois
My Commission Expires Jan 25, 2025

genOa healthcare

Genoa Healthcare LLC

FEIN: 27-0556097
Corporate Address: 707 S. Grady Way., Ste 700
Renton, WA 98057
Phone: (253) 218-0830
Fax: (253) 217-4306
Email: genpharmlic@optum.com

Officers of the Board of Genoa Healthcare LLC

** Officers have 0% ownership in Genoa Healthcare LLC.*

Name	Title	Address	Ownership Percentage
Todd V. Gustin	President/ CEO	11000 Optum Circle Suite 100 Eden Prairie, MN 55344	0%
Karen Elizabeth Bohmer	Secretary	11000 Optum Circle Suite 100 Eden Prairie, MN 55344	0%
Timothy Joseph Langdon	Assistant Secretary	11000 Optum Circle Suite 100 Eden Prairie, MN 55344	0%
Heather Anastasia Lang	Assistant Secretary	11000 Optum Circle Suite 100 Eden Prairie, MN 55344	0%
Peter Marshall Gill	Treasurer	11000 Optum Circle Suite 100 Eden Prairie, MN 55344	0%

Owner of Genoa Healthcare LLC	Ownership Percentage	FEIN	Address
Specialized Pharmaceuticals, Inc.	100%-direct owner	25-1868213	707 S. Grady Way, Ste. 700 Renton, WA 98057

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **GENOA HEALTHCARE LLC**, as a FOREIGN LIMITED-LIABILITY COMPANY duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 09/14/2018, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/28/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202307283838278
You may verify this certificate online at http://www.nvsos.gov

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Genoa Healthcare LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 6039 Eldora Ave, Suite E

City Las Vegas State NV Zip 89146

Mailing Address (if different from physical address) 11000 Optum Circle, Suite 100

City Eden Praire State MN Zip 55344

Telephone 725-279-2999 Website www.genoahealthcare.com

Licensing Company Email genpharmlic@optum.com

Section 2: Personal Information

First Jodie Middle Lynn Last Becker

Alias(es, nicknames, name changes, etc.) Schmidt

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] via colonna Ter

City Davis State CA Zip 95618

Telephone 916-719-0012 Email jbecker@genoahealthcare.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Thomas J. Long School of Pharmacy, University of the Pacific		08/07 - 08/10	
Address	**City**	**State**	**Zip**
751 Brookside Rd	Stockton	CA	95211
Diploma/Degree obtained, if any			
Doctor of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
California State University, Sacramento		09/04 - 07/06	
Address	**City**	**State**	**Zip**
6000 J St.	Sacramento	CA	95819
Diploma/Degree obtained, if any			
Biological Science (Bachelor of Arts)			
School Name		**From - To (MM/YY – MM/YY)**	
Sierra Junior College		09/02 - 06/04	
Address	**City**	**State**	**Zip**
5000 Rocklin Rd	Rocklin	CA	95677
Diploma/Degree obtained, if any			
Associates of Arts & Science			
School Name		**From - To (MM/YY – MM/YY)**	
Ceres High School		08/91 06/95	
Address	**City**	**State**	**Zip**
2320 Central Ave	Ceres	CA	95307
Diploma/Degree obtained, if any			
Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/19 → 07/23 Current	[redacted] via Colonna Terrace	Davis	CA	95618
06/17 - 08/19	[redacted] Arroyo Pte	Davis	CA	95618
09/12 - 06/17	[redacted] Allen Wood Cir	Lincoln	CA	95648
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Genoa Healthcare LLC.			10/22 – 03/23 Current
Business Address	**City**	**State**	**Zip**
6950 65th Street	Sacramento	CA	95823
Phone	**Title**	**Number of Employed Hours**	
916-490-3824	Float Pharmacist	1797	
Description of Duties			
Verifying orders, Receiving Inventory, DUR, CMR, MTM, typing orders, helping Providers.			

Business Name			From - To (MM/YY – MM/YY)
Eagle Drug			06/15 – 07/21
Business Address	**City**	**State**	**Zip**
101 main St	Winters	CA	95694
Phone	**Title**	**Number of Employed Hours**	
530-795-4123	Owner/Pharmacist in Charge	15,600	
Description of Duties			
Verifying orders, Receiving inventory, managing pharmacy, front-end, employees, Profit/loss accounting, compliance, advertising, merchandising, community outreach.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/07/2000	05/02/2000	CA	Modesto	Stanislaus

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
1004711	Modesto Police Department

Reason/Charge
Driving under the influence - alcohol

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Nolo contendre / plaintiff	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:

See attached:

next page.

J. W. Baker

Original Signature (electronic, copies or stamps not accepted)

07/24/2023

Date

On March 7th 2000 I violated a very important California law by driving under the influence of alcohol with a blood alcohol level of between .10 and .11. My charges were the following: VC 23152: (a) It is unlawful for any person who is under the influence of any alcoholic beverage or drug, or under the combined influence of any alcoholic beverage and drug, to drive a vehicle. (b) It is unlawful for any person who has 0.08 percent or more, by weight, of alcohol in his or her blood to drive a vehicle. For purposes of this article and Section 34501.16, percent, by weight, of alcohol in a person's blood is based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath. In this case I paid a heavy fine of over eleven hundred dollars, in addition to this, my driver's license was suspended and I had to attend a weekly education program for three months. The location of this situation took place in Modesto, Califomia. The circumstances surrounding this situation, was in part work-related. At this time I worked at a local restaurant where I was a server. After work I stayed to have some food and a drink with co-workers and before I knew it one of our co-workers ended up drinking more than her fair share of alcoholic beverages. Therefore I miss judged my body weight per alcohol consumption and offered to drive her home. It was on my way to her house that I was pulled over and given this citation. By no way am I denying my lack volaton,. on october 10, 2802 velin violation nave 28 over Acna: ass. inis baling a smilar stuation. dr workng ata restaurant in Sacramento, California, were we would frequently be asked by management to do wine pairing tests with wine and food. This particular evening I received a phone call from a friend in distress that needed me to come pick her up downtown Sacramento, California. At this time, I didn't feel impaired to drive my vehicle and being shaken up by my friend's phone call, I quickly left without thinking about the alcohol that I had just consumed. In this particular situation I felt that my alcohol content was well within the limits of the law, therefore I hired an attorney to help me with this case. My attorney and I found numerous mistakes within the arresting officer's documentation and therefore the court drastically reduced my fine. In addition, DMV dismissed this charge and my license was not suspended, due to reasonable doubt on being over the legal limit. Likewise with the court, I received a fine of eight hundred dollars and community service of five days. This situation was very upsetting, embarrassing, and disturbing for myself, which invoked major changes to my life. I quit my place of employment, of working in a restaurant, and started pursuing my education full-time with work in a screen printing shop on a part-time bases. I can honestly say without a doubt that this situation scared me to never drink and drive again. These two horrible choices of drinking and driving and the circumstances surrounding the outcome of doing such a thing, has made me the person I am today. I am strong, determined, educated on the facts of drinking and driving, and motivated in making my life successful. In addition, when I get the chance of watching a person who is thinking about getting in the car after a few alcoholic beverages I strongly advise them not to do something so stupid, and I follow up with discussion about my situations of the past. If this letter requires any further information please feel free in contacting me at
916-719-0012. Also my attorney stated that if need be he could provide any assistance on this matter with letters or conversations (phone: 916-457-0132).

07/24/2023

I, Jodie Becker, **certify that as the designated representative for**

Genoa Healthcare LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jodie Becker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/24/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jodie Becker
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/24/2023
Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Yolo

I, Jodie Becker, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

07/24/2023
Date

Subscribed and Sworn to before me this 24 day of July 2023.

Notary Public Signature

SENECA V. WASHINGTON
COMM. # 2359476
NOTARY PUBLIC - CALIFORNIA
SACRAMENTO COUNTY
COMM. EXPIRES MAY 29, 2025

(Seal)

4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☐ Out-of-State	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: PRIME CARE PHARMACY

Physical Address: 4445 S EASTERN AVE STE 2

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): 2585 S Nellis Blvd Ste 3

City: Las Vegas State: NV Zip: 89121

Telephone: (702) 745-3500 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: (702) 745-4093 Contact Email: _____

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): WASEEM SARWAR

Supervising/Managing Pharmacist NV Pharmacist Registration #: 20752

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: WASEEM SARWAR	NV Pharmacist Registration #: 20752
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEVADA

Parent Company (if any): _____

Corporation/Organization Name: PRIME CARE PHARMACY

Mailing Address: 2585 S Nellis Blvd Ste 3

City: Las Vegas State: NV Zip: 89121

Telephone: (702) 745-3500 Email: info.primecarerx@gmail.com

Contact Person Name: WASEEM SARWAR

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PRESIDENT (title) for PRIME CARE PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

WASEEM SARWAR

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

06/06/23

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: WASEEM SARWAR Pharmacist Registration #: 20752

Pharmacy Name: PRIME CARE PHARMACY

Initial each statement below to indicate you have read and agree with the following:

WS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

WS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

WS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

WS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

WS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

06/06/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

WASEEM SARWAR

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

06/06/23

Date

Board Use Only	Date Received: 8/23/23	Amount: 500-CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PRIME CARE PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 4555 S EASTERN AVE STE 2

City Las Vegas State NV Zip 89119

Mailing Address (if different from physical address) 2585 S Nellis Blvd Ste 3

City Las Vegas State NV Zip 89121

Telephone (702) 745-3500 Website _____

Licensing Company Email info.primecarerx@gmail.com

Section 2: Personal Information

First WASEEM Middle _____ Last SARWAR

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] S Nellis Blvd Ste [redacted]

City Las Vegas State NV Zip 89121

Telephone [redacted] Email info.primecarerx@gmail.com

Are you a citizen of the United States? ☑ Yes ☑ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF THE PUNJAB		01/2008-05/2013	
Address	**City**	**State**	**Zip**
ALLAMA IQBAL CAMPUS, MALL ROAD	LAHORE	PUNJAB	54000
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
GOVT ISLAMIA COLLEGE		01/2005-12/2007	
Address	**City**	**State**	**Zip**
NEAR KACHEHRI,LOWER MALL ROAD	LAHORE	PUNJAB	54000
Diploma/Degree obtained, if any			
HIGHER SECONDARY SCHOOL CERTIFICATE			

School Name		From - To (MM/YY – MM/YY)	
DON BOSCO HIGH SCHOOL		01/1994 - 12/2005	
Address	**City**	**State**	**Zip**
NEAR POLICE LINES, EMPRESS ROAD	LAHORE	PUNJAB	54000
Diploma/Degree obtained, if any			
SECONDARY SCHOOL CERTIFICATE			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/22-PRESENT	[redacted]E HARMON AVE APT [redacted]	LAS VEGAS	NV	89119
10/21-10/22	[redacted]OGALLALA STREET UNIT[redacted]	PAHRUMP	NV	89048
06/18-09/21	[redacted]116 STREET	SOUTH RICHMOND HILL	NY	11419
03/18-05/18	1[redacted]LIBERTY AVENUE	SOUTH RICHMOND HILL	NY	11419
06/15-02/18	[redacted]LEFFERTS BLVD	SOUTH OZONE PARK	NY	11420
04/14-04/15	[redacted]97 STREET	WOOHHAVEN	NY	11421
03/89-04/14	[redacted]QAZAL BASH ROAD	LAHORE, PAKISTAN	PUNJAB	54000
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SAHARA PHARMACY			12/12 - PRESENT
Business Address	**City**	**State**	**Zip**
2585 S NELLIS BLVD STE 3	LAS VEGAS	NV	89121
Phone	**Title**		
(702) 912-0800	PHARMACIST - OWNER / OPERATOR		

Description of Duties

SUPERVISE DAILY OPERATIONS OF THE PHARMACY

Business Name			From - To (MM/YY – MM/YY)
PAHRUMP CARE PHARMACY			08/21 - PRESENT
Business Address	**City**	**State**	**Zip**
1500 E HIGHWAY 372, STE E	PAHRUMP	NV	89048
Phone	**Title**		
(775) 727-3905	PHARMACIST - OWNER / OPERATOR		

Description of Duties

SUPERVISE DAILY OPERATIONS OF THE PHARMACY

Business Name			From - To (MM/YY – MM/YY)
RITE AID PHARMACY			02/20 - 12/20
Business Address	**City**	**State**	**Zip**
840 WESTCHESTER AVE	BRONX	NY	10459
Phone	**Title**		
(718) 378-4600	PHARMACIST MANAGER		

Description of Duties

SUPERVISE DAILY OPERATIONS OF THE PHARMACY

Business Name			From - To (MM/YY – MM/YY)
MEERAJ PHARMACY			01/18 - 02/20
Business Address	**City**	**State**	**Zip**
115-17 LIBERTY AVENUE	SOUTH RICHMOND HILL	NY	11419
Phone	**Title**		
(718) 641-4400	PHARMACIST		

Description of Duties

SUPERVISE DAILY OPERATIONS OF THE PHARMACY

Business Name			From - To (MM/YY – MM/YY)
MEERAJ PHARMACY			06/15 - 01/18
Business Address	**City**	**State**	**Zip**
115-17 LIBERTY AVENUE	SOUTH RICHMOND HILL	NY	11419
Phone	**Title**		
(718) 641-4400	PHARMACY INTERN		

Description of Duties

WORK UNDER THE SUPERVISION OF PHARMACIST AND ASSIST THE PHARMACIST IN CARRYING OUT THE DAILY ACTIVITIES OF THE PHARMACY.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
MS BASHIR PHARMACY			07/13-06/15	
Business Address		City	State	Zip
SHOP NO 1& 2, STREET 13, WALTON ROAD		LAHORE	PUNJAB	54000
Phone	Title			
03214061992	PHARMACIST			
Description of Duties				
SUPERVISE DAILY OPERATIONS OF THE PHARMACY				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

WASEEM SARWAR

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/06/23

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, WASEEM SARWAR, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/06/23

Date

Subscribed and Sworn to before me this 06 day of JUNE 2023.

Notary Public Signature

SHAUN J FEDERICO
Notary Public-State of Nevada
APPT. NO. 19-9303-01
My Appt. Expires 08-04-2023

(Seal)

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

PRIME CARE PHARMACY

Nevada Business Identification # NV20232806741
Expiration Date: 06/30/2024

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 06/05/2023.

Certificate Number: B202306053706970
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State

FRANCISCO V. AGUILAR
Secretary of State

GABRIEL DI CHIARA
Chief Deputy

STATE OF NEVADA

OFFICE OF THE
SECRETARY OF STATE

Commercial Recordings Division
202 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

06/05/2023

Work Order Item Number:	W2023060502086 - 2953493
Filing Number:	20233247502
Filing Type:	Articles of Incorporation-For-Profit
Filing Date/Time:	06/05/2023 22:49:59 PM
Filing Page(s):	2

Indexed Entity Information:

Entity ID: E32475032023-0

Entity Name: PRIME CARE PHARMACY

Entity Status: Active

Expiration Date: None

Non-Commercial Registered Agent
WASEEM SARWAR
2585 S NELLIS BLVD STE 3, Las Vegas, NV 89121, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

FRANCISCO V. AGUILAR
Secretary of State

LIST OF OFFICERS AND DIRECTORS

WASEEM SARWAR is the sole member of PRIME CARE PHARMACY, and he is the President / Authorized official of PRIME CARE PHARMACY He own 100% shares of the corporation.

Contact Info:

WASEEM SARWAR

Address: [redacted] E Harmon Ave Apt [redacted]

Las Vegas, NV 89119

Phone : [redacted]

Email: [redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PRIME CARE PHARMACY

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 4555 S EASTERN AVE STE 2

City Las Vegas State NV Zip 89119

Mailing Address (if different from physical address) 2585 S Nellis Blvd Ste 3

City Las Vegas State NV Zip 89121

Telephone (702) 745-3500 Website _____

Licensing Company Email info.primecarerx@gmail.com

Section 2: Personal Information

First WASEEM Middle _____ Last SARWAR

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]S Nellis Blvd Ste[redacted]

City Las Vegas State NV Zip 89121

Telephone [redacted] Email info.primecarerx@gmail.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF THE PUNJAB		01/2008-05/2013	
Address	**City**	**State**	**Zip**
ALLAMA IQBAL CAMPUS, MALL ROAD	LAHORE	PUNJAB	54000
Diploma/Degree obtained, if any			
PHARM D			

School Name		From - To (MM/YY – MM/YY)	
GOVT ISLAMIA COLLEGE		01/2005-12/2007	
Address	**City**	**State**	**Zip**
NEAR KACHEHRI,LOWER MALL ROAD	LAHORE	PUNJAB	54000
Diploma/Degree obtained, if any			
HIGHER SECONDARY SCHOOL CERTIFICATE			

School Name		From - To (MM/YY – MM/YY)	
DON BOSCO HIGH SCHOOL		01/1994 - 12/2005	
Address	**City**	**State**	**Zip**
NEAR POLICE LINES, EMPRESS ROAD	LAHORE	PUNJAB	54000
Diploma/Degree obtained, if any			
SECONDARY SCHOOL CERTIFICATE			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/22-PRESENT	[redacted] E HARMON AVE APT [redacted]	LAS VEGAS	NV	89119
10/21-10/22	[redacted] OGALLALA STREET UNIT[redacted]	PAHRUMP	NV	89048
06/18-09/21	[redacted]116 STREET	SOUTH RICHMOND HILL	NY	11419
03/18-05/18	[redacted] LIBERTY AVENUE	SOUTH RICHMOND HILL	NY	11419
06/15-02/18	[redacted] LEFFERTS BLVD	SOUTH OZONE PARK	NY	11420
04/14-04/15	[redacted]97 STREET	WOOHHAVEN	NY	11421
03/89-04/14	[redacted]QAZAL BASH ROAD	LAHORE, PAKISTAN	PUNJAB	54000
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
SAHARA PHARMACY			12/12 - PRESENT
Business Address	**City**	**State**	**Zip**
2585 S NELLIS BLVD STE 3	LAS VEGAS	NV	89121
Phone	**Title**		**Number of Employed Hours**
(702) 912-0800	PHARMACIST - OWNER / OPERATOR		40HOURS / WEEK
Description of Duties			
SUPERVISE DAILY OPERATIONS OF THE PHARMACY			

Business Name			From - To (MM/YY – MM/YY)
PAHRUMP CARE PHARMACY			08/21 - PRESENT
Business Address	**City**	**State**	**Zip**
1500 E HIGHWAY 372, STE E	PAHRUMP	NV	89048
Phone	**Title**		**Number of Employed Hours**
(775) 727-3905	PHARMACIST - OWNER / OPERATOR		5 HOURS / WEEK
Description of Duties			
SUPERVISE DAILY OPERATIONS OF THE PHARMACY			

Business Name			From - To (MM/YY – MM/YY)
RITE AID PHARMACY			02/20 - 12/20
Business Address	**City**	**State**	**Zip**
840 WESTCHESTER AVE	BRONX	NY	10459
Phone	**Title**		**Number of Employed Hours**
(718) 378-4600	PHARMACIST MANAGER		38 HOURS / WEEK
Description of Duties			
SUPERVISE DAILY OPERATIONS OF THE PHARMACY			

Business Name			From - To (MM/YY – MM/YY)
MEERAJ PHARMACY			01/18 - 02/20
Business Address	**City**	**State**	**Zip**
115-17 LIBERTY AVENUE	SOUTH RICHMOND HILL	NY	11419
Phone	**Title**		**Number of Employed Hours**
(718) 641-4400	PHARMACIST		40 HOURS / WEEK
Description of Duties			
SUPERVISE DAILY OPERATIONS OF THE PHARMACY			

Business Name			From - To (MM/YY – MM/YY)
MEERAJ PHARMACY			
Business Address	**City**	**State**	**Zip**
115-17 LIBERTY AVENUE	SOUTH RICHMOND HILL	NY	11419
Phone	**Title**		**Number of Employed Hours**
(718) 641-4400	PHARMACY INTERN		40 HOURS / WEEK
Description of Duties			
WORK UNDER THE SUPERVISION OF PHARMACIST AND ASSIST THE PHARMACIST IN CARRYING OUT THE DAILY ACTIVITIES OF THE PHARMACY.			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
MS BASHIR PHARMACY			07/13-06/15	
Business Address		**City**	**State**	**Zip**
SHOP NO 1& 2, STREET 13, WALTON ROAD		LAHORE	PUNJAB	54000
Phone	**Title**		**Number of Employed Hours**	
03214061992	PHARMACIST		40 HOURS / WEEK	
Description of Duties				
SUPERVISE DAILY OPERATIONS OF THE PHARMACY				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, WASEEM SARWAR, **certify that as the designated representative for**

PRIME CARE PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. WS I am at least 21 years of age;
3. WS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. WS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. WS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. WS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. WS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

WASEEM SARWAR
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/06/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

WASEEM SARWAR

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/06/23

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, WASEEM SARWAR, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/06/2023

Date

Subscribed and Sworn to before me this 06 day of JUNE, 2023.

Notary Public Signature

SHAUN J FEDERICO
Notary Public-State of Nevada
APPT. NO. 19-9303-01
My Appt. Expires 08-04-2023

(Seal)

4XX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☑ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☑ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☐ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☑ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*	M MP01223	☑ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Prism Medical Products, LLC

MDEG Physical Address: 6345 South Pecos Road, Suite 203

City: Las Vegas State: Nevada Zip: 89120

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Email: compliance@prism-medical.com

Name of MDEG Administrator (NAC 639.694): Rana Villamor

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
☑ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☑ Others: See Attached
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____ Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8am - 6pm	■ Tue: 8am - 6pm	■ Wed: 8am - 6pm	■ Thurs: 8am - 6pm	■ Fri: 8am - 6pm
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed for major holidays		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
CMS PTAN for Corporate Office: 5823260001
CMS PTAN for Las Vegas, NV Office Only: 5823260002
Please see attached for additional numbers

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: Prism Medical Products, LLC - See attached documents

Mailing Address: P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 x.4373 Email: compliance@prism-medical.com

Contact Person Name: Elizabeth Hyde

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Cartwright

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7/20/23

Date

Board Use Only	Date Received: 7/25/23	Amount: $500 CK - 02372

PRISM
HOME MEDICAL SUPPLY SPECIALISTS

P. O. BOX 476
ELKIN, NC 28621
PHONE: 1-888-244-6421
FAX: 1-800-975-6321
WWW.PRISM-MEDICAL.COM

July 17, 2023

Nevada State Board of Pharmacy 985
Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

Type of MDEG Products being Sold:

Prism Medical Products, L.L.C. is a DME provider based out of North Carolina that specializes in providing Ostomy Supplies, Surgical Dressings, Urological Supplies, limited Compression Garments, and Breast Pumps to patients via a shipping courier, e.g., FedEx, and accepts assignment for health plan reimbursement.

If you have any questions, please let us know.

ELIZABETH HYDE
ADMINISTRATIVE COMPLIANCE COORDINATOR
COMPLIANCE & GOVERNMENT AFFAIRS

Office (336) 258-4373
Fax (855) 496-2996
elizabethw@prism-medical.com

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Prism Medical Products, LLC Information Sheet

TRADITIONAL STATE MEDICAID ENROLLMENTS

AK: 1652871 (eff. 09/01/2016)

AL: 125216 (eff. 02/03/2007)

AR: 238670741 (eff. 01/15/2020)

AZ: 900533 (eff. 11/01/2013)

CA: 1548367063 (eff. 02/07/2017)

CT: 1548367063 (eff. 11/01/2016)

CO: 1548367063 (eff. 08/03/2018)

DC: 089550700 (eff. 02/26/2013)

DE: 200141712 (eff. 01/19/2016)

FL: 112645100 (eff. 12/31/2020)

GA: 003101519A (eff. 02/01/2011)

IA: 1548367063 (eff. 10/01/2013)

ID: 1548367063 (eff. 04/10/2014)

IL: 753221011001 (eff. 03/07/2012)

IN: 201002170A (eff. 11/01/2011)

KS: 30003958520001 **(Primary)** (eff. 06/30/2017)

KS: 30003958520002 **(MCOs Only)** (eff. 12/30/2020)

KY: 7100723680 (eff. 03/01/2021)

LA: 2137671 (eff. 02/01/2011)

MA: 110112813A (eff. 05/20/2016)

MD: 551509200 (eff. 01/01/2012)

ME: 1548367063 (eff. 10/01/2015)

MI: 1548367063 (eff. 03/13/2012)

MN: 1548367063 (eff. 06/06/2016)

MO: 620007567 (eff. 07/01/2013)

MS: 009376349 - FFS : 009450798 - CHIP (eff. 02/07/2011)

MT: 1548367063 (eff. 08/15/2018)

NC: 7704585 (eff. 02/01/2007)

NE: 10026550601 (eff. 04/12/2016)

NH: 3127231 (eff. 01/27/2021)

NJ: 0766011 (eff. 06/11/2021)

NM: 51225514 (eff. 02/11/2014)

NV: 100541636 (eff. 06/18/2014)

NY: 03581275 (eff. 09/01/2017)

OH: 0060286 (eff. 02/01/2011)

OK: 200243820A (eff. 01/31/2011)

OR: 500671501 (eff. 05/12/2014)

PA: 102564320-0002 (Promise ID) (eff. 05/01/2011)

RI: 1548367063 (eff. 05/23/2016)

SC: DM1293 (eff. 07/01/2006)

SD: 2022288 (eff. 1/21/2021)

TN: 1508032 (eff. 02/03/2007)

TX: (a.k.a 'TPI') 205277101 Traditional Medicaid (eff. 07/13/2008)

205277103 CSHCN (eff. 07/13/2008)

UT: 1548367063 (eff. 06/10/2015)

VA: 30015257160001 (eff. 06/03/2008)

VT: 1027114 (eff. 04/22/2016)

WA: 1548367063 (eff. 01/07/2014)

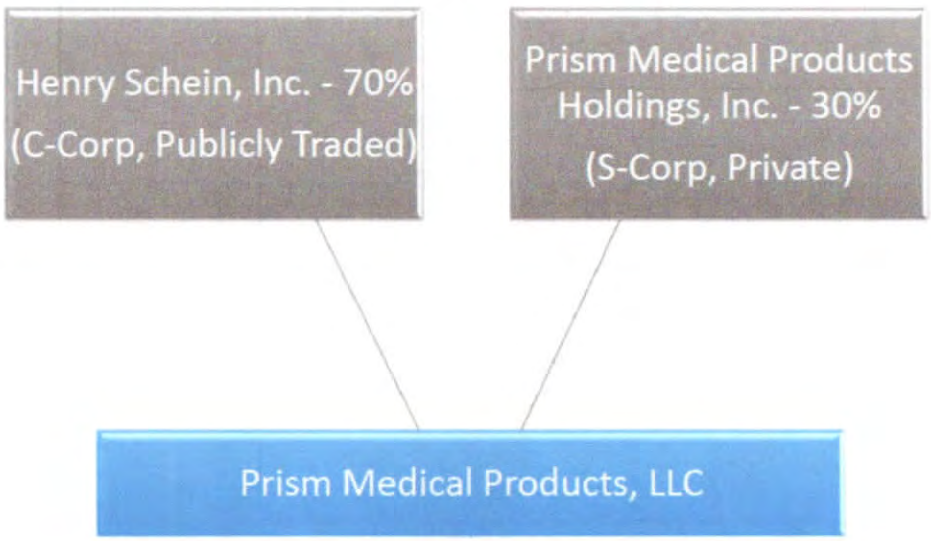
WI: 100152285 (eff. 01/01/2021)

WV: 888 (eff. 06/08/2012)

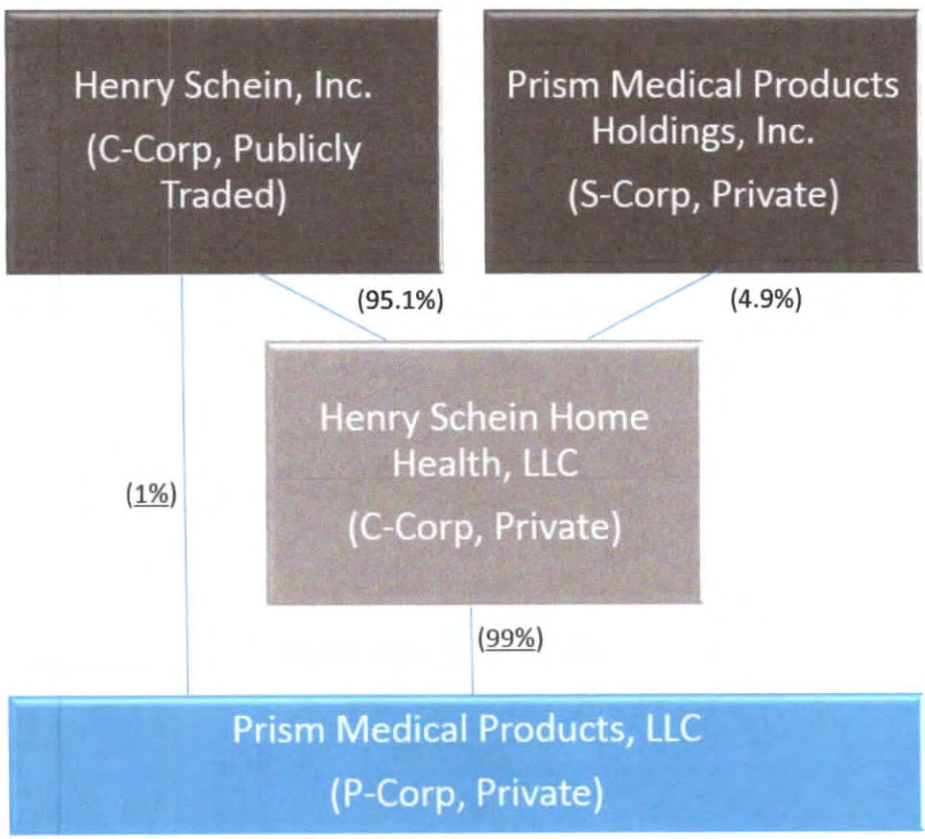
WY: 1548367063 (eff. 10/01/2016)

Prism Pre/Post Closing Information

Pre-Closing Structure



Post-Closing Structure



Address Information

Prism Medical Products, LLC
All demographic and contact information remains the same for the Elkin, NC location.

Parent Level Company
Henry Schein Home Health, L.L.C.
135 Duryea Rd.,
Melville NY 11747

Henry Schein, Inc.
135 Duryea Rd.,
Melville NY 11747

Grandparent Level Company
Prism Medical Products Holdings, Inc.
112 Church Street, Suite 102
Elkin, NC 28621

Henry Schein, Inc.
135 Duryea Rd.,
Melville NY 11747

Prism Medical Products, LLC

Prism Medical Products, LLC Officers/Board/Directors:

Prism Medical Products Holdings, Inc Representatives:

- Christopher Cartwright, President
- Kenneth Reel, Vice President

Henry Schein, Inc Representatives:

- Eileen Rosenbaum, Vice President
- Brad Connett, Senior Vice President
- Walter Siegel, SVP & General Council
- Michael Ettinger, EVP, Corporate & Legal Affairs

Henry Schein Home Health, LLC: 99% Direct Ownership

Directors

- Walter Siegel, SVP & General Council
- Michael Ettinger, EVP, Corporate & Legal Affairs
- Ronald South, SVP, CFO
- Brad Connett, SVP,
- Christopher Cartwright, VP

Officers

- Walter Siegel, SVP & General Council
- Michael Ettinger, EVP, Corporate & Legal Affairs
- Ronald South, SVP, CFO
- Brad Connett, SVP,
- Christopher Cartwright, VP
- Bob Ponzo, VP Tax
- Michael Amodio, VP and Treasurer

Henry Schein, Inc.: 1% Direct Ownership

Henry Schein is a publicly traded company with over 19,000 employees worldwide. Henry Schein does not have a traditional organizational chart. Provided below is a list of the Board of Directors and Executive Management. Please contact us if you require additional information.

Board of Directors

- Stanley M. Bergman, Chairman of the Board and Chief Executive Officer
- Mohamad Ali, Former Chief Executive Officer, IDG, Inc.
- James P. Breslawski, Vice Chairman of the Board and President
- Deborah Derby, President & CEO, Carrols Restaurant Group, Inc.
- Joseph L. Herring, Former Chief Executive Officer Covance, Inc.
- Kurt P. Kuehn, Former Chief Financial Officer, United Parcel Service, Inc.
- Philip A. Laskawy, Lead Director, Henry Schein, Inc.; and Retired Chairman, Ernst & Young, LLP (now known as EY LLP)
- Anne H. Margulies, Former Vice President and Chief Information Officer, Harvard University
- Mark E. Mlotek, Executive Vice President, Chief Strategic Officer
- Steven Paladino, Former Executive Vice President, Chief Financial Officer, Henry Schein, Inc.
- Carol Raphael, National Advisor, Manatt Health Solutions; and Former President and Chief Executive Officer, Visiting Nurse Service of New York
- Scott Serota, Former President and Chief Executive Officer of Blue Cross Blue Shield Association
- Bradley T. Sheares, Ph.D., Former Chief Executive Officer, Reliant Pharmaceuticals, Inc.; and Former President of U.S. Human Health, Merck & Co.
- Reed V. Tuckson, M.D., FACP, Managing Director of Tuckson Health Connections, LLC, and Founder, Black Coalition Against COVID-19

Executive Management

- Stanley M. Bergman, Chairman of the Board and Chief Executive Officer
- Andrea Albertini, Chief Executive Officer, International Distribution Group
- Leigh Benowitz, Senior Vice President and Chief Global Digital Transformation Officer
- James P. Breslawski, Vice Chairman of the Board and President
- David Brous, Chief Executive Officer, Strategic Business Group
- Trinh Clark, Senior Vice President and Chief Global Customer Experience Officer
- Brad Connett, Chief Executive Officer, North America Distribution Group
- Michael S. Ettinger, Executive Vice President and Chief Operating Officer
- Lorelei McGlynn, Senior Vice President, Chief Human Resources Officer
- Mark E. Mlotek, Executive Vice President, Chief Strategic Officer, Member of the Board of Directors
- James Mullins, Senior Vice President, Global Supply Chain
- Kelly Murphy, Senior Vice President and General Counsel
- Christopher Pendergast, Senior Vice President and Chief Technology Officer
- Michael Racioppi, Senior Vice President, Chief Merchandising Officer
- Walter Siegel, Senior Vice President and Chief Legal Officer
- Ronald N. South, Senior Vice President, Chief Financial Officer
- René Willi, Ph.D., Chief Executive Officer, Global Oral Reconstruction Group

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PRISM MEDICAL PRODUCTS, L.L.C." IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PRISM MEDICAL PRODUCTS, L.L.C." WAS FORMED ON THE THIRTY-FIRST DAY OF DECEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4587530 8300

SR# 20233022349

Authentication: 203769831

Date: 07-18-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HENRY SCHEIN HOME HEALTH, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HENRY SCHEIN HOME HEALTH, LLC" WAS FORMED ON THE NINTH DAY OF JUNE, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

7507294 8300

SR# 20233022350

Authentication: 203769832

Date: 07-18-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HENRY SCHEIN, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HENRY SCHEIN, INC." WAS INCORPORATED ON THE TWENTY-THIRD DAY OF DECEMBER, A.D. 1992.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2320192 8300

SR# 20233023629

Authentication: 203770874

Date: 07-18-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
06/01/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	QBE Specialty Insurance Company	11515
INSURER B:	Liberty Mutual Fire Ins Co	23035
INSURER C:	ProAssurance Specialty Insurance Company	17400
INSURER D:	Liberty Insurance Corporation	42404
INSURER E:		
INSURER F:		

INSURED
Prism Medical Products
P O Box 476
112 Church Street, Suite 101
Elkin NC 28621 USA

COVERAGES **CERTIFICATE NUMBER:** 570099690193 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT X LOC OTHER:			TB2621093363033	06/01/2023	06/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $100,000 $5,000 $1,000,000 $2,000,000 Excluded
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			AS2-621-093363-043	06/01/2023	06/01/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
D	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION			TH7621093363073	06/01/2023	06/01/2024	EACH OCCURRENCE AGGREGATE	$2,000,000 $2,000,000
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		WA762D093363013 AOS	06/01/2023	06/01/2024	X PER STATUTE OTH-ER	
D				WC7621093363023 WI	06/01/2023	06/01/2024	E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000
C	Products Liability			N23NY380024 Products Liability Claims	06/01/2023	06/01/2024	Per Occurrence Aggregate	$3,000,000 $3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Prism Medical Products, LLC
P O Box 476,112 Church Street, Suite 101
Elkin NC 28621 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier :

Certificate No : 570099690193

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AGENCY CUSTOMER ID: 570000025511

LOC #:

ADDITIONAL REMARKS SCHEDULE

Page _ of _

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Prism Medical Products
POLICY NUMBER: See Certificate Number: 570099690193	
CARRIER: See Certificate Number: 570099690193 / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Locations

PRISM MEDICAL PRODUCTS - OFFICE LOCATIONS:
112 Church Street, Suite 101, Elkin, NC 28621
2445 Directors Row, Ste G, Indianapolis, IN 46241
4705 N Sonora Ave # 110, Fresno, CA 93722
119 W Main Street, Elkin, NC 28621
4900 Outland Center Drive, Ste 103, Memphis, TN 38118
416 Oakland Drive, Elkin, NC 28621
900 Albany Shaker Road Ste 1, Latham, NY 12110
3190 100th Street, Urbandale, IA 50322
2700 Commerce Square East. Irondale, AL 35210
6345 S Pecos Road #203-205, Las Vegas, NV 89120
111 Market Street Apt 203, Elkin, NC 28621
1421 Champion Drive Suite 100, Carrollton, TX 75006
12019 NE 99th Street Suite 1720, Vancouver, WA 98682
118 Circle Court, Elkin, NC 28621
197 Piedmont Blvd., Suite 212, Rock Hill, SC 29732
7003 Presidents Drive, Orlando, FL 32809
7060 103rd Street Ste 107, Jacksonville, FL 32210
1919 N. Bridge Street Suite 240; Elkin, NC 28621.
2800 Percy Machin Drive, Ste. 112, North Little Rock, AR 72114
1605 North Bridge Street; Elkin, NC 28621

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Prism Medical Products, LLC — MDEG License # (if applicable): MP01223

Physical Address: 6345 South Pecos Road, Suite 203

City: Las Vegas — State: NV — Zip: 89120

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin — State: NC — Zip: 28621

Telephone: (888) 244-6421 — Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: Rana Rei — Middle: Anacta — Last: Villamor

Alias(es, nicknames, name changes, etc.): Rana

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin — State: NC — Zip: 28621

Telephone: (888) 244-6421 x.4373 — Email: rana@prism-medical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ateneo de Manila Univeristy		06/2005 - 05/2009	
Address	**City**	**State**	**Zip**
Katipunan Ave	Quezon City, Metro Manila	Philippines	1503
Diploma/Degree obtained, if any			
Bachelor's in Health Sciences			

School Name		From - To (MM/YY – MM/YY)	
Operation Brotherhood Montessori Center (OBMC) - Greenhills Campus		06/1991 - 04/2005	
Address	**City**	**State**	**Zip**
#3 Eisenhower Street	San Juan City, Metro Manila	Philippines	1503
Diploma/Degree obtained, if any			
H.S. Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2016 - Present	[redacted] Woodcarver Street	Henderson	NV	89012
04/2014 - 05/2016	[redacted] Crest Valley Place	Henderson	NV	89011
10/2010 - 04/2014	[redacted] Desert Knolls Street	Henderson	NV	89014

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Prism Medical Products, LLC		10/03/2022 - Present	
Business Address	**City**	**State**	**Zip**
6345 South Pecos Road, Suite 203	Las Vegas	NV	89120
Phone	**Title**	**Number of Employed Hours**	
(888) 244-6421	Client Operations Manager	1,600 Hours	

Description of Duties

Provide education to teams and team leaders. Implement company policies and procedures, and assist with creating new company processes. Facilitate Recruitment. Interdepartmental Communications.

Business Name		From - To (MM/YY – MM/YY)	
Prism Medical Products, LLC		04/2017 - 10/2022	
Business Address	**City**	**State**	**Zip**
6345 South Pecos Road, Suite 203	Las Vegas	NV	89120
Phone	**Title**	**Number of Employed Hours**	
(888) 244-6421	Coordinator	15,000+ Hours	

Description of Duties

Oversee multiple team members. Facilitate the on-boarding process of new supplies. Knowledge of a multitude of insurance. Patient file reviews and Order Processing procedures.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case # N/A		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

07/18/2023
Date

I, Rana Villamor, **certify that as the MDEG Administrator for**

Prism Medical Products, LLC,

that I (initial that you have read and meet the following requirements):

1. RAV Have a high school diploma or its equivalent;
2. RAV Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RAV Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RAV Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rana Villamor
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/18/2023
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prism Medical Products, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP03103

Physical Address: 112 Church Street, Suite 101

City: Elkin State: NC Zip: 28621

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: Christopher Middle: Jon Last: Cartwright

Alias(es, nicknames, name changes, etc.): Chris

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin State: NC Zip: 28621

Telephone: 888-244-6421 x.4373 Email: chris@prism-medical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wingate University		1996-2000	
Address	**City**	**State**	**Zip**
315 E. Wilson Street	Wingate	NC	28174
Diploma/Degree obtained, if any			
B.S.			

School Name		From - To (MM/YY – MM/YY)	
Oviedo High School		1992-1996	
Address	**City**	**State**	**Zip**
601 King Street	Oviedo	FL	32765
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016 - Present	[redacted] Colonial Lane	State Road	NC	28676
2010 - 2016	[redacted] Carter Mill Road	Elkin	NC	28621

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Prism Medical Products, LLC	08/2006 - Present

Business Address	City	State	Zip
112 Church Street, Suite 101	Elkin	NC	28621

Phone	Title
(888) 244-6421	President

Description of Duties

Executive Duties, Planning, Daily Oversight

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/20/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Cartwright

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/20/23

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Surry

I, Christopher Cartwright, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/20/23

Date

Subscribed and Sworn to before me this 20 day of July 2023.

Elizabeth L. Hyde

Notary Public Signature

Elizabeth L. Hyde NOTARY PUBLIC SURRY COUNTY, NC

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prism Medical Products, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP03103

Physical Address: 112 Church Street, Suite 101

City: Elkin State: NC Zip: 28621

Mailing Address (if different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: Kenneth Middle: Herbert Last: Reel, Jr.

Alias(es, nicknames, name changes, etc.): Ken

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin State: NC Zip: 28621

Telephone: 888-244-6421 x.4373 Email: ken@prism-medical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nova Southeastern School of Law		08/2001 - 05/2004	
Address	**City**	**State**	**Zip**
3300 S University Drive	Fort Lauderdale	FL	33328
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
University of Florida		01/1999 12/2000	
Address	**City**	**State**	**Zip**
Museum Road 7 Reitz Union Drive	Gainsville	FL	32611
Diploma/Degree obtained, if any			
B.A Degree			

School Name		From - To (MM/YY – MM/YY)	
Valencia Community College		06/1998 - 12/1998	
Address	**City**	**State**	**Zip**
1800 S Kirkman Road	Orlando	FL	32811
Diploma/Degree obtained, if any			
A.A. Degree			

School Name		From - To (MM/YY – MM/YY)	
University of Central Florida		08/1996 - 05/1998	
Address	**City**	**State**	**Zip**
4000 Central Florida Blvd	Orlando	FL	32816
Diploma/Degree obtained, if any			
Transfer			

School Name		From - To (MM/YY – MM/YY	
Oviedo High School		1992-1996	
Address	**City**	**State**	**Zip**
601 King Street	Oviedo	FL	32765
Diploma/Degree obtained, if any			
Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2019 - Present	[redacted] Queens Road W.	Charlotte	NC	28209
04/2014 - 12/2018	[redacted]dlewood Circle	Charlotte	NC	28209
04/2011 - 03/2014	[redacted] Red Oak Lane	Winston-Salem	NC	27106
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Prism Medical Products, LLC	01/2009 - Present

Business Address	City	State	Zip
112 Church Street, Suite 101	Elkin	NC	28621

Phone	Title
(888) 244-6421	Vice President

Description of Duties

Executive Duties, Company Oversight, Legal, Compliance HR, Sales

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/21/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kenneth Reel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7·21·23

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Surry

I, Kenneth Reel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7·21-23

Date

Subscribed and Sworn to before me this 21 day of July 2023

Elizabeth L. Hyde

Notary Public Signature

Elizabeth L. Hyde NOTARY PUBLIC SURRY COUNTY, NC

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prism Medical Products, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (If applicable): MP03103

Physical Address: 112 Church Street, Suite 101

City: Elkin State: NC Zip: 28621

Mailing Address (If different from physical address): P.O. Box 476

City: Elkin State: NC Zip: 28621

Telephone: (888) 244-6421 Website: www.prism-medical.com

Licensing Company Email: compliance@prism-medical.com

Section 2: Personal Information

First: James Middle: Robert Last: St. Cyr

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: P.O. Box [redacted]

City: Elkin State: NC Zip: 28621

Telephone: 888-244-6421 x.4373 Email: james@prism-medical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wingate University		1998-2002	
Address	**City**	**State**	**Zip**
315 E. Wilson Street	Wingate	NC	28174
Diploma/Degree obtained, if any			
B.S. Business Marketing			
School Name		**From - To (MM/YY – MM/YY)**	
Milford High School		1994-1998	
Address	**City**	**State**	**Zip**
100 West Street	Milford	NH	03055
Diploma/Degree obtained, if any			
Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2013 - Present	[redacted]Laurel Hill Lane	State Road	NC	28676
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Prism Medical Products, LLC			05/2010 - Present
Business Address	**City**	**State**	**Zip**
112 Church Street, Suite 101	Elkin	NC	28621
Phone	**Title**		
(888) 244-6421	President		
Description of Duties			
Executive Duties, Company Oversight, Operations, IT			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A			
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/20/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James St. Cyr

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 7/20/23

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Surry

I, James St. Cyr, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date 7/20/23

Subscribed and Sworn to before me this 20 day of July 2023.

Elizabeth L. Hyde

Notary Public Signature

Elizabeth L. Hyde NOTARY PUBLIC SURRY COUNTY, NC

(Seal)

PRISM
HOME MEDICAL SUPPLY SPECIALISTS

P. O. BOX 476
ELKIN, NC 28621
PHONE: 1-888-244-6421
FAX: 1-800-975-6321
WWW.PRISM-MEDICAL.COM

Change of Ownership Application Introduction & Index

Prism Medical Products, LLC is entering into a Contribution and Exchange Agreement between Henry Schein Home Health, LLC and Henry Schein, Inc. **The effective date of the proposed transaction is projected to be on or about August 7, 2023**. Prism Medical Products, LLC's tax classification is a partnership. This partnership is between two corporations, one partner is publicly traded and one non-public. The partnership section of the application asks for Personal History Records for each partner. We included Personal History Records for each managing employee. Mr. Christopher Cartwright, Mr. Kenneth Reel, and Mr. James St. Cyr will remain as managing employees at the Operating Entity as well as partial owners of Prism Medical Products Holdings, Inc., a grandparent-level owner.

For the publicly traded partner, Henry Schein, Inc., we provided a list of Directors and Management and the Certificate of Good Standing as requested on the publicly traded page of the application. We did not complete the application publicly and non-publicly traded corporation pages as a result of guidance from the Board that only one of the four ownership type sections should be completed. We did put N/A on Sections 5 and 6, even though they both apply to the owning partners; however, the ownership type of the entity being issued a license (Prism Medical Products, LLC) is a partnership. We hope that the information provided in this application will satisfy the Board's requirement.

Prism Medical Products, LLC has been licensed by Nevada Board of Pharmacy since 2014. Henry Schein, Inc. holds 11 Nevada Board of Pharmacy permits. Both entities have been previously vetted by Nevada Board of Pharmacy. Both entities have also conducted MDEG business transactions within Nevada, as appropriately licensed. As our original notice indicated, this ownership adjustment does not affect the daily management of Prism Medical Products, LLC. If additional information is required, please request via email to: compliance@prism-medical.com. Regards,
Lucy Ketner
Associate Vice President, Compliance & Government Affairs
(336) 258-4314

Index:

Check for all THREE Applications, p. 3
Original Notification, p. 4-5
Application for License MP03103 (Elkin, NC), p. 6-9
Application Supporting Documentation:
- Type of MDEG Products being Sold, p. 10
- Traditional State Medicaid Enrollments, p.11
- Pre-Closing/Post-Closing Structure, p. 12
- Ownership information with Addresses/Board of Directors/Officers, p. 13-15
- Secretary of State:
  - Prism Medical Products, LLC, p.16
  - Henry Schein Home Health, LLC, p. 17
  - Henry Schein, Inc, p. 18
- Prism, LLC-2023 NC BOP License, p. 19
- Certificate of Insurance, p. 20-21

Administrator Application, p. 22-27
Application for License MP01223 (Las Vegas, NV), p. 28-31
Application Supporting Documentation:
- Type of MDEG Products being Sold, p. 32
- Traditional State Medicaid Enrollments, p.33
- Pre-Closing/Post-Closing Structure, p. 34
- Ownership information with Addresses/Board of Directors/Officers, p. 35-37
- Secretary of State:

  - Prism Medical Products, LLC, p.38
  - Henry Schein Home Health, LLC, p. 39
  - Henry Schein, Inc, p. 40
- Prism, LLC-2023 NV BOP License, p. 41
  - NV BOP 2022Inspection Report, p. 42-44
- Certificate of Insurance, p. 45-46

Administrator Application, p. 47-52

Application for License MP01354 (Fresno, CA), p. 53-56

Application Supporting Documentation:

- Type of MDEG Products being Sold, p. 57
- Traditional State Medicaid Enrollments, p.58
- Pre-Closing/Post-Closing Structure, p. 59
- Ownership information with Addresses/Board of Directors/Officers, p. 60-62
- Secretary of State:
  - Prism Medical Products, LLC, p.63
  - Henry Schein Home Health, LLC, p. 64
  - Henry Schein, Inc, p. 65
- Prism, LLC-2024 CA DPH License, p. 66
- Certificate of Insurance, p. 67-68

Administrator Application, p. 69-74

***PLEASE FIND ONE SET OF PERSONAL HISTORY RECORDS FOR ALL THREE APPLICATIONS FOR THE FOLLOWING:**

- Christopher Cartwright
- Kenneth Reel
- James St. Cyr

4YY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-State	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH 04260	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Curexa – West, LLC d/b/a Curexa

Physical Address: 1343 North Colorado Street, Suite 109

City: Gilbert State: AZ Zip: 85233

Mailing Address (if different from physical address): same as above.

City: _____ State: _____ Zip: _____

Telephone: (602) 649-4145 Toll Free # (NAC 639.708, NRS 639.23286): (855) 927-0390

Fax: (602) 962-2234 Contact Email: mtaylor@curexa.com / kjudeich@curexa.com

Website: https://curexa.com/

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Brian Gellenbeck

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23517

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Brian Gellenbeck	NV Pharmacist Registration #: 23517
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Curexa LLC

Corporation/Organization Name: Curexa – West, LLC

Mailing Address: 1343 North Colorado Street, Suite 109

City: Gilbert State: AZ Zip: 85233

Telephone: (602) 649-4145 Email: mtaylor@curexa.com

Contact Person Name: Mark Kelso Taylor

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Curexa – West, LLC d/b/a Curexa (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Mark Kelso Taylor

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/10/2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Mark Kelso Taylor hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO (title) for Curexa – West, LLC d/b/a Curexa (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 10th day of July, 2023

Notary Public

JENNIFER A. ETHERINGTON
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 8/13/2024

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Kelso Taylor

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

7/10/2023

Date

Board Use Only	Date Received: 7/25/23	Amount: 500-CK-1333839

Curexa – West, LLC
Nevada Non-Resident Pharmacy Application Disclosure

Section 3: History of Company

3. **Have the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry?**

As an initial matter, the answer is "No" on behalf of the pharmacy applicant, Curexa – West, LLC.

However, out of an abundance of caution and in the interest of full disclosure, we are providing the following materials related the ***prior owner*** AdhereRx Inc. ("AdhereRx"), which is a fulsome representation of all disciplinary history that we are aware of. Both instances of disciplinary action listed below are regarding Notice of Change in AdhereRx's Pharmacist-In-Charge ("PIC") during June/July 2021.

Please see all corresponding documents enclosed.

- **February 28, 2022 - Alabama State Board of Pharmacy** ("Alabama Board"). The Alabama Board disciplined and fined AdhereRx for a failure to timely notify the Alabama Board of the 2021 change in PIC. AdhereRx paid the fine and its Alabama pharmacy license remains active and is currently in good standing.

- **July 13, 2022 - Maine Board of Pharmacy** ("Maine Board"). The Maine Board entered into a Consent Agreement with AdhereRx based on a failure to timely notify the Maine Board of the 2021 change in PIC. AdhereRx paid the fine and its Maine pharmacy license remains active and is currently in good standing.

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DocuSign Envelope ID: 666FD218-7296-41A8-AC04-F7C471B86DF0

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
ADHERERX INCORPORATED	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy Permit No.: 115015	)	**CASE NO: 21-L-0202**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against AdhereRx Incorporated which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that AdhereRx Incorporated has violated the provisions of law based upon the conduct set out in Count One of the Statement. Counts Two and Three of the Statement shall be dismissed.

2. AdhereRx Incorporated shall pay an administrative fine in the amount of One Thousand Dollars ($1,000.00) within thirty (30) days of the effective date of this Consent Order, that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall AdhereRx Incorporated attempt to discharge the same.

3. AdhereRx Incorporated expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. AdhereRx Incorporated further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, AdhereRx Incorporated hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. AdhereRx Incorporated acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against AdhereRx Incorporated's permit, including, but not limited to revocation.

6. That AdhereRx Incorporated acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. AdhereRx Incorporated acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 23 of February, 2022.

ADHERERX INCORPORATED

BY: J.R. Garrett

ITS: Chief Legal Officer

DONE this the 28th of February, 2022.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Chris Phung, R.Ph., President

By: _____
James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

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DocuSign Envelope ID: 886FD218-7296-41A8-AC04-F7C471B86DF0

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
ADHERERX INCORPORATED	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy Permit No.: 115015	)	**CASE NO: 21-L-0202**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: AdhereRx Incorporated
1343 N. Colorado Street
Suite 109
Gilbert, Arizona 85233

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92 (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on March 15, 2022 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate AdhereRx Incorporated should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that AdhereRx Incorporated has been guilty of the following, to wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(12) in that you violated Board Rule 680-X-2.12(8) by not being unable to maintain a designated Supervising Pharmacist and failing to notify the Board within ten (10) days with an action plan to designate another pharmacist as Supervising Pharmacist to-wit: Bret Koertge ceased to be your Supervising Pharmacist on or about June 11, 2021; however, the Board did not receive notification until on or about August 23, 2021.

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COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of the preceding Count.

Further, pursuant to the provisions of Code of Alabama, (1975), § 20-2-53 and § 41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), § 20-2-1, et. seq., issued pursuant to Code of Alabama (1975), § 20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT THREE

Violating Code of Alabama (1975), § 20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), § 34-23-1 et seq., said violation being based upon the allegations contained in any or all of the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 28th day of October, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

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STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
ADHERERX INCORPORATED	)	CONSENT AGREEMENT
	)	
Complaint No. 2022-PHA-18078	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order prescription pharmacy license of AdhereRx Incorporated ("AdhereRx") in the State of Maine. The parties to this Consent Agreement are AdhereRx, the Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times relevant to this matter, AdhereRx was licensed by the Board as a mail order prescription pharmacy, license no. MO40002970, with a registered location of 1343 N. Colorado Street, Suite 109 in Gilbert, Arizona.
2. On June 21, 2021, AdhereRx hired a pharmacist to be its pharmacist-in-charge ("PIC") thereby requiring AdhereRx to submit a change of PIC application to the Board within 7 days after the PIC change.
3. AdhereRx, however, never submitted a change of PIC application, and its newly hired PIC resigned on July 2, 2021
4. On July 16, 2021, Debbe Kristen Escamillo took over as the PIC of AdhereRx, thereby requiring AdhereRx to submit a change of PIC application to the Board within 7 days after the PIC change.

5. AdhereRx, however, did not file a change of PIC application with the Board until July 29, 2021.
6. On February 8, 2022, Board Staff filed a complaint with the Board alleging that AdhereRx had failed to file a timely Change of PIC application.
7. The Board docketed this complaint as Complaint No. 2022-PHA-18078.
8. Under Board Rules Chapter 11, § 3, upon a change of PIC, a mail order pharmacy must file a new application with the Board by registered mail no later than seven (7) days after the change.
9. On May 5, 2022, following a presentation of the complaint, the Board voted to offer AdhereRx this Consent Agreement to resolve Complaint No. 2022-PHA-18078.
10. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Jessica Gowell, Professional Licensing Supervisor, Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333-0035 by June 24, 2022, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

3

11. AdhereRx admits to the facts as stated above and admits that such conduct constitutes grounds for imposing discipline against its license pursuant to 10 M.R.S. § 8003(5-A)(A)(5) for violating a rule of the Board, specifically Board Rules Chapter 11, § 3, by failing to file a new application with the Board by registered mail no later than 7 days after a change of PIC on two separate occasions.
12. As DISCIPLINE for the violations admitted to in paragraph 11 above, AdhereRx agrees to accept the imposition of:
    a. A CENSURE; and

b. A CIVIL PENALTY in the amount of one thousand seven hundred fifty dollars ($1,700.00). Payment of the civil penalty shall be made by certified check or money order payable to the "Treasurer, State of Maine" and delivered to Jessica Gowell, Professional Licensing Supervisor, Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333-0035, within thirty (30) days of the execution of this Consent Agreement.

13. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

14. Violation of any of the terms or conditions of this Consent Agreement by AdhereRx shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

15. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

16. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

17. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

18. The Board and AdhereRx agree that no further agency action will be initiated against AdhereRx by the Board based upon the specific violations admitted to herein, except or unless AdhereRx fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against AdhereRx, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearings

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involving AdhereRx. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining discipline in any further complaints against AdhereRx.

19. This Consent Agreement may be signed in counterparts, with all counterparts together constituting one original instrument. Signatures below may be applied and/or saved electronically, and such electronic signatures will be given the same effect as a paper document signed in ink.

20. AdhereRx acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

ADHERERX INCORPORATED

DATED: 7/8/2022

BY: J.R. Garrett
Authorized Representative

J.R. Garrett
Printed Name

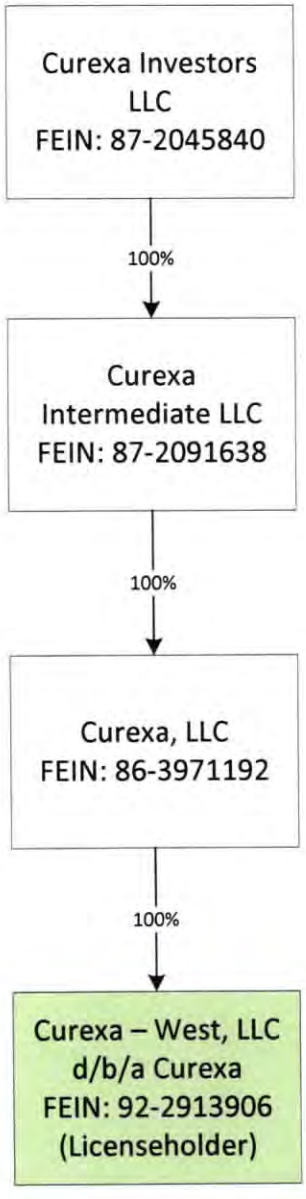
DATED: 7/13/2022

EDWARD J. KANE, President
MAINE BOARD OF PHARMACY

DATED: 7/13/2022

ANDREW L. BLACK
Assistant Attorney General

Curexa – West, LLC d/b/a Curexa
Corporate Structure



CUREXA – WEST, LLC d/b/a CUREXA

Officer and Ownership Information for Curexa – West, LLC

Curexa – West, LLC d/b/a Curexa
410 Park Ave., Suite 1710
New York, NY 10022
FEIN: 92-2913906

Curexa – West, LLC has one officer, who is also a pharmacist licensed in New Jersey:

- Mark Kelso Taylor
  CEO
  Home Address: [redacted] S. 4th Avenue, Galloway, NJ 08205
  DOB: [redacted]
  Telephone: [redacted]
  Email: mtaylor@curexa.com
  SSN: [redacted]
  New Jersey Pharmacist License Number/Expiration Date: 28RI02157700 / 04-30-2025

Curexa – West, LLC is wholly owned by its parent company, Curexa, LLC.

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

Curexa - West, LLC

ACC file number: 23541540

was incorporated under the laws of the State of Arizona on 06/12/2023, and that, according to the records of the Arizona Corporation Commission, said limited liability company is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **06/13/2023**

Douglas R. Clark, Executive Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Curexa – West LLC d/b/a Curexa

Pharmacy/Wholesaler License # (if applicable): PH04260

Physical Address: 1343 North Colorado Street, Suite 109

City: Gilbert State: AZ Zip: 85233

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: (602) 649-4145 Website: https://curexa.com/

Licensing Company Email: mtaylor@curexa.com / kjudeich@curexa.com

Section 2: Personal Information

First: Brian Middle: Last: Gellenbeck

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 1343 North Colorado Street, Suite 109

City: Gilbert State: AZ Zip: 85233

Telephone: 602-649-4145 Email: bgellenbeck@curexa.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
University of Iowa	08/07 - 05/11

Address	City	State	Zip
125 North Madison Street	Iowa City	IA	52242

Diploma/Degree obtained, if any: PharmD

School Name	From - To (MM/YY – MM/YY)
Purdue University	8/84 - 5/93

Address	City	State	Zip
610 Purdue Mall	W. Lafayette	IN	47907

Diploma/Degree obtained, if any: BSIM

School Name	From - To (MM/YY – MM/YY)
McCutcheon High School	8/85 - 5/89

Address	City	State	Zip
4951 US-231	Lafayette,	In	47909

Diploma/Degree obtained, if any: HS Diploma

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2013 - Present	[redacted] E Renee Dr.	Phoenix	AZ	85050
7/2013 - 9/2013	[redacted] E Corral Rd	Phoenix	AZ	85044
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Curexa West LLC			From - To (MM/YY – MM/YY): 05/23 - Present	
Business Address: 1343 North Colorado Street Ste 109	City: Gilbert		State: AZ	Zip: 85233
Phone: 855-927-0390	Title: Pharmacist-in-Charge		Number of Employed Hours: Approx. 350	
Description of Duties: Pharmacist-in-Charge of mail order pharmacy.				
Business Name: AdhereRx			From - To (MM/YY – MM/YY): 05/22 - 05/23	
Business Address: 1343 North Colorado Street Ste. 109	City: Gilbert		State: AZ	Zip: 85233
Phone: N/A	Title: Staff Pharmacist/Pharmacist-in-Charge		Number of Employed Hours: Approx. 1900	
Description of Duties: Staff Pharmacist/Pharmacist-in-Charge of mail order pharmacy.				
Business Name: Dependable Staffing			From - To (MM/YY – MM/YY): 08/19 - 05-22	
Business Address: 1111 N 3rd Street	City: Phoenix		State: AZ	Zip: 85004
Phone: 602-264-1444	Title: Staff Pharmacist		Number of Employed Hours: Approx 4000	
Description of Duties: Pharmacist for hospital out patient and retail pharmacy setting through contracts.				
Business Name: One Point			From - To (MM/YY – MM/YY): 01/19 - 8/19	
Business Address: 1275 W Washington St Suite 105	City: Tempe		State: Az	Zip: 85288
Phone: 480-240-1111	Title: Staff Pharmacist		Number of Employed Hours: Approx 1000	
Description of Duties: Staff pharmacist for a hospice pharmacy.				
Business Name: GenRx			From - To (MM/YY – MM/YY): 08/16 - 11/18	
Business Address: 17250 N Hartford Dr	City: Scottsdale		State: Az	Zip: 85255
Phone: 866-453-6143	Title: Staff Pharmacist		Number of Employed Hours: Approx. 6500	
Description of Duties:				

Continue on next page if additional space is needed.

Applicant's initials BA

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Brian Gallucci
Original Signature (electronic, copies or stamps not accepted)

7/7/23
Date

I, Brian Gellenbeck, **certify that as the designated representative for**

Curexa – West, LLC d/b/a Curexa,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BG I am at least 21 years of age;
3. BG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Brian Gellenbeck

Print Name (First, Last)

Brian Gellenbeck

Original Signature (electronic, copies or stamps not accepted)

7/7/21

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brian Gellenbeck

Print Name (First, Last)

Brian Gellenbeck

Original Signature (electronic, copies or stamps not accepted)

7/7/23

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Brian Gellenbeck, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Brian Gellenbeck

Original Signature

7/7/23

Date

Subscribed and Sworn to before me this 7 day of July.

Notary Public Signature

JIMMY SILVA
Notary Public - State of Arizona
MARICOPA COUNTY
Commission # 635799
Expires September 2, 2026

(Seal)

Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 05/31/2023
Amount:
License #: 23517

Brian K. Gellenbeck

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:05/31/2023
Expires:10/31/2023

Brian K. Gellenbeck

License #
23517
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

NEVADA
STATE BOARD OF PHARMACY
Pharmacist

License Type: Pharmacist
License #: 23517
Effective Date:05/31/2023

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Expires: 10/31/2023
STATUS: Active

Brian K. Gellenbeck

NONTRANSFERABLE

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit# :	AZ Permit Exp.Date :	Business Name :
Y009582	10/31/2024	Curexa - West, LLC
Address :		
1343 North Colorado Street		
Zip :	City :	State :
85233	Gilbert	AZ
Phone :	Fax :	Email :
(602) 649-4145	(602) 962-2234	bgellenbeck@curexa.com
Inspection Date :	PIC :	Pic License Exp Date :
06/27/2023	Brian Gellenbeck	2024-10-31T00:00:00
DEA # :	Inspection type :	
FC3017375	Change of Ownership	
Inspection Conducted By :		
Benjamin Castaneda		

ACTIVITIES

1	Nonsterile Compounding	(•) YES ( ) NO
2	Nonsterile Hazardous Compounding	(•) YES ( ) NO
3	Sterile Compounding	( ) YES (•) NO
4	Sterile Hazardous Compounding	( ) YES (•) NO

Hospital Facility Data

# Licensed Beds	DHS License #

PHARMACY DEPARTMENT

1	Size/Personnel 13,500 sq ft. dispensing area, Max 62 people (based on counter space for dispensing.) 900 sq ft. of non-dispensing area used for mail order processing. Max 30 people.	(•) S ( ) C/P ( ) U ( ) N/A R4-23-609(A); R4-23-655(B)(C); R4-23-670 to 675
2	Shelves	(•) S ( ) C/P ( ) U ( ) N/A R4-23-609(A); R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

3	Design-efficient, safe pharmacy practice	◉ S ○ C/P ○ U ○ N/A	R4-22-609(A); R4-23-655(C); R4-23-672(A); R4-23-673(A)(B); R4-23-674(A)(3); R4-23-675(A)
4	Counter 187 sq ft.	◉ S ○ C/P ○ U ○ N/A	R4-23-609(B); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Aisles	◉ S ○ C/P ○ U ○ N/A	R4-23-609(C); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
6	Consultation area	○ S ○ C/P ○ U ◉ N/A	R4-23-609(D)
7	Enclosed (barrier)	◉ S ○ C/P ○ U ○ N/A	R4-23-609(F); R4-23-655(D); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675
8	Entry doors PIC to change to back door to only allow PIC badge access.	◉ S ○ C/P ○ U ○ N/A	R4-23-609(F); R4-23-610(B); R4-23-655(D); R4-23-657(A)(2); R4-23-672(A)(F)(2); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
9	Lighting	◉ S ○ C/P ○ U ○ N/A	R4-23-609(G); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
10	Temperature controlled/Ventilation HVAC throughout with monitoring.	◉ S ○ C/P ○ U ○ N/A	R4-23-609(G); R4-23-655(E); R4-23-656(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Working counter barrier	○ S ○ C/P ○ U ◉ N/A	R4-23-609(H)
12	Receiving/checking area	◉ S ○ C/P ○ U ○ N/A	R4-23-610(E); R4-23-655(E); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
13	Opening for Rx receipt when closed	○ S ○ C/P ○ U ◉ N/A	R4-23-610(F)
14	Walls	◉ S ○ C/P ○ U ○ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
15	Ceilings	◉ S ○ C/P ○ U ○ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
16	Windows	◉ S ○ C/P ○ U ○ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
17	Floors	◉ S ○ C/P ○ U ○ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
18	Restroom	◉ S ○ C/P ○ U ○ N/A	R4-23-611(A)(4)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

19	Sink (hot and cold running water)	◉ S ○ C/P ○ U ○ N/A R4-23-611(A)(9); R4-23-656(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
20	Nonsterile compounding area Currently no compounding is performed. Facility and equipment must be approved by CO prior to compounding. If remodeling, complete and submit a remodel application with a detailed floor plan no less than 30 days before starting your remodel.	○ S ◉ C/P ○ U ○ N/A R4-23-410(E)

SECURITY

1	Controlled substances CII locked in cabinet and CIII-CV dispersed throughout. 23 cameras in dispensing area.	◉ S ○ C/P ○ U ○ N/A R4-23-609(E); R4-23-657(A)(1); R4-23-658(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Pharmacist access PIC and CEO have keys, no emergency key. (See note for entry door)	◉ S ○ C/P ○ U ○ N/A R4-23-609(F); R4-23-610(B); R4-23-657(A)(1); R4-23-671(B)(1); R4-23-672(A)(B)(F); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Additional pharmacy drug storage areas	○ S ○ C/P ○ U ◉ N/A R4-23-609(G)(2); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Filled Rx medication storage Mail only.	◉ S ○ C/P ○ U ○ N/A R4-23-610(G); R4-23-673(E); R4-23-674(C); R4-23-675(C)
5	Remote drug storage (hospitals)	○ S ○ C/P ○ U ◉ N/A R4-23-654(D); R4-23-672(C)

PHARMACY LIBRARY

1	Pharmacology or Toxicology reference	◉ S ○ C/P ○ U ○ N/A R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Therapeutics reference	◉ S ○ C/P ○ U ○ N/A R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Drug compatibility reference	◉ S ○ C/P ○ U ○ N/A R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Drug product equivalency reference	◉ S ○ C/P ○ U ○ N/A R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Sterile products reference	○ S ○ C/P ○ U ◉ N/A R4-23-612(A)(9); R4-23-656(1); R4-23-670(B)(6); R4-23-672(A); R4-23-673(C); R4-23-675(A)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

6	Policy and procedure manual-pharmacy operations Online	(S) C/P U N/A R4-23-610(A); R4-23-653(A); R4-23-658(A); R4-23-671(E); R4-23-672(A)(G); R4-23-673(G); R4-23-674(F); R4-23-675(D)
7	Policy and procedure manual-technicians	(S) C/P U N/A R4-23-610(A); R4-23-653; R4-23-672(A)(G); R4-23-673(C); R4-23-674(F); R4-23-675(D)
8	Policy and procedure manual-automation	(S) C/P U N/A R4-23-614; R4-23-615; R4-23-616; R4-23-654(D); R4-23-701.02; R4-23-701.04
9	Policy and procedure manual-compounding Suggest notifying CO prior to beginning compounding.	(S) C/P U N/A R4-23-410; R4-23-670
10	Arizona statutes/rules	(S) C/P U N/A R4-23-612(A)(8); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Current antidote/drug interaction information	(S) C/P U N/A R4-23-612(A)(12); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
12	Poison Control # displayed	(S) C/P U N/A R4-23-612(A)(13); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

PHARMACY EQUIPMENT/FORMS

1	Refrigerator	(S) C/P U N/A R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670; R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Freezer	(S) C/P U N/A R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670(B)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Computer-security/data storage Pioneer system. Each employee has unique login.	(S) C/P U N/A R4-23-408
4	Computer-patient profiles	(S) C/P U N/A R4-23-408(B)(3)
5	Computer-single drug usage report	(S) C/P U N/A R4-23-408(B)(4)
6	Computer-pharmacist log book/hard copy print out	(S) C/P U N/A R4-23-408(C)(4)
7	Prescription label	(S) C/P U N/A ARS 32-1963.01; ARS 32-1968; R4-23-612(A)(10); R4-23-658(D)(1)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)(D); R4-23-701.01(2); R4-23-703(C)
8	Federal transfer labels	(S) C/P U N/A R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

9	Warning labels	◉ S ○ C/P ○ U ○ N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
10	Written patient information Reminder to discard bottom portion portion of patient label if it is not to be included with prescription.	◉ S ○ C/P ○ U ○ N/A	R4-23-402(C)(4); R4-23-402(I)
11	Consultation log	○ S ○ C/P ○ U ◉ N/A	R4-23-402(G)
12	Federal medication guides	◉ S ○ C/P ○ U ○ N/A	21 CFR part 208
13	Hospital IV label	○ S ○ C/P ○ U ◉ N/A	R4-23-658
14	Generic Rx blanks	◉ S ○ C/P ○ U ○ N/A	R4-23-402(A); R4-23-407(D)
15	Immunization administration recordkeeping	○ S ○ C/P ○ U ◉ N/A	R4-23-411(F)
16	Schedule V register	○ S ○ C/P ○ U ◉ N/A	R4-23-612(A)(2)
17	Methamphetamine precursor sales log	○ S ○ C/P ○ U ◉ N/A	ARS 32-1977
18	Red C stamp	○ S ○ C/P ○ U ◉ N/A	R4-23-612(A)(11); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	CSPMP reporting	◉ S ○ C/P ○ U ○ N/A	R4-23-502
20	Graduates	◉ S ○ C/P ○ U ○ N/A	R4-23-612(A)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
21	Mortar & Pestle Currently no compounding is performed. Facility and equipment must be approved by CO prior to compounding.	○ S ◉ C/P ○ U ○ N/A	R4-23-612(A)(4); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
22	Steel spatulas	◉ S ○ C/P ○ U ○ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
23	Rubber (nonmetallic) spatula	◉ S ○ C/P ○ U ○ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
24	Approved Rx balance Currently no compounding is performed. Facility and equipment must be approved by CO prior to compounding.	○ S ○ C/P ○ U ◉ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

25	Weights for Rx balance Currently no compounding is performed. Facility and equipment must be approved by CO prior to compounding.	○ S ○ C/P ○ U ◉ N/A R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
26	Ointment tile Currently no compounding is performed. Facility and equipment must be approved by CO prior to compounding.	○ S ○ C/P ○ U ◉ N/A R4-23-612(A)(7); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
27	Automated storage and distribution system (patient access)	○ S ○ C/P ○ U ◉ N/A R4-23-614(A)(B)(1)(2)
28	Automated storage and distribution system (hospital)	○ S ○ C/P ○ U ◉ N/A R4-23-614(A)(B)(1)(3); R4-23-654(D)
29	Mechanical storage and counting device Discussed Board Rules for compliance for Parata machine.	◉ S ○ C/P ○ U ○ N/A R4-23-615
30	Mechanical counting device	○ S ○ C/P ○ U ◉ N/A R4-23-616
31	Emergency drug supply units (LTC)	○ S ○ C/P ○ U ◉ N/A R4-23-701.02
32	Automated emergency drug supply units (LTC)	○ S ○ C/P ○ U ◉ N/A R4-23-701.02(E)
33	Automated dispensing system (LTC)	○ S ○ C/P ○ U ◉ N/A R4-23-701.04

STERILE PRODUCT COMPOUNDING AREA/EQUIPMENT:

1	Size	○ S ○ C/P ○ U ◉ N/A R4-23-670(A)
2	Dedicated to compounding sterile products	○ S ○ C/P ○ U ◉ N/A R4-23-670(A)(1); R4-23-656(5)
3	Isolated from other pharmacy functions	○ S ○ C/P ○ U ◉ N/A R4-23-670(A)(2)
4	Restricts entry/access	○ S ○ C/P ○ U ◉ N/A R4-23-670(A)(3)
5	Free from unnecessary disturbances airflow	○ S ○ C/P ○ U ◉ N/A R4-23-670(A)(4)
6	Nonporous and cleanable floor	○ S ○ C/P ○ U ◉ N/A R4-23-670(A)(5)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

7	Nonporous and cleanable walls	○ S ○ C/P ○ U ◉ N/A	R4-23-670(A)(5)
8	Nonporous and cleanable ceiling	○ S ○ C/P ○ U ◉ N/A	R4-23-670(A)(5)
9	Environment ISO 7	○ S ○ C/P ○ U ◉ N/A	R4-23-670(A)(6)
10	Hood ISO 5	○ S ○ C/P ○ U ◉ N/A	R4-23-670(B)
11	Prep area ISO 7/ISO 8	○ S ○ C/P ○ U ◉ N/A	R4-23-110; R4-23-670(E)(F)

NOTES

Maximum 62 people allowed in pharmacy and 30 people in mail order processing area.

Hours: 8am to 5pm M-F. Closed Sat and Sun.

Verified with PIC that this is a closed door mail order facility same business model as previous owner. (see previous permit number Y008343)
Reminder:
Update all Shared Services contracts to include this location information.
Provide a copy of the shared services agreement between facilities and proof of how notification to patients are provided.
Provide a list of wholesaler/suppliers with address that have a valid AZ permit to ship medications to Curexa.
Automated dispensing cell count validation is to be done for each cell every 90 days.

Compliance Pending:
Currently no compounding is performed. Facility and equipment must be approved by CO prior to compounding.
Back door badge access must be limited to not allow entry when pharmacist is not present.

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 04/05/2023
Receipt Number: 2023149145
Receipt Amount $: 480.00

Pharmacy - Limited Service

Closed Door,Compounding – Non-Sterile,Mail Order

PERMIT NO	**EXPIRES**
Y009582	**10/31/2024**

Issued to :

Curexa - West, LLC
Curexa - West, LLC
1343 NORTH COLORADO STREET SUITE 109
GILBERT, AZ 85233

Curexa - West, LLC
1343 NORTH COLORADO STREET SUITE 109
GILBERT, AZ 85233

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Curexa - West, LLC
LICENSE NUMBER : Y009582
EXPIRES : 10/31/2024

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Curexa - West, LLC
Address :	1343 North Colorado Street Suite 109 Gilbert AZ 85233
Registration No :	Y009582
Permit Type :	Pharmacy
Sub Type :	Limited Service
Date Issued :	05/09/2023
Expiration Date :	10/31/2024
Status :	OPEN
Discipline :	No

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 07/17/2023

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC3017375	08-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	06-21-2023

CUREXA - WEST, LLC
1343 N COLORADO ST STE 109
GILBERT, AZ 852331618

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC3017375	08-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	06-21-2023

CUREXA - WEST, LLC
1343 N COLORADO ST STE 109
GILBERT, AZ 852331618

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Form DEA-223 (9/2016)

4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-State	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Mail-Order Pharmacy	☐ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	* ☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	* ☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	* ☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

* An on-call pharmacist will be available at the toll-free number provided (833-396-0309) on Saturday and Sunday from 9:00 a.m. to 5:00 p.m. MST.

Section 1: General Information

Pharmacy Name: CarelonRx Pharmacy, Inc.

Physical Address: 4821 North Stone Avenue, Suite C

City: Tucson State: AZ Zip: 85704-5727

Mailing Address (if different from physical address): 5800 Northampton Boulevard

City: Norfolk State: VA Zip: 23502-5513

Telephone: (833) 396-0309 Toll Free # (NAC 639.708, NRS 639.23286): (833) 396-0309

Fax: _____ Contact Email: CarelonRxPharmacyLicensing@carelon.com

Website: _____

Nevada Business License # (if applicable) NV20212034904

Supervising/Managing Pharmacist Name (NRS 639.220): Parixit H. Modi

Supervising/Managing Pharmacist NV Pharmacist Registration #: ~~Parixit H. Modi (Nevada license pending)~~ 23858

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Parixit H. Modi	NV Pharmacist Registration #: ~~Pending~~ 23858
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: CarelonRx Pharmacy, Inc. (incorporated in Delaware)

Parent Company (if any): CarelonRx, Inc. (incorporated in Indiana)

Corporation Name: Elevance Health, Inc. (Ultimate Parent Company, incorporated in Indiana)

Mailing Address: 220 Virginia Avenue

City: Indianapolis State: IN Zip: 46204

Telephone: (800) 331-1476 Email:

Contact Person Name: Shelley Smoot

Date of SEC Registration: | SEC Registration Number: 001-16751 | Stock Exchange Symbol: ELV

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☒ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President (title) for CarelonRx Pharmacy, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Richard G. Hill

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

5-26-23

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Richard G. Hill hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Vice President (title) for CarelonRx Pharmacy, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 26 day of May, 2023

Notary Public

TARA PEACOCK
Notary Public, State of Texas
Comm. Expires 06-10-2024
Notary ID 132516222

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard G. Hill, Vice President

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

5-26-23

Date

Board Use Only	Date Received: 6/5/23	Amount: $500-CK-63102636

carelon Rx | Pharmacy

CARELONRX PHARMACY, INC. OWNERS, OFFICERS & DIRECTORS

Name	Title	Business Address	Federal Tax Identification Number	Ownership %
CarelonRx, Inc.	Owner	220 Virginia Avenue Indianapolis, IN 46204	82-3062245	100%

Name	Title	Business Address	Home Address	Ownership %
Paul E. Marchetti	President/ Director	108 Leigus Road Wallingford, CT 06492	[redacted]Manitou Road Westport, CT 06880	0%
Richard G. Hill	Vice President	2505 N. Highway 360 Suite 300 Grand Prairie, TX 75050	[redacted]Crosswind Drive Fort Worth, TX 76179	0%
Vincent E. Scher	Treasurer/ Director	220 Virginia Avenue Indianapolis, IN 46204	[redacted]erenity Court Indianapolis, IN 46280	0%
Eric K. Noble	Assistant Treasurer	220 Virginia Avenue Indianapolis, IN 46204	[redacted]Lions Head Drive, Apt. A Indianapolis, IN 46260	0%
Kathleen S. Kiefer	Secretary	220 Virginia Avenue Indianapolis, IN 46204	[redacted]Morningside Drive Indianapolis, IN 46240	0%
Jay H. Wagner	Director	220 Virginia Avenue Indianapolis, IN 46204	[redacted]Devon Lane Carmel, IN 46032	0%

carelon Rx | Pharmacy

CarelonRx Pharmacy, Inc. Ownership Structure



Elevance Health, Inc. is the parent health company serving communities by using a whole-health approach to address their health needs.

Carelon Holdings, Inc. is the holding company which doesn't manufacture, sell, or conduct business operations.

CarelonRx, Inc. is the Pharmacy Benefit Management company.

CarelonRx Pharmacy, Inc. is the Pharmacy.

carelon Rx | Pharmacy

Elevance Health, Inc. Major Stockholders

As of today's date, the following are the largest four stockholders of Elevance Health, Inc.:

1. BlackRock, Inc. – holds 9.0% of Outstanding Shares
2. The Vanguard Group – holds 8.99% of Outstanding Shares
3. T. Rowe Price Group, Inc. – holds 5.3% of Outstanding Shares
4. State Street Corporation – holds 4.8% of Outstanding Shares

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CARELONRX PHARMACY, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF DECEMBER, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5688829 8300

SR# 20224309526

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 205132188

Date: 12-19-22

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 09/02/2022
Receipt
Number: 2022130762
Receipt Amount $: 480.00

Pharmacy - Limited Service

Closed Door,Mail Order

PERMIT NO	EXPIRES
Y009433	10/31/2024

Issued to :

CarelonRx Pharmacy, Inc.
IngenioRx, Inc.
4821 NORTH STONE AVENUE
TUCSON, AZ 85704

CarelonRx Pharmacy, Inc.
4821 NORTH STONE AVENUE SUITE C
TUCSON, AZ 85704

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : IngenioRx, Inc.
LICENSE NUMBER : Y009433
EXPIRES : 10/31/2024

http://www.azpharmacy.gov

- Your license must be available for inspections during business hours.
- Permit holder(s) must display permit in the location to which it is issued.
- Please note it is your responsibility to keep this license/permit current.

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/permit but serves as the primary source of verification.

Name :	CarelonRx Pharmacy, Inc.
Address :	4821 North Stone Avenue Suite C Tucson AZ 85704
License No :	Y009433
Permit Type :	Pharmacy
Sub Type :	Limited Service
Date Issued :	04/17/2023
Expiration Date :	10/31/2024
Status :	OPEN
Discipline :	No

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 05/17/2023

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC2714916	08-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-19-2023

CARELONRX PHARMACY, INC.
4821 N STONE AVE
STE C
TUCSON, AZ 857045727

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC2714916	08-31-2025	$888

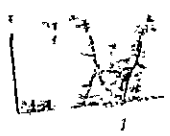
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Form DEA-223 (9/2016)



Arizona State Board of Pharmacy

PHARMACY SECURITY/EQUIPMENT INSPECTION on 04/17/2023 for CarelonRx Pharmacy, Inc.

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit# :	AZ Permit Exp.Date :	Business Name :
Y009433	10/31/2024	CarelonRx Pharmacy, Inc.

Address : 4821 North Stone Avenue

Zip :	City :	State :
85704	Tucson	AZ

Phone :	Email :	Inspection Date :
(833) 396-0309		04/17/2023

PIC :	Inspection Reviewed With :	Inspection type :
Parixit Modi	PIC	Opening

Inspection Conducted By : Truman Leong

ACTIVITIES

1	Nonsterile Compounding	○YES ◉NO
2	Nonsterile Hazardous Compounding	○YES ◉NO
3	Sterile Compounding	○YES ◉NO
4	Sterile Hazardous Compounding	○YES ◉NO

Hospital Facility Data

# Licensed Beds	DHS License #
0	0

PHARMACY DEPARTMENT

1 Size/Personnel — ◉S ○C/P ○U ○N/A

R4-23-609(A); R4-23-655(B)(C); R4-23-670 to 675

1905 sq ft excluding medication vault space/conference rooms/office rooms/break room. 29 authorized persons.

2 Shelves — ○S ○C/P ○U ◉N/A

R4-23-609(A); R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

No ownership of medications. No MFG drug storage. Patient in transit/will call medications might be staged overnight and locked in the controlled substance area that has a RPh only access badge.

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3 Design-efficient, safe pharmacy practice ◉S ○C/P ○U ○N/A
R4-22-609(A); R4-23-655(C); R4-23-672(A); R4-23-673(A)(B); R4-23-674(A)(3); R4-23-675(A)
15 cubicles. Will seat RPhs and Technicians.

4 Counter ○S ○C/P ○U ◉N/A
R4-23-609(B); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
Not a dispensing pharmacy. No countertops.

5 Aisles ◉S ○C/P ○U ○N/A
R4-23-609(C); R4-23-672(A), R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

6 Consultation area ○S ○C/P ○U ◉N/A
R4-23-609(D)
Closed door mail order. No counseling is expected on site. Discussed with PIC if counseling occurs that a designated area with signage would be required.

7 Enclosed (barrier) ◉S ○C/P ○U ○N/A
R4-23-609(F); R4-23-655(D); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675
Barriers checked that shared walls with CareMoore facility space. No gaps observed.

8 Entry doors ◉S ○C/P ○U ○N/A
R4-23-609(F); R4-23-610(B); R4-23-655(D); R4-23-657(A)(2); R4-23-672(A)(F)(2); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
1 entry door from exterior of building into the lobby space. One entry door into the pharmacy from lobby. 1 Exit door for emergencies. Badge access with physical key lock. Badge access has a feature that requires a RPh to sign out end of day and beginning of day prior to any technicians entering the pharmacy. An alarm is trigged if a badge is attempted while no Pharmacists are on shift in the physical space.

9 Lighting ◉S ○C/P ○U ○N/A
R4-23-609(G); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

10 Temperature controlled/Ventilation ◉S ○C/P ○U ○N/A
R4-23-609(G); R4-23-655(E); R4-23-656(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
HVAC units with electronic thermostat.

11 Working counter barrier ○S ○C/P ○U ◉N/A
R4-23-609(H)

12 Receiving/checking area ◉S ○C/P ○U ○N/A
R4-23-610(E); R4-23-655(E); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
Prescriptions delivered from central fill will arrive through the front check in lobby and authorized personnel will sign for it.

13 Opening for Rx receipt when closed ○S ○C/P ○U ◉N/A
R4-23-610(F)

14 Walls ◉S ○C/P ○U ○N/A
R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

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15 Ceilings — ◉S ○C/P ○U ○N/A

R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

16 Windows — ○S ○C/P ○U ◉N/A

R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

17 Floors — ◉S ○C/P ○U ○N/A

R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

18 Restroom — ◉S ○C/P ○U ○N/A

R4-23-611(A)(4)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

19 Sink (hot and cold running water) — ◉S ○C/P ○U ○N/A

R4-23-611(A)(9); R4-23-656(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

20 Nonsterile compounding area — ○S ○C/P ○U ◉N/A

R4-23-410(E)

SECURITY

1 Controlled substances — ◉S ○C/P ○U ○N/A

R4-23-609(E); R4-23-657(A)(1); R4-23-658(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

A controlled substance safe with locking mechanism was observed. Discussed DEA opening and biennial inventory and May 1st inventory (potentially on hand indication of patient will call Rx's).

2 Pharmacist access — ◉S ○C/P ○U ○N/A

R4-23-609(F); R4-23-610(B); R4-23-657(A)(1); R4-23-671(B)(1); R4-23-672(A)(B)(F); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

4 RPh keys. Will be stored in a lock box/vault area. 1 Physical key will be utilized by the PIC. Badge access is controlled electronically through a database under PIC control.

3 Additional pharmacy drug storage areas — ○S ○C/P ○U ◉N/A

R4-23-609(G)(2); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

4 Filled Rx medication storage — ◉S ○C/P ○U ○N/A

R4-23-610(G); R4-23-673(E); R4-23-674(C); R4-23-675(C)

Located in the locked area where the controlled substance safe is.

5 Remote drug storage (hospitals) — ○S ○C/P ○U ◉N/A

R4-23-654(D); R4-23-672(C)

PHARMACY LIBRARY

1 Pharmacology or Toxicology reference — ◉S ○C/P ○U ○N/A

R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

Online access to clinical pharmacology and micromedex.

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2 Therapeutics reference ◉S ○C/P ○U ○N/A

R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

Online reference and a hard bound therapeutics reference book observed.

3 Drug compatibility reference ○S ○C/P ○U ◉N/A

R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

4 Drug product equivalency reference ◉S ○C/P ○U ○N/A

R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

5 Sterile products reference ○S ○C/P ○U ◉N/A

R4-23-612(A)(9); R4-23-656(1); R4-23-670(B)(6); R4-23-672(A); R4-23-673(C); R4-23-675(A)

6 Policy and procedure manual-pharmacy operations ◉S ○C/P ○U ○N/A

R4-23-610(A); R4-23-653(A); R4-23-658(A); R4-23-671(E); R4-23-672(A)(G); R4-23-673(G); R4-23-674(F); R4-23-675(D)

7 Policy and procedure manual-technicians ◉S ○C/P ○U ○N/A

R4-23-610(A); R4-23-653; R4-23-672(A)(G); R4-23-673(C); R4-23-674(F); R4-23-675(D)

Discussed with PIC requirements of R4-23-1105(B)(D. Discussed technician on-the-job review of Arizona State rules and permissible/non-permissible activities.

8 Policy and procedure manual-automation ○S ○C/P ○U ◉N/A

R4-23-614, R4-23-615, R4-23-616, R4-23-654(D); R4-23-701.02, R4-23-701.04

9 Policy and procedure manual-compounding ○S ○C/P ○U ◉N/A

R4-23-410; R4-23-670

10 Arizona statutes/rules ◉S ○C/P ○U ○N/A

R4-23-612(A)(8); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

online references available.

11 Current antidote/drug interaction information ◉S ○C/P ○U ○N/A

R4-23-612(A)(12); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

12 Poison Control # displayed ◉S ○C/P ○U ○N/A

R4-23-612(A)(13); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

On break room fridge and also observed on cubicles.

PHARMACY EQUIPMENT/FORMS

1 Refrigerator ◉S ○C/P ○U ○N/A

R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670; R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

Refrigerator located in the will call room was observed and temperature (digital display) within allowed excursions. Discussed with PIC review/monitor of temps per policy and procedure. No intention of storing vaccines.

2 Freezer ○S ○C/P ○U ◉N/A

R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670(B)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

3 Computer-security/data storage ◉S ○C/P ○U ○N/A

R4-23-408

RPh and Tech individual credentials were verified. System also has an auto log out feature enabled.

4 Computer-patient profiles ◉S ○C/P ○U ○N/A

R4-23-408(B)(3)

Allergies and medical conditions sections were observed. Discussed with PIC for requirements and marking no known or not provided if applicable after intake/DUR/Fill history/Counseling interactions.

5 Computer-single drug usage report ◉S ○C/P ○U ○N/A

R4-23-408(B)(4)

6 Computer-pharmacist log book/hard copy print out ◉S ○C/P ○U ○N/A

R4-23-408(C)(4)

Manual log book template reviewed.

7 Prescription label ◉S ○C/P ○U ○N/A

ARS 32-1963.01; ARS 32-1968; R4-23-612(A)(10); R4-23-658(D)(1)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)(D); R4-23-701.01(2); R4-23-703(C)

Label contained required compliance components along with central fill name/location/number. Toll free mail order # found on label. Pharmacy address was checked for accuracy.

8 Federal transfer labels ◉S ○C/P ○U ◉N/A

R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)

9 Warning labels ◉S ○C/P ○U ○N/A

R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)

10 Written patient information ◉S ○C/P ○U ○N/A

R4-23-402(C)(4); R4-23-402(I)

Written information sheets met compliance requirements for deliveries.

11 Consultation log ◉S ○C/P ○U ○N/A

R4-23-402(G)

Electronic demonstration of counseling notes (accepted) within a patient demo profile. A report can also be generated for counseling notes saved post s old status. The counseling note shows RPH ID.

12 Federal medication guides ◉S ○C/P ○U ○N/A

21 CFR part 208

13 Hospital IV label ○S ○C/P ○U ◉N/A

R4-23-658

14 Generic Rx blanks ◉S ○C/P ○U ○N/A

R4-23-402(A); R4-23-407(D)

Reads generic for or interchangeable biologic for.

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15	Immunization administration recordkeeping	○S ○C/P ○U ◉N/A	R4-23-411(F)
16	Schedule V register	○S ○C/P ○U ◉N/A	R4-23-612(A)(2)
17	Methamphetamine precursor sales log	○S ○C/P ○U ◉N/A	ARS 32-1977
18	Red C stamp	○S ○C/P ○U ◉N/A	R4-23-612(A)(11); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	CSPMP reporting PMP reporting set up will be confirmed with Compliance Officer once DEA registrant is received for zero reporting.	○S ◉C/P ○U ○N/A	R4-23-502
20	Graduates Graduated cylinders observed.	◉S ○C/P ○U ○N/A	R4-23-612(A)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
21	Mortar & Pestle Mortar and pestle found.	◉S ○C/P ○U ○N/A	R4-23-612(A)(4); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
22	Steel spatulas Steel spatulas found.	◉S ○C/P ○U ○N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
23	Rubber (nonmetallic) spatula	◉S ○C/P ○U ○N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
24	Approved Rx balance	○S ○C/P ○U ◉N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
25	Weights for Rx balance	○S ○C/P ○U ◉N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
26	Ointment tile	○S ○C/P ○U ◉N/A	R4-23-612(A)(7); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
27	Automated storage and distribution system (patient access)	○S ○C/P ○U ◉N/A	R4-23-614(A)(B)(1)(2)
28	Automated storage and distribution system (hospital)	○S ○C/P ○U ◉N/A	R4-23-614(A)(B)(1)(3); R4-23-654(D)
29	Mechanical storage and counting device	○S ○C/P ○U ◉N/A	R4-23-615

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30	Mechanical counting device	○S ○C/P ○U ◉N/A	R4-23-616
31	Emergency drug supply units (LTC)	○S ○C/P ○U ◉N/A	R4-23-701.02
32	Automated emergency drug supply units (LTC)	○S ○C/P ○U ◉N/A	R4-23-701.02(E)
33	Automated dispensing system (LTC)	○S ○C/P ○U ◉N/A	R4-23-701.04

STERILE PRODUCT COMPOUNDING AREA/EQUIPMENT:

1	Size	○S ○C/P ○U ◉N/A	R4-23-670(A)
2	Dedicated to compounding sterile products	○S ○C/P ○U ◉N/A	R4-23-670(A)(1); R4-23-656(5)
3	Isolated from other pharmacy functions	○S ○C/P ○U ◉N/A	R4-23-670(A)(2)
4	Restricts entry/access	○S ○C/P ○U ◉N/A	R4-23-670(A)(3)
5	Free from unnecessary disturbances airflow	○S ○C/P ○U ◉N/A	R4-23-670(A)(4)
6	Nonporous and cleanable floor	○S ○C/P ○U ◉N/A	R4-23-670(A)(5)
7	Nonporous and cleanable walls	○S ○C/P ○U ◉N/A	R4-23-670(A)(5)
8	Nonporous and cleanable ceiling	○S ○C/P ○U ◉N/A	R4-23-670(A)(5)
9	Environment ISO 7	○S ○C/P ○U ◉N/A	R4-23-670(A)(6)
10	Hood ISO 5	◉S ○C/P ○U ◉N/A	R4-23-670(B)
11	Prep area ISO 7/ISO 8	○S ○C/P ○U ◉N/A	R4-23-110; R4-23-670(E)(F)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

NOTES

CarelonRx Pharmacy. Opening Pharmacy Security and Equipment inspection. Mail order pharmacy with shared services/central fill agreement. Facility will proces s all front end dispensing (receipt of script order, data entry, recordkeeping, drug utilization reviews, refill orders etc). The medication physically is being fulfilled from a central fill pharmacy under contractual agreements with "white labeling" (dba/doing business as). A real time operating system/computer is not shared b/ t the pharmacy and central fill. Technical support converts data to allow a shared informational flow for processing the fill. Working outside the pharmacy was di scussed as a potential future staffing model. Discussed R4-23-621(D) for State compliance. Pharmacist in charge selected and added into the Arizona State Board of Pharmacy profile. Operating a standard M-F 9-5:30 no Sat/Sun. No compounding. No TPN. Current business model involves mail deliveries to patient home res idence only. Central fill will route to CarelonRx at permitted location for mail stop, reconcilliation check, then transitioned to mail delivery to patient's home. No i mmunizations at this location.

Address updated to include suite C.
DEA# pending application.
CSPMP zero reports required once DEA registrant is granted. No waiver available.

Compliance Pending:
- CSPMP reporting.
- DEA registrant.

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-State	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Chewy Pharmacy, LLC

Physical Address: 360 Research Drive

City: Pittston State: PA Zip: 18640

Mailing Address (if different from physical address): 7700 West Sunrise Blvd

City: Plantation State: FI Zip: 33322

Telephone: 570-669-4673 Toll Free # (NAC 639.708, NRS 639.23286): 877-977-3879

Fax: _____ Contact Email: PharmacyLicensing@chewy.com

Website: www.chewy.com/pharmacy

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Alexia Westerhausen

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21442

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name:	NV Pharmacist Registration #:
Joseph Ligotski	22050
Kerry Pallien	22007
Tiffany Santarelli	22474
Michael Bulkely	22459
Lora Panzik	22566
Richard Skultety	22567
Sandra Scavo	22110
Nevina Trunzo	22111
Stephen Bernard	22475
Michael Bulkley	22459
Debra Gangemi	22324

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
N/A		

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Chewy Pharmacy, LLC.
360 Research Dr.
Pittston, Pa 18640

List of Nevada Registered Pharmacists Continued

Pharmacist	Registration Number
Barbara Skultety	22566
Elliott Silkowski	22733
Annie-Marie Urbanski	22736
Kevin C. Coughlin	22636

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Chewy, Inc.

Corporation/Organization Name: Chewy Pharmacy LLC

Mailing Address: 7700 West Sunrise Blvd

City: Plantation State: Fl Zip: 33322

Telephone: 570-569-4673 Email: PharmacyLicensing@chewy.com

Contact Person Name: Geoffrey Christ

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist In Charge (title) for Chewy Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Alexia Westerhausen

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/17/23

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Alexia Westerhausen hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist In Charge (title) for Chewy Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 17th day of August, 2023

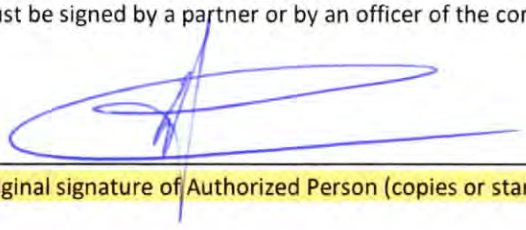
Notary Public

Commonwealth Of Pennsylvania
- Notary Seal -
JOSHUA MINETOLA, Notary Public
Luzerne County
My Commission Expires July 20, 2026
Commission Number 1256984

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ornel Cotera

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

8/31/23

Date

Board Use Only	Date Received: 9/11/23	Amount: 500-CK-18373

Chewy Pharmacy, LLC Officers List and Corporate Shareholder Information:

Name	Title/ Percent of Ownership	Business Address
Chewy Pharmacy, LLC	Owner, 100%	7700 West Sunrise Blvd, Plantation FL 33322
Ornel Cotera	President, 0%	7700 West Sunrise Blvd, Plantation FL 33322
Justin Mills	Vice President, 0%	2815 Watterson Trail, Louisville, KY 40299

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CHEWY PHARMACY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTIETH DAY OF AUGUST, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CHEWY PHARMACY, LLC" WAS FORMED ON THE NINETEENTH DAY OF JULY, A.D. 2018.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6981831 8300

SR# 20213117519

Authentication: 204041332

Date: 03-23-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

Commonwealth of Pennsylvania Department of State
Bureau of Professional and Occupational Affairs

Pharmacy

License Number
PP483043

Expiration Date
08/31/2025

Active

CHEWY PHARMACY, LLC
ALEXIA NANNETTE WESTERHAUSEN
360 RESEARCH DRIVE
PITTSTON, PA 18640

OFFICIAL DOCUMENT

READ THE FOLLOWING INFORMATION CAREFULLY CONCERNING YOUR LICENSE:

1. SIGN THE WALLET CARD AND CERTIFICATE WHERE INDICATED.
2. DETACH THE WALLET CARD AND CERTIFICATE AT PERFORATION.

Pennsylvania Licensing System (PALS)

Visit our website at: www.pals.pa.gov to renew your license, change your personal or license address, or order duplicate licenses.

CHEWY PHARMACY, LLC
ALEXIA NANNETTE WESTERHAUSEN
360 RESEARCH DRIVE
PITTSTON, PA 18640

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

23 0056494

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO BOX 2649 Harrisburg PA 17105-2649

License Type
Pharmacy

CHEWY PHARMACY, LLC
ALEXIA NANNETTE WESTERHAUSEN
360 RESEARCH DRIVE
PITTSTON, PA 18640

License Status
Active

Initial License Date
11/02/2021

Expiration Date
08/31/2025

License Number
PP483043

Arion R. Claggett

Acting Commissioner Arion R. Claggett

Signature

ALTERATION OF THIS DOCUMENT IS A CRIMINAL OFFENSE UNDER 18 Pa.C.S. 4911

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

08/21/2023

License Information

CHEWY PHARMACY, LLC

360 RESEARCH DRIVE
PITTSTON, Pennsylvania 18640

Board/Commission:	State Board of Pharmacy	Status Effective Date:	11/02/2021
LicenseType:	Pharmacy	Issue Date:	11/02/2021
Specialty Type:		Expiration Date:	08/31/2025
License Number:	PP483043	Last Renewal:	07/13/2023
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
ALEXIA NANNETTE WESTERHAUSEN	Pharmacist Manager	Pharmacist	RP450386	Active	11/02/2021	09/30/2024

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Chewy Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 360 Research Drive

City: Pittston State: PA Zip: 18640

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 570-569-4673 Website: www.chewy.com/pharmacy

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Alexia Middle: Nannette Last: Westerhausen

Alias(es, nicknames, name changes, etc.): Alexia Nannette Luthye

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 360 Research Drive

City: Pittston State: PA Zip: 18640

Telephone: [redacted] Email: awesterhau@chewy.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Nroth Carolina-kenan-Flagler Business School		05/19-08/18	
Address	**City**	**State**	**Zip**
300 Kenan Center Drive	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
Executive MBA			

School Name		From - To (MM/YY – MM/YY)	
Texas A&M Irma Lerma Rangel College of Pharmacy		08/06-05/10	
Address	**City**	**State**	**Zip**
1010 W Ave B	Kingsville	TX	78363
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Baylor University			
Address	**City**	**State**	**Zip**
1311 S 5th Street	Waco	TX	76706
Diploma/Degree obtained, if any			
B.S-Neuroscience, Minor-Biology, Double Honors			

School Name		From - To (MM/YY – MM/YY)	
Lonestar College		08/98-08/02	
Address	**City**	**State**	**Zip**
30555 Tomball Parkway	Tomball	TX	77375
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Tomball Senior High School		08/98-05/00	
Address	**City**	**State**	**Zip**
30330 Quinn Road	Tomball	TX	77375
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/21-present	[redacted] Karin Drive	Mountain Top	PA	18707
05/19-08/21	[redacted] Berry Creek Circle	Raleigh	NC	27613
06/18-05/19	[redacted] Riverwood Circle Apt# [redacted]	Raleigh	NC	27612
06/17-06/18	[redacted] Fairsted Dr Apt [redacted]	Raleigh	NC	27612
10/16-06/17	[redacted] Misty Meadow Lane	Houston	TX	77079
12/15-10/16	[redacted] Almeda Rd Apt# [redacted]	Houston	TX	77004
05/15-12/15	[redacted] S. Voss Rd Apt# [redacted]	Houston	TX	77057
10/11-05/15	[redacted] Glen Knoll Drive	Houston	TX	77077
05/11-10/11	[redacted] Pin Oak Park	Houston	TX	77081
From - To (MM/YY – MM/YY)	Address	City	State	Zip

School:

Escuela Americana de El Salvador 08/96-05/98

Address: Colonia Maquilishuat, Avenida las Azaleas, San Salvador, El Salvador

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Chewy Pharmacy			06/21-present
Business Address	**City**	**State**	**Zip**
360 Research Drive	Pittston	PA	18640
Phone	**Title**	**Number of Employed Hours**	
570-569-4673	Pharmacist in Charge	40+ 4000	

Description of Duties
Responsible for onboard pharmacists, training pharmacists, compliance with laws and multiple states regulations

Business Name			From - To (MM/YY – MM/YY)
US Pharmamed			06/17-06/21
Business Address	**City**	**State**	**Zip**
3450 Tarheel Drive	Raleigh	NC	27609
Phone	**Title**	**Number of Employed Hours**	
800-787-6331	Pharmacist In Charge/Sr Clinical Pharmacist	40+ 4000	

Description of Duties
Compliance with VIPPS, URAC; Training techs and pharmacists, history of patients, Quality Improvement projects, Quality assurance projects

Business Name			From - To (MM/YY – MM/YY)
Specialty Veterinary Pharmacy (SVPMEDS)			06/15-06/17
Business Address	**City**	**State**	**Zip**
4159 Bluebonnet Dr	Stafford	TX	77477
Phone	**Title**	**Number of Employed Hours**	
877-673-3705	Staff Pharmacist & Pharmacist in Charge	40+	

Description of Duties
Preceptor, Adherence to multiple state laws and regulations, sterile & non sterile compliance, increasing throughput with accurancy, quality assurance,

Business Name			From - To (MM/YY – MM/YY)
Hotze Pharmacy			06/13-06/15
Business Address	**City**	**State**	**Zip**
20214 Braidwood Dr#140	Katy	TX	77450
Phone	**Title**	**Number of Employed Hours**	
281-828-9088	Director of Dispensing Room Pharmacist	40+	

Description of Duties
Increase throughput of pharmacists and counseling.

Business Name			From - To (MM/YY – MM/YY)
CVS Pharmacy			05/11-06/16
Business Address	**City**	**State**	**Zip**
5401 Washington Ave	Houston	TX	77007
Phone	**Title**	**Number of Employed Hours**	
713-861-3883	Pharmacist in Charge		

Description of Duties
Comply with Texas pharmacy law and training of techs and pharmacists, counseling,

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Alexia Westerhausen, certify that as the designated representative for

Chewy Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AW I am at least 21 years of age;
3. AW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Alexia Westerhausen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexia Westerhausen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 9/25/23

Please have this section completed in the presence of a Notary Public.

State of PA, ss. County of LUZERNE

I, Alexia Westerhausen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date 9/25/23

Subscribed and Sworn to before me this 25th day of September, 2023.

Notary Public Signature

Commonwealth Of Pennsylvania
- Notary Seal -
JOSHUA MINETOLA, Notary Public
Luzerne County
My Commission Expires July 20, 2026
Commission Number 1256984

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Chewy Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 360 Research Drive

City: Pittston State: PA Zip: 18640

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 570-569-4673 Website:

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Ornel Middle: Last: Cotera

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] SE 12th Avenue

City: Deerfield Beach State: FL Zip: 33441

Telephone: Email: ocotera@chewy.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Mast Academy		06/96 - 05/00	
Address	City	State	Zip
3979 Rickenbacker Causeway	Miami	FL	33149
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Florida		06/00 - 08/06	
Address	City	State	Zip
205 Fletcher Dr	Gainesville	FL	32611
Diploma/Degree obtained, if any			
B.S Economics			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19 - Current	[redacted] SE 12th Ave	Deerfield Beach	FL	33441
10/09 - 05/19	[redacted] SE 17th Ave	Deerfield Beach	FL	33441
03/11 - 11/14	[redacted] utton Dr, Apt [redacted]	Matawan	NJ	07747
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Chewy, Inc.			09/15 - current
Business Address	**City**	**State**	**Zip**
7700 West Sunrise Blvd	Plantation	FL	33322
Phone	**Title**		
786 320 7111	VP, Category Management		
Description of Duties			
Monitor & oversee Chewy Pharmacy, compounding, OTC, F&T and the Practice Hub business teams.			

Business Name			From - To (MM/YY – MM/YY)
Office Depot			11/14 - 09/15
Business Address	**City**	**State**	**Zip**
6600 N. Military Trail	Boca Raton	FL	33487
Phone	**Title**		
561-438-4800	Sr. Category Manager		
Description of Duties			
Managed assortment for digital storage category			

Business Name			From - To (MM/YY – MM/YY)
Hess Corp.			06/07 - 11/14
Business Address	**City**	**State**	**Zip**
1 Hess Plaza	Woodbridge	NJ	07095
Phone	**Title**		
732-750-6888	Category Manager		
Description of Duties			
Managed center store assortment for convenience stores.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ornel Cotera

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/2/23

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, Ornel Cotera, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/2/23

Date

Subscribed and Sworn to before me this 2 day of August, 2023

Notary Public Signature

BRITTNY KAREL ANNE RODRIGUEZ
Notary Public-State of Florida
Commission # GG 961625
My Commission Expires
February 24, 2024

(Seal)

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

CHEWY PHARMACY, LLC

360 RESEARCH DRIVE

PITTSTON, Pennsylvania, 18640

Phone: 877-977-3879
Owner: CHEWY PHARMACY, LLC

LICENSE

License No: PP483043
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: Non-Directed Routine

Inspection Date: 04/14/2023
Inspection Result: Passed

Remarks: Pharmacy inspection was conducted with a walk through of entire pharmacy work area accompanied by Pharmacy Director Alexia Westerhausen. Standard operating procedures were discussed along with cold chain procedures.

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

WILLIAM ZUPKO	4/14/2023 9:47:10 AM	Alexia Nannette Westerhausen - RP 450386
Signature of Inspector	Date/Time	Signature of Owner/Representative

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

CHEWY PHARMACY, LLC

360 RESEARCH DRIVE

PITTSTON, Pennsylvania, 18640

Phone: 877-977-3879

Owner: CHEWY PHARMACY, LLC

LICENSE

License No: PP483043

Profession: Pharmacy

License Type: Pharmacy

Inspection Type: Non-Directed Routine

Inspection Date: 04/14/2023

Inspection Result: Passed

Remarks: Pharmacy inspection was conducted with a walk through of entire pharmacy work area accompanied by Pharmacy Director Alexia Westerhausen. Standard operating procedures were discussed along with cold chain procedures.

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	YES
Is the automated medication systems properly validated?	YES
Are there policies and procedures for the operation of the automated medication systems?	YES
Is there a program for quality assurance for the automated medication systems?	YES
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician (PT) Application

Non-Refundable $50 fee

Rev (06/22/2022)

Section 1: General Information

First: LEEANN Middle: JAVIER Last: CARLOS

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] SOMNET COURT

City: LAS VEGAS State: NV Zip: 89147

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP-approved PT school or training program.)

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

Section 3: Application Qualifications (If you answer "NO" to any questions in this section, you CANNOT submit this application)	Yes	No
1. Are you 18 years of age or older?	X	
2. Are you a high school graduate or the equivalent?	X	

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following where applicable:

Date of Event/Arrest	Disposition Date	State	City	County
2000		HI	HONOLULU	HONOLULU
Case #		Governing, Licensing, Arresting/Presiding Body/Agency/Court		
Reason/Charge: DOMESTIC ABUSE				
Plaintiff/Defendant/Claimant/Respondent: SELF / EX HUSBAND		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity: HOME				

Provide explanation below: Ex husband (HUSBAND AT THAT TIME) got into a disagreement that escalated to physical. Everything happened so fast. I remembered he pushed me and hit my head & bleed. I took what was near me (a stick) and tried as self defense. Officers took that as a weapon and took me in. Ex husband dropped the case that following day

Original Signature (electronic, copies or stamps not accepted)

August 1, 2023
Date

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 **Provide all the following *where applicable*:**

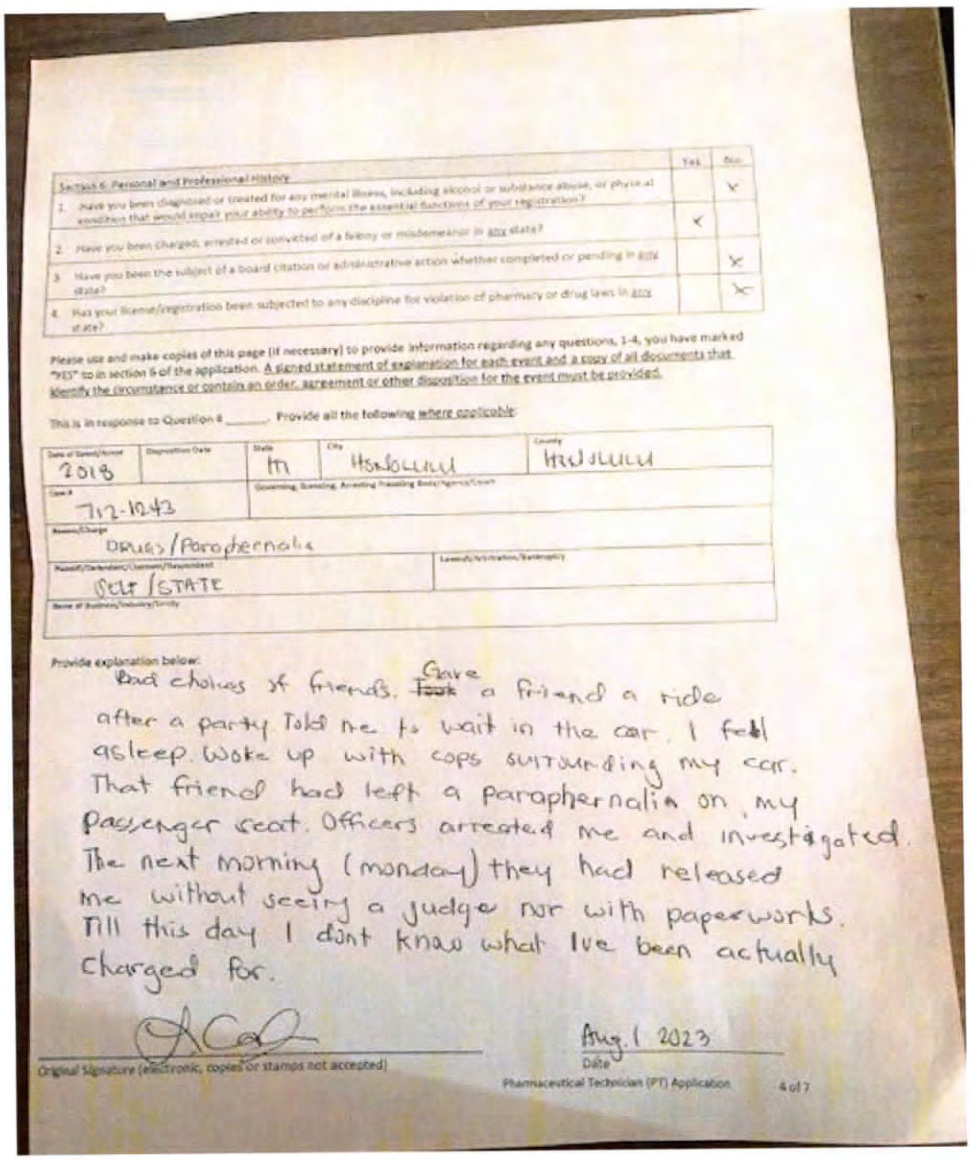
Date of Event/Arrest	Disposition Date	State	City	County
2015		HI	PEARL CITY	HONOLULU
Case #		Governing, Licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
NOISE COMPLAINT				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
SELF/STATE				
Name of Business/Industry/Entity				
HOME/RESIDENT				

Provide explanation below:

(couple)
Our tenants, where we resided were having arguements that lead to violence early in the morning. I tried to help by deescalating the situation but the ~~this~~ time the officers ARRIVED never questioned and read me my rights. I went to court twice and gave it settled it on the third time as a misdemeanor.

Original Signature (electronic, copies or stamps not accepted)

August 1, 2023
Date



Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical conditions that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following where applicable:

Date of Event/Arrest	Disposition Date	State	City	County
2018		HI	HONOLULU	HONOLULU
Case #	Governing, Licensing, Arresting, Presiding Body/Agency/Court			
712-1243				
Arrest/Charge				
DRUGS/Paraphernalia				
Plaintiff/Complainant/Licensee/Respondent		Lawsuit/Arbitration/Bankruptcy		
SELF/STATE				
Name of Business/Industry/Entity				

Provide explanation below:

Had choices of friends. ~~Took~~ Gave a friend a ride after a party. Told me to wait in the car. I fell asleep. Woke up with cops surrounding my car. That friend had left a paraphernalia on my passenger seat. Officers arrested me and investigated. The next morning (monday) they had released me without seeing a judge nor with paperworks. Till this day I dont know what Ive been actually charged for.

Original Signature (electronic, copies or stamps not accepted)

Aug. 1 2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Original Signature, no copies or stamps accepted

10/19/22
Date

Board Use Only	Date Received: 10-25-22	Amount: 50.00 MO-777488777283

Processed 10.25.22 ✓

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Nevada Managing Pharmacist Certification of Training Hours for Pharmaceutical Technician in Training (PTT)

Rev (06/22/2022)

This form cannot be returned by fax or email.
We must have an original signature and fee to process.

Section 1: Certification of PTT (NAC 639.242) MUST BE COMPLETED BY THE PHARMACY MANAGER

Name of PTT: LEEANN CARLOS
PTT License #: PT25487

Pharmacy Manager Name: OLIVE BAYLE
Pharmacy Manager License #: 19TT

Name of Pharmacy: CVS Pharmacy
Pharmacy License #: PH07020

Pharmacy Address: 7285 S DURANGO DRIVE

City: LAS VEGAS
State: NV
Zip: 89113

Time period PTT employed (mm/yy-mm/yy): JULY 2021 - PRESENT

I certify to the Board that the above-named PTT has successfully completed 1543.05 hours of training and experience performing the tasks of a PT listed in NRS 639.1371 (3)(c) and NAC 639.245(2). The specific training and experience completed is listed below:

- PICK UP
- WAITING BIN
- RTS
- INVENTORY
- DROP OFF
- ANSWER CALL
- FILE
- TYPE SCRIPS
- CYCLE COUNT
- DELIVERY/MAIL
- COVID TESTING
- DRIVE THRU
- PATIENT CARE
- COMPUTER TRAINING

Do you certify that the PTT is competent to perform the duties of a pharmaceutical technician? ☑Yes ☐No (If you answered "No" please explain why below):

I certify under penalty of perjury that the information contained on this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this form and any portion thereof is a public record unless otherwise declared confidential by law, and may be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020.

OLIVE BAYLE

Print Name (First, Last)

Original Signature of Managing Pharmacist, no copies or stamps accepted

10-19-2022

Date

Board Use Only	Date Received: 10-25-22

4CCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician (PT) Application
Non-Refundable $50 fee

Rev (03/17/2023)

Section 1: General Information

First: JONATHAN Middle: _____ Last: MUNDI

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] E ALTA VIS AVE #02

City: LAS VEGAS State: NV Zip: 89120

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP and Board approved PT school or training program.)

Program/School Name: DINA MEDICAL

Address: 3755 L LAMANCE

City: LAS VEGAS State: NV Zip: 89121

Name of Program Director: LORINDA LANIER

Section 3: Employment Information

Pharmacy Name: _____ License #: _____

Address: _____

City: _____ State: _____ Zip: _____

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	X	
2. Are you a high school graduate or the equivalent?	X	

High School Name: NORCROSS HIGH Graduation Date OR Date GED obtained (mm/yy): 05/2008

Address: 8800 SPALDING DR

City: NORCROSS State: GA Zip: 30092

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 6: List all pharmacist license/registration you have/had in other states. Use another sheet if additional space is needed.

State	License/ Registration #	Issued Date	Expiry Date	License/Registration Status (check applicable box)				
				Active	Inactive	Expired	Revoked	Surrendered

Section 7: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 8: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 9: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?	X	
3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 9 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/21		ND	WILLISTON	WILLIAMS
Case # 53-2020-CR-184		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge: Possession of concealed firearm/Possesion of narcotics				
Plaintiff/Defendant/Claimant/Respondent: JONATHAN MUKENDI/STATE OF ND		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

~~what~~ My brother picked me up from the airport and while driving home we stopped for gas. When I went into the station my brother put his gun & drugs into my luggage. About a mile away from home we are pulled over due to his speeding. I was unaware of any of my brothers previous charges but it lead to a car search. They found the paraphenalia in my bag, with my flight tags still on. I was charged instead of him. I had to appeal to the courts to get my charges dismissed as they prevented me from pursuing a teaching career.

Original Signature (electronic, copies or stamps not accepted)

8/9/23
Date

STATE OF NORTH DAKOTA — IN DISTRICT COURT

COUNTY OF WILLIAMS COUNTY — NORTHWEST DISTRICT COURT

State of North Dakota,

Plaintiff,

VS

JONATHAN MUKENDI

Defendant,

ORDER OF DISMISSAL

Case No. 53-2020-CR-01844

Date of Birth: 05/19/1990
Charge: Carrying Concealed Firearm Or Weapon;

1. Please be notified that the above-named Defendant has satisfied the conditions of the deferred imposition of sentence under Rule 32.1, N.D.R.Crim.P. The period of the deferred has expired and there is no pending motion to revoke. This case is now dismissed, and the file is sealed. A copy of this notice has been sent to the State's Attorney.

Dated this 11/5/2021

BY THE COURT:

Signed: 11/5/2021 2:58:53 PM Joshua Rustad

Josh B. Rustad
District Court Judge

Signed: 11/5/2021 3:01:55 PM

Section 8: You MUST submit the documents below with your application base on your qualifications as a PT.	
Select your qualification as a PT (please check a box).	**Required documents to be submitted with your application.**
☒ The successful completion of an ASHP-approved PT school or training program	a. Provide a copy of the certification of completion of the program.
☐ **Active practice in good standing** in another state as a PT, and the successful completion of at least 1,500 hours of employment as a PT in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, which must be verified by a **signed affidavit** by the managing pharmacist of the pharmacy.	a. Provide a copy of your PT registration, license, or certificate (if it is a requirement by that state to practice as a PT), which must be current, active, and in good standing. b. Provide the signed affidavit from your managing pharmacist that you have completed at least 1,500 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application).
☐ The successful completion of at least 1,500 hours of training and experience as a registered pharmaceutical technician in training (PTT), performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy.	a. Provide the signed form from your managing pharmacist that you have completed 1,500 hours of training and experience in a pharmacy **in this state** as a registered PTT (see form provided in this application).
☐ The successful completion of a pharmaceutical technician training program conducted by a branch of the U.S. Armed Forces, the Indian Health Service of United States Department of Health and Human Services or the U.S. Department of Veterans Affairs.	a. Provide a copy of the certification of completion of the program.

Section 9: Fingerprints for a background check. ALL APPLICANTS MUST COMPLETE THIS SECTION. NRS 639.1371

In addition to the requirements in section 7, submit fingerprints for a background check by following the instructions https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/FP%20Instructions%20NRS%20639.127%20639.1371.pdf

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

JONATHAN STEPHANE MUKENDI
Print Name

Original Signature, no copies or stamps accepted

6/2/23
Date

Board Use Only	Date Received: 6/15/23	Amount: $50- HO-19-5411026455

Pima Medical Institute

ON RECOMMENDATION OF THE FACULTY AND BY AUTHORITY
OF THE BOARD OF DIRECTORS THIS

Certificate

IS HEREBY AWARDED TO

Jonathan Mukendi

FOR SATISFACTORY COMPLETION OF

Pharmacy Technician

33.5 Semester Credit Hours

IN ACCORDANCE WITH STANDARDS AND PROCEDURES SET BY THIS INSTITUTION

SIGNED AND GIVEN UNDER OUR HAND

AT Las Vegas Nevada

THIS 1st *DAY OF* June, 2023

DIRECTOR

FACULTY

4DDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician (PT) Application

Non-Refundable $50 fee

Rev (03/17/2023)

Section 1: General Information

First: TIKICI Middle: _____ Last: Ramirez

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] S arroyo grande blvd

City: henderson State: NV Zip: 89012

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP and Board approved PT school or training program.)

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

Section 3: Employment Information

Pharmacy Name: CVS pharmacy License #: 18330

Address: 9695 S. Maryland Pkwy

City: Las Vegas State: NV Zip: 89123

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	X	
2. Are you a high school graduate or the equivalent?	X	

High School Name: Foothill high School Graduation Date OR Date GED obtained (mm/yy): 06/2007

Address: 800 College dr Henderson

City: Henderson State: NV Zip: 89002

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 7: Personal and Professional History		
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: **WARNING** **You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.**	**Initials** RR	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state even if the case or charge has been dismissed, sealed, acquitted, or expunged?		X
3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/12/2009	9/22/10	NV	las vegas	clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
C-07136149A		City of las vegas NV		
Reason/Charge				
Unlawful use / Possesion of drug parafanilia				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

Took my friend to go pay a ticket and i let her borrow my purse the week before we went into the court they checked my bag and found a unused tabacco pipe in my purse got arrested and officer forced me to say it was mine got a ticket went to take care of it they couldnt find me in the system a month later driving home from work got told i had a warrent for my arrest went to jail for 2 weeks got let out for time served

See attached doc

Original Signature (electronic, copies or stamps not accepted)

8/22/2023
Date

Date Printed: August 22, 2023

Las Vegas Municipal Court
100 E.Clark Ave P.O. Box 3920
Las Vegas, Nevada 89127
38-COURT (702-382-6878)

THE CITY OF LAS VEGAS,
Plaintiff,
vs.
RAMIREZ, RICHARD A
Defendant

Violation Code: **9527**
Violation Description: **UNLAWFUL USE/POSSESSION OF DRUG PARAPHE**
Violation Date: **12/12/2007**
Case No.: **C0713649A**
History No.: **1276245**
Amended Code:
Amended Description:

JUDGMENT

Complaint: Disposition: **JAIL TIME** Finding: Disposition Date: **9/22/2008**

Date	Proceedings	Purpose	Court Date/Time	Dept
12/12/2007	CONTINUANCE GRANTED(CONT)	AR	1/7/08 1:00 pm	3
1/7/2008	RESET POSTCARD SENT(RESET)	AR	4/17/08 1:00 pm	3
4/17/2008	BENCH WARRANT-CASH BL DUE=(BW.5000)			
4/17/2008	NO WALKIN COURT DATE ON THIS CASE(WALKINNA)			
9/9/2008	BENCH WAR SATIS-ARRESTED(BWSA0909)			
9/9/2008	IN CUSTODY AT STEWART/MOJAVE JAIL(ICATSM)	P	9/10/08 9:00 am	3
9/10/2008	PLED NOT GUILTY(PNG)			
9/10/2008	PUBLIC ATTORNEY:(PA8702)			
9/10/2008	TAPE BEGINS:(TBA1000)	PT	9/18/08 9:00 am	3
9/18/2008	TRANSPORT(TRANS)	PT	9/22/08 8:00 am	3
9/22/2008	TAPE BEGINS:(TBA0912)			
9/22/2008	CHG PLEA NOLO-JAIL TIME=(CN-14DN)			
9/22/2008	CREDIT JAIL TIME SERVED(CTS-14D)			
9/22/2008	ADMIN ASSESSMNT WAIVED(AAW)			
9/22/2008	CONS ASSES FEE WAIVED(CAW)			
9/22/2008	SPECIALTY AA ASSESSMNT WAIVED(SFW)			

Section 8: You MUST submit the documents below with your application base on your qualifications as a PT.	
Select your qualification as a PT (please check a box).	**Required documents to be submitted with your application.**
☐ The successful completion of an ASHP-approved PT school or training program	a. Provide a copy of the certification of completion of the program.
☐ **Active practice in good standing** in another state as a PT, and the successful completion of at least 1,500 hours of employment as a PT in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, which must be verified by **a signed affidavit** by the managing pharmacist of the pharmacy.	a. Provide a copy of your PT registration, license, or certificate (if it is a requirement by that state to practice as a PT), which must be current, active, and in good standing. b. Provide the signed affidavit from your managing pharmacist that you have completed at least 1,500 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application).
☐ The successful completion of at least 1,500 hours of training and experience as a registered pharmaceutical technician in training (PTT), performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy.	a. Provide the signed form from your managing pharmacist that you have completed 1,500 hours of training and experience in a pharmacy **in this state** as a registered PTT (see form provided in this application).
☐ The successful completion of a pharmaceutical technician training program conducted by a branch of the U.S. Armed Forces, the Indian Health Service of United States Department of Health and Human Services or the U.S. Department of Veterans Affairs.	a. Provide a copy of the certification of completion of the program.

Section 9: Fingerprints for a background check. ALL APPLICANTS MUST COMPLETE THIS SECTION. NRS 639.1371

In addition to the requirements in section 7, submit fingerprints for a background check by following the instructions https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/FP%20Instructions%20NRS%206.99-127%206.99-131.pdf

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Rikki Ramirez

Print Name

Original Signature, no copies or stamps accepted

6/27/23

Date

check #do #1091552414 3

Board Use Only	Date Received: 5/24/23	Amount: $150

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Nevada Managing Pharmacist Certification of Training Hours for Pharmaceutical Technician in Training (PTT)

Rev (06/22/2022)

This form cannot be returned by fax or email.
We must have an original signature and fee to process.

Section 1: Certification of PTT (NAC 639.242) MUST BE COMPLETED BY THE PHARMACY MANAGER

Name of PTT: Rikki Ramirez — PTT License #: PT 27080

Pharmacy Manager Name: Thanh Tran — Pharmacy Manager License #: 18330

Name of Pharmacy: CVS 5043 — Pharmacy License #: PH 01890

Pharmacy Address: 9695 S Maryland

City: Las Vegas — State: NV — Zip: 89123

Time period PTT employed (mm/yy-mm/yy): 7/11/22

I certify to the Board that the above-named PTT has successfully completed 1500 hours of training and experience performing the tasks of a PT listed in NRS 639.1371 (3)(c) and NAC 639.245(2). The specific training and experience completed is listed below:

- Data Entry
- Insurance issue resolve
- Filling prescriptions
- Customer service as counter
- Inventory

Do you certify that the PTT is competent to perform the duties of a pharmaceutical technician? ☒ Yes ☐ No (If you answered "No" please explain why below):

I certify under penalty of perjury that the information contained on this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this form and any portion thereof is a public record unless otherwise declared confidential by law, and may be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020.

THANH TRAN
Print Name (First, Last)

Original Signature of Managing Pharmacist, no copies or stamps accepted

5/19/23
Date

Board Use Only	Date Received: 6/23/23

5

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
YE failed to recognize the incorrect filling of the prescription upon data entry and final verification resulting in the sale of the prescription and failed to provide counseling to patient.	N/A	Fined $1,000.00; assessed $500.00 in attorney's fees and costs.	CVS fined $2,000.00; assessed $1,000.00 in attorney's fees and costs.
AV made false representation(s) to the Board in two of her PTT applications submitted to the Board.	N/A	Revoked two years; $358.36 in attorney's fees and costs.	N/A
JLW prescribed controlled substances to Nevada patients during the period where his controlled substance registration was expired.	N/A	Fined $5,000.00 and $500.00 in attorney's fees and costs.	N/A
JG: NSBME imposed discipline on JG's license to practice medicine for allowing unlicensed persons to act under his authority to unlawfully operate Image Med Spa and to access, possess, administer, dispense, and/or prescribe dangerous drugs and hypodermic devices to perform cosmetic injections and topical administration of dangerous drugs onsite to patients who had not been examined by a practitioner and without direct practitioner supervision. Some of the drug products and devices purchased are intended for distribution in foreign markets and are not approved for marketing, distribution or use in the U.S.	N/A	Fined $5,000.00; assessed $1,000.00 in recoverable attorney's fees and costs.	N/A
MR: NSBME placed MR's license to practice medicine on probation for engaging in conduct in violation of standards of practice related to writing prescriptions for controlled substances.	N/A	2 year suspension; suspension is stayed and MR is placed on probation; fined $5,000.00; $1,000.00 in attorney's fees and costs; establish policies	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
		and procedures related to controlled substance prescriptions issued for the treatment of acute or chronic pain.	
DL disciplined by the NSBME on DL's license to practice medicine for failure to maintain medical records related to prescribing controlled substances.	N/A	1 year suspension; suspension is stayed; fined $2,000.00; $500.00 attorney's fees and costs; establish policies and procedures to ensure that any controlled substance prescription complies with all applicable federal and state statutes and regulations.	N/A
JS surrendered her NSBME to practice medicine and no longer qualifies for a controlled substance registration.	N/A	Revoked 1 year.	N/A
ES stipulated to responsibility, and the CA Board disciplined ES for violations related to compounding pharmacy regulations.	N/A	5 hours CE in pharmacy operations and pharmacy law and 5 hours CE in USP 797 in addition to CEs required for renewal; not own, have any legal or beneficial interest nor serve as manager, administrator, trustee, associate, or partner of any pharmacy and/or business licensed by the Board for 3; not compound any drugs that are intended to/or result in the shipment into Nevada for 3 years; assessed $750.00 in attorney's fees and costs.	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
HM diverted controlled substances for personal use from his employer.	N/A	Revoked; fined $5,000; assessed $500 in recoverable attorney's fees and costs.	N/A
JLS failed to disclose that she was subject to a Board citation or administrative action on her pharmaceutical technician-in-training application.	N/A	Revoked; fined $5,000; assessed $446.23 in recoverable attorney's fees and costs.	N/A
Z, Inc. failed to disclose that they were subject to a Board citation or administrative action on their renewal pharmacy application.	N/A	Fined $5,000.00; assessed $500.00 in recoverable attorney's fees and costs.	N/A
GT surrendered her DEA Registration for Cause; unlawfully diverted and self-administered controlled substances during work hours.	N/A	Revoked; fined $5,000; assessed $1,000 in recoverable attorney's fees and costs; must submit an evaluation for substance use disorder and comply with any and all recommendations set forth by evaluation/ practitioner.	N/A
CH failed to disclose charges pending in US district court on his 2020 renewal application.	N/A	Fined $5,000; assessed $500 in recoverable attorney's fees and costs.	N/A
KMC, LLC appealed the Board's Findings of Fact, Conclusions of Law and Order filed on March 2, 2022. The case was remanded, and the Board heard the appeal on April 12, 2023. The Board found violations that the Respondent engaged in the business of furnishing medical devices in Nevada without a license.	N/A	KMC's license status is currently non-renewed. They may not engage in the business of furnishing medical devices in Nevada unless and until they apply for a license and appears before the Board to answer questions and give testimony regarding the application.	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
CL's NSBVME license to practice veterinary medicine was suspended on December 12, 2022, for non-compliance with NSBVME orders entered in Case No. 06-2016DVM-21 arising from alcohol abuse.	N/A	Revoked 1 year; assessed $500.00 in recoverable attorney's fees and costs.	N/A
GW was convicted in June 2022, in *California vs. Gary Royce Wisner*, Sacramento County, California, Superior Court Case No. 18FE013037 on 10 felony counts of health care insurance fraud.	N/A	Revoked for 5 years; assessed $500.00 in recoverable attorney's fees and costs.	N/A
RF: NSBME imposed discipline on his license to practice medicine for engaging in conduct in violation of the standards of practice established by the NSBME related to prescribing controlled substances.	N/A	RF's CS registration is suspended for a period of 2 years. The suspension is stayed and RF is placed on probation;fined $5,000.00; assessed $500.00 in recoverable attorney's fees and costs.	N/A
RZ prescribed controlled substances to Nevada patients during the period where his controlled substance registration was non-renewed.	N/A	Fined $5,000.00.	N/A
SG prescribed controlled substances to Nevada patients during the period where her controlled substance registration was expired.	N/A	Fined $5,000.00; $500.00 in recoverable attorney's fees and costs.	N/A
CC prescribed controlled substances to Nevada patients during the period where her controlled substance registration was expired.	N/A	Fined $5,000.00; $500.00 in recoverable attorney's fees and costs.	N/A
EN failed to recognize the incorrect filling of the prescription upon data entry, verified and dispensed the incorrect dosage. He also failed to create a physical or	N/A	EN: fined $3,000.00; assessed $500.00 in recoverable attorney's fees and costs.	Fined $4,500.00; assessed $500.00 in recoverable attorney's fees and costs.

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
electronic record of patient counseling or the refusal of patient counseling for the dispensing of the prescription. CS failed to recognize the incorrect filling of the prescription upon data entry, verified and dispensed the incorrect dosage.		CS: fined $1,500.00; assessed $500.00 in recoverable attorney's fees and costs.	
ES prescribed controlled substances to Nevada patients during the period that he did not hold a valid CS.	N/A	Fined $5,000.00; assessed $500.00 in recoverable attorney's fees and costs.	N/A
KN, CM, TT verified a final product as accurate when it was not, failed to contact the prescriber to clarify potential duplication errors, overrode Drug Utilization Review alerts and/or erroneously dispensed medication.	N/A	Fined $1,000.00 per Respondent.	WG fined $10,000.00; assessed $5,137.00 in recoverable attorney's fees and costs.
DE disciplined for violations related to failure to place a fill sticker on the back of the original hard-copy of a prescription resulting in duplicate prescriptions.	N/A	Fined $1,000.00; assessed $500.00 in recoverable attorney's fees and costs.	WG fined $2,000.00; assessed $1,000.00 in recoverable attorney's fees and costs.
MN disciplined for failure to place a fill sticker on the back of the original hard-copy of a prescription; engaged in unprofessional conduct when he performed data entry review and final verification and failed to identify that the patient had already received three fills prescribed on her patient profile; failed to segregate and/or dispose of adulterated and/or expired drugs in the pharmacy's inventory; misrepresented to the Board inspector that all adulterated and/or expired	N/A	Revoked. The revocation is stayed and MN is placed on probation for 2 years; fined $5,000.00; assessed $1,000.00 in recoverable attorney's fees and costs. Respondent currently owns a pharmacy and serves as the managing pharmacist. That pharmacy will be subject to quarterly unannounced inspections at the Respondent's expense.	WG fined $2,000.00; assessed $1,000.00 in recoverable attorney's fees and costs.

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
drugs in the pharmacy's inventory had been segregated and/or disposed of.			
VB disciplined for violations related to prescribing of controlled substances and review of prescriber activity through the PMP.	N/A	Fined $5,000.00; assessed $500.00 in recoverable attorney's fees and costs.	N/A
CT disciplined for violations related to failure to enter prescription data correctly and filled a prescription written for trazodone with tramadol.	N/A	Fined $1,000.00; assessed $500.00 in recoverable attorney's fees and costs.	N/A
MC prescribed controlled substances to Nevada patients during the period where her CS registration was expired.	N/A	Fined $5,000.00 and $500.00 in recoverable attorney's fees and costs.	N/A
WR permitted an employee or staff member to access and utilize his secondary hard token authenticator and/or provided log-on information to his staff member with instructions to e-prescribe prescriptions.	N/A	Fined $4,000.00, $500.00 in recoverable attorney's fees and costs and 2 hours of CE, in addition to any medical CE required, regarding prescribing controlled substances.	N/A
JS permitted staff members not licensed as practitioners in Nevada to regularly use his credentials and act under his authority to issue electronic prescriptions for controlled substances. He failed to review his prescriber activity in the PMP between September 23, 2016, and August 13, 2022, and permitted staff members to access the PMP using his credentials; failed to verify the accuracy of dispensed prescriptions and to initial each prescription.	N/A	JS' CS and PD registrations are suspended for 1 year. The suspensions are stayed and he is placed on probation. Fined $10,000.00 and $5,363.00 in recoverable attorney's fees and costs; establish and put into practice policies and procedures to ensure that any prescription complies with the provisions of federal and state law, shall be subject to quarterly PMP	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
		compliance checks, and quarterly inspections by Board staff at Respondent's expense.	
RC permitted unlicensed staff to access and/or possess controlled substances and/or dangerous drugs, failure to maintain effective security controls by allowing unregistered persons key access to controlled substances and/or dangerous drugs, failure to issue a written prescription for each medication dispensed, failed to verify medications for accuracy prior to dispensing, failure to maintain complete, accurate and readily retrievable records of all controlled substances and/or dangerous drugs purchased and dispensed, failure to inventory controlled substances at least once every 2 years, failure to properly store and maintain the inventory, failure to segregate and/or dispose of adulterated and/or expired dangerous drugs, possessed pre-drawn, unlabeled syringes containing unidentified dangerous drugs.	N/A	RC's CS and PD registrations are suspended the; suspension is stayed, and RC placed on probation for a period of one year. During the probationary period, his dispensing practice shall undergo 2 inspections by the Board at his expense. Update policies and procedures withing 6 months; fined $5,000.00 and $1,000.00 in recoverable attorney's fees and costs.	N/A
LH unlawfully authorized dispensation of medications to patients when she was not present, failure to maintain effective security controls by allowing unregistered persons key access to controlled substances and/or dangerous drugs, failure to issue a written prescription for each	N/A	LH's CS and PD registrations are suspended the; suspension is stayed, and LH placed on probation for a period of one year. During the probationary period, her dispensing practice shall undergo 2 inspections	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
medication dispensed, failure to verify medications for accuracy prior to dispensing, failure to maintain complete, accurate and readily retrievable records of all controlled substances and/or dangerous drugs purchased and dispensed, failure to inventory controlled substances at least once every 2 years, failure to properly store and maintain the inventory, and failure to segregate and/or dispose of adulterated and/or expired dangerous drugs, possessed pre-drawn, unlabeled syringes containing unidentified dangerous drugs.		by the Board at her expense. Update policies and procedures withing 6 months; fined $2,500.00 and $1,000.00 in recoverable attorney's fees and costs.	
Smith's Pharmacy #389 operated without a managing pharmacist during August 12, 2022, to September 1, 2022.	N/A	N/A	Fined $5,000; assessed $500 in recoverable attorney's fees and costs.
JD as managing pharmacist is responsible for a dispensing error caused by pharmacy employees.	N/A	Fined $3,000; assessed $500.00 in recoverable attorney's fees and costs.	Fined $4,000; assessed $952.60 in recoverable attorney's fees and costs.
BR engaged in the sale of veterinary drugs prior to the issuance of a Nevada Veterinary Drug Supplier License which they were served cease and desist/citation. BR appealed the citation.	N/A	N/A	The Board upheld the $5,000 fine.
PH neglected to timely notify the Board of the departure of its facility administrator and continued its operations as aMDEG without timely obtaining approval of a qualified facility administrator.	N/A	N/A	Fined $1,000.00; assessed $500 in recoverable attorney's fees and costs.

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
KS as the managing pharmacist is responsible for the violations allowing a CRNA to circumvent Nevada Pharmacy laws concerning licensed dispensing and sale of drugs, biologicals, medicines, substances, or devices. CTRMC permitted a certified CRNA physician/practitioner level independent access to the hospital's Pyxis Machines to engage in prescribing and/or chart ordering of controlled substances without the appropriate certificate, license, or permit.	Yes	Fined $2,500; assessed $500.00 in recoverable attorney's fees and costs.	Fined $10,000 for the violations; assessed $3,500.00 in recoverable attorney's fees and costs.
NE responsible for prescriptions filled with copied signatures and use of preprinted prescriptions forms.		Suspended; suspension is stayed; NE placed on probation for one year beginning September 8, 2022; fined $2,500; assessed $900 in recoverable attorney's fees and costs.	Suspended; suspension is stayed; LVS is placed on probation for one year beginning on September 8, 2022; fined of $5,000; assessed $900 in recoverable attorney's fees and costs.
CP dispensed a prescription for an adult dose of alprazolam to a minor patient. Minor patient ingested two tablets.	Yes	Fined $1,000; assessed $500 in recoverable attorney's fees and costs.	N/A
JF overrode DUR warnings noting that the patient has an allergy to propylene glycol and failed to contact the prescriber for an alternative medication.	Yes	Fined $1,000; assessed $500 in recoverable attorney's fees and costs.	Fined $2,000; assessed $1,000 in recoverable attorney's fees and costs.
Pharmaceutical technician RR falsely represented himself to be a registered pharmacist.	N/A	Suspended; suspension is stayed; RR placed on probation for a period of 1 year; fined $500; assessed $500 in recoverable attorney's fees and costs.	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
Smith's Pharmacy operated without a managing pharmacist between March 2, 2022, to April 11, 2022.	N/A	N/A	Fined $2,000; assessed $500 in recoverable attorney's fees and costs.
SL verified as accurate a prescription for misoprostol instead of Endometrin as prescribed; overrode a DUR pertaining to the data entry error relating to misoprostol. SL and KP verified as accurate a prescription for Zithromax for the same patient which contained the incorrect quantity and instructions for use as prescribed.	Yes	SL revoked; the revocation is stayed and SL is placed on probation for a period of 1 year; fined $2,000; assessed $352.20 in recoverable attorney's fees and costs; 5 continuing education credits related to the practice of pharmacy with an emphasis on safe medication practices. KP revoked; the revocation is stayed and KP is placed on probation for a period of 1 year; fined $750; assessed $352.20 in recoverable attorney's fees and costs; and three 3 continuing education credits related to the practice of pharmacy with an emphasis on safe medication practices.	CVS fined $10,000; assessed $352.20 in recoverable attorney's fees and costs.
RW issued 119 controlled substance prescriptions from March 2022 to March 2023 for 6 family members with whom he had not established a bona fide therapeutic relationship, had neither diagnosed nor determined that a controlled substance was medically necessary, and without reviewing each patient's utilization report in	N/A	Revoked for a period of five (5) years.	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January – September 2023			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
the Prescription Monitoring Program. In October 2022, Respondent surrendered his Registration No. FW4079427 to the Drug Enforcement Administration by executing DEA Form 104 – "Voluntary Surrender of Controlled Substance Privileges." The Respondent no longer qualifies for a controlled substance registration.			

5A

FILED
JUN 29 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ITZEL R. CASIAN, PTT,** **Certificate of Registration No. PT27604, and** **OSVALDO D. HERNANDEZ, PTT,** **Certificate of Registration No. PT27243,** **Respondents.**	**CASE NOS. 22-401-PTT-A-S** **22-401-PTT-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Itzel R. Casian, Certificate of Registration No. PT27604, and Respondent Osvaldo D. Hernandez, Certificate of Registration No. PT27243, were pharmaceutical technicians in training registered with the Board.

FACTUAL ALLEGATIONS

2. On or about June 6, 2022, Respondent Hernandez fraudulently secured registration as a pharmaceutical technician in training by falsely representing on his application that he was a high school graduate or the equivalent when he was not.

3. On or about September 16, 2022, Respondent Casian fraudulently secured registration as a pharmaceutical technician in training by falsely representing on her application that she was a high school graduate or the equivalent when she was not.

APPLICABLE LAW

4. An applicant for registration as a pharmaceutical technician in training must be a high school graduate or the equivalent. NAC 639.242(1)(b).

5. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

6. Obtaining any certificate or license by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

7. Any certificate, license or permit issued by the Board on information later found to be false or fraudulent must be automatically cancelled by the Board. NRS 639.281(2).

COUNT ONE
FRAUDULENTLY SECURING REGISTRATION

8. Respondents Hernandez and Casian engaged in unprofessional conduct as defined in NAC 639.945(1)(h) when they fraudulently secured registration as pharmaceutical technicians in training and are therefore subject to discipline pursuant to NRS 639.210(4) and (10).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these respondents.

DATED this 24th day of JUNE, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ITZEL R. CASIAN, PTT,** **Certificate of Registration No. PT27604,** **Respondent.**	**Case No. 22-401-PTT-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 29th day of JUNE, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ITZEL R. CASIAN, PTT,** **Certificate of Registration No. PT27604,** **Respondent.**	**Case No. 22-401-PTT-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

ITZEL R. CASIAN, PTT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 19th day of July 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Itzel R. Casian, PTT
[redacted] Manalang Rd.
Las Vegas, NV 89123

Osvaldo D. Hernandez, PTT
[redacted] Pennwood Ave., Apt. 264
Las Vegas, NV 89102

SHIRLEY HUNTING

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Complete Name (**no abbreviations**):

First: Itzel Middle: Rosa Last Casian

Home Address: [redacted] Maralang Rd Apt#:

City: Las Vegas State: NV Zip Code: 89123

Telephone: [redacted] SS# or ITIN: [redacted]

Date of Birth: [redacted] Place of Birth: Las Vegas, NV Sex: ☐ M or ☑ F

E-mail Address: [redacted]

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number:

I am requesting registration at the following pharmacy:

Pharmacy: ASP Cares Store #: Las Vegas, NV

Address: 501 S Rancho Dr, Suite G46

City: Las Vegas State: NV Zip Code: 89106

Signature of Managing Pharmacist: Shelley L Hausrath Lic #: 16929 Date: 9/16/22

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older? Yes ☑ No ☐
2. Are you a high school graduate or the equivalent? Yes ☑ No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☑
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked **YES** to any of the numbered questions (3-5) above, include the following information & **provide an explanation & documentation**:

Board Administrative Action:	State	Date:	Case #:
		/ /	

Criminal Action:	State	Date:	Case #:	County	Court
		/ /			

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	☒
IF you marked **YES** to the question, above are you in compliance with the court order?	☐	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

[signature] 09/16/22

Original Signature, no copies or stamps accepted Date

Board Use Only Date Processed: Amount: 50.00 CC Rcvd - 9.20.22

5B

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **OSVALDO D. HERNANDEZ, PTT,** **Certificate of Registration No. PT27243,** **Respondent.**	**Case No. 22-401-PTT-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 29th day of June, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 19th day of July 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Itzel R. Casian, PTT
[redacted] Manalang Rd.
Las Vegas, NV 89123

Osvaldo D. Hernandez, PTT
[redacted] Pennwood Ave., Apt. 264
Las Vegas, NV 89102

SHIRLEY HUNTING

FILED
AUG 08 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **OSVALDO D. HERNANDEZ, PTT,** **Certificate of Registration No. PT27243,** **Respondent.**	**Case No. 22-401-PTT-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows: I Osvaldo Hernandez Started Working at ASPCares pharmacy on April of 2022 as a clerk. I don't Recall ever filling out on application since I was hired on the spot at the interview by Shelley Hausrath. Weeks after my training Shelley offered me the application to became a pharmacy tech in trainig at that exact moment is when I mention to her that I was NOT high School graduate but I was in process of getting my diploma. She assure me she will find out with a friend the exact requirement to apply for this license, about 8-10 days after this I asked Shelley on an update she then proceeded to tell me that she didn't think this would be a problem since I was already in the process of getting my diploma she took an application and started to fill out with the pharmacy information and her signature then she asked me to fill out the rest and sent it out now and then I went and drop it off in a mailbox that is just outside the pharmacy trusting that this was okay since it had been approved from Shelley my manager, a pharmacist and someone with years of experience on this field now this has brought me a huge problem that I never intented of getting since all I ever wanted was to Learn and grow in the pharmacy industry since it was something I Really enjoyed. I Haveat worked in a pharmacy since I was terminated from Asplares October 2022 by Sabrina Hernandez. My Apologies, Sincerely Osvaldo Hernandez.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 2nd day of August, 2023.

OSVALDO D. HERNÁNDEZ, PTT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Complete Name (**no abbreviations**):

First: Osvaldo Middle: Daniel Last Hernandez

Home Address: [redacted] Pennwood Ave Apt#: [redacted]

City: Las Vegas State: Nevada Zip Code: 89102

Telephone: [redacted] SS# or ITIN: [redacted]

Date of Birth: [redacted] Place of Birth: Las Vegas Sex: ☑ M or ☐ F

E-mail Address: [redacted]

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number: N/A

I am requesting registration at the following pharmacy:

Pharmacy: ASP Cares Pharmacy Store #: Las Vegas

Address: 5015 Rancho Drive suite G46

City: Las Vegas State: NV Zip Code: 89106

Signature of Managing Pharmacist: Shelley R Hausrath Lic #: 16979 Date: 6/2/22

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older? Yes ☑ No ☐
2. Are you a high school graduate or the equivalent? Yes ☑ No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☑
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked **YES** to any of the numbered questions (3-5) above, include the following information & **provide an explanation & documentation**:

Board Administrative Action:	State	Date:	Case #:
		/ /	

Criminal Action:	State	Date:	Case #:	County	Court
		/ /			

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	☑
IF you marked **YES** to the question, above are you in compliance with the court order?	☐	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Osvaldo D Hernandez 6/2/22

Original Signature, no copies or stamps accepted Date

Board Use Only Date Processed: Amount: $50 CC

5C

FILED
JUN 29 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHIL YUAN-CHUNG CHEN, DO,** **Certificate of Registration No. CS19806,** **Respondent.**	**Case No. 23-016-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Phil Yuan-Chung Chen, held an expired Nevada controlled substance registration, Certificate of Registration No. CS19806, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent failed to timely renew his Certificate of Registration No. CS19806, which expired on October 31, 2022.

3. Respondent wrote six hundred and five (605) prescriptions for controlled substances between November 1, 2022, and January 18, 2023.

4. On or about January 19, 2023, Respondent renewed his Certificate of Registration No. CS19806.

APPLICABLE LAW

5. It is unlawful to prescribe a controlled substance except as authorized by law. NRS 453.321(1)(a).

6. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

7. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

8. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

9. The Board may suspend or revoke a registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

10. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

11. The Board may suspend or revoke a registration if the holder has failed to renew a certificate of registration by failing to submit the application for renewal. NRS 639.210(13).

12. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE
Unprofessional Conduct – Prescribing without a Valid Registration

13. By writing six hundred and five (605) prescriptions for controlled substances between November 1, 2022, and January 18, 2023, without a valid registration, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT TWO
Violations of Federal Controlled Substances Act

14. By writing six hundred and five (605) prescriptions for controlled substances between November 1, 2022, and January 18, 2023, without a valid registration, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11).

COUNT THREE
Violations of State Controlled Substances Act

15. By writing six hundred and five (605) prescriptions for controlled substances between November 1, 2022, and January 18, 2023, without a valid registration, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1)and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT FOUR
Failure to Time Renew Controlled Substance Registration

16. By failing to timely renew his Certificate of Registration CS09766, Respondent is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(13).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

17. By writing six hundred and five (605) prescriptions for controlled substances between November 1, 2022, and January 18, 2023, without a valid registration, and falsely representing himself as a practitioner entitled to write prescriptions in this state, Respondent committed an act that would render his registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(e) and/or NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 29th day of JUNE 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHIL YUAN-CHUNG CHEN, DO,** **Certificate of Registration No. CS19806,** **Respondent.**	**Case No. 23-016-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JUNE, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHIL YUAN-CHUNG CHEN, DO,** **Certificate of Registration No. CS19806,** **Respondent.**	**Case No. 23-016-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

PHIL YUAN-CHUNG CHEN, DO

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 19th day of July 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Phil Yuan-Chung Chen, DO
[redacted] N. Pecos Road
Henderson, NV 89074

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHIL YUAN-CHUNG CHEN, DO,** **Certificate of Registration No. CS19806,** **Respondent.**	**Case No. 23-016-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through General Counsel Brett Kandt, and Respondent Phil Yuan-Chung Chen, Certificate of Registration No. CS19806, by and through counsel, Sean M. Kelly, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about June 29, 2023, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions

of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*:

A. Respondent failed to timely renew his Certificate of Registration No. CS19806, which expired on October 31, 2022;

B. By writing six hundred and five (605) prescriptions for controlled substances between November 1, 2022, and January 18, 2023, without a valid registration, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state in violation of 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 CFR § 1306.03(a)(1), NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1);

C. By failing to timely renew his Certificate of Registration CS09766, Respondent is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(13); and

D. Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k) and committed an act that would render his registration inconsistent with the public interest.

7. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210 and/or NRS 639.255.

8. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Phil Yuan-Chung Chen, Certificate of Registration No. CS19806, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5000.00) for the violations, through monthly payments pursuant to the following schedule:

Due Date	Amount
11/1/2023	500.00
12/1/2023	500.00
1/1/2024	500.00
2/1/2024	500.00
3/1/2024	500.00
4/1/2024	500.00
5/1/2024	500.00
6/1/2024	500.00
7/1/2024	500.00
8/1/2024	500.00
TOTAL	**$5000.00**

Respondent shall make the monthly payments of the fine by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments;

B. Pursuant to NRS 622.400, Respondent shall pay Five Hundred Dollars ($500.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause

hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 11, 2023. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of October 2023

8-30-2023

PHIL YUAN-CHUNG CHEN, DO
Certificate of Registration No. CS19806

Signed this ___ day of October 2023

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 1st day of ~~October~~ September 2023

SEAN M. KELLY, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Phil Yuan-Chung Chen, Certificate of Registration No. CS19806,, in Case No. 23-016-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of October 2023.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5D

FILED
JUN 29 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAMES R. EELLS, M.D.,** **Certificate of Registration No. CS22639,** **Respondent.**	**Case No. 19-081-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent James R. Eells, M.D. (Respondent), because Respondent holds a Nevada controlled substance registration, Certificate of Registration No. CS22639, authorizing him to prescribe controlled substances.

2. The Board has jurisdiction over the subject matter of this accusation because Respondent, as alleged below, engaged in conduct that implicates his fitness to prescribe controlled substances and/or to hold a certificate of registration issued by the Board.

FACTUAL ALLEGATIONS

3. Respondent is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada. During the time periods discussed herein, Respondent was a "practitioner" as that term is defined at NRS 453.126 and NRS 639.0125.

4. Between January 1, 2018, and June 4, 2019, Respondent maintained an office at 7020 Smoke Ranch Road, Suite 110, in Las Vegas, Nevada, where he operated a business under the name "Hangover Rescue." Respondent advertised and/or marketed the business as a medical practice in which health care professionals deliver and administer intravenous (IV) hydration treatments to patients

in their homes and/or in their hotel rooms. Respondent represented to prospective customers that these treatments were beneficial for persons suffering from headaches, nausea, muscle pain, and other symptoms associated with excess consumption of alcohol.

5. At all times relevant to this accusation, Respondent identified himself as the "medical director" of Hangover Rescue. Respondent either employed or worked in partnership with Staci Wilcox, R.N. (Nurse Wilcox), a registered nurse, and Bryce Wilcox, a licensed paramedic (Paramedic Wilcox). Respondent rarely supervised Nurse Wilcox and Paramedic Wilcox in the performance of their medical duties.

6. With the knowledge and consent of Respondent, and/or at his direction, Nurse Wilcox and/or Paramedic Wilcox ordered, purchased, stored, possessed, sold, transported, delivered, furnished, dispensed, and/or administered IV fluids and/or injectable medications, including sodium chloride, ketorolac, famotidine, ondansetron, glutathione, and diphenhydramine. These constitute "parenteral solutions" as that term is defined at NRS 639.0105. These are also "dangerous drugs" as that term is defined at NRS 454.201.

7. At various times between January 1, 2018, and June 4, 2019, Nurse Wilcox and/or Paramedic Wilcox delivered parenteral solutions to Hangover Rescue's customers in their homes, in their hotel rooms, or at other sites remote from Respondent's office. Upon arrival at any given site, Nurse Wilcox and/or Paramedic Wilcox administered parenteral solutions to the customer outside of Respondent's presence and without a prescription. In the few instances where Respondent may have issued a prescription for the customer, Respondent did not establish a bona fide therapeutic relationship with the customer.

8. At no time relevant to this accusation was Nurse Wilcox or Paramedic Wilcox a "practitioner" as that term is defined at NRS 453.126 and NRS 639.0125. At no time relevant to this accusation did Nurse Wilcox or Paramedic Wilcox hold a registration or license to prescribe or dispense dangerous drugs.

9. During the periods described herein, Respondent failed to maintain patient treatment charts and/or records from which a person could reasonably determine whether Respondent had established bona fide therapeutic relationships with the customers to whom Nurse Wilcox and/or Paramedic Wilcox furnished parenteral solutions.

10. Respondent caused, directed, or permitted Nurse Wilcox and/or Paramedic Wilcox to furnish customers with parenteral solutions even though Nurse Wilcox and/or Paramedic Wilcox were not licensed or registered by the Board to prescribe or dispense dangerous drugs. Respondent knew or should have known that Nurse Wilcox and/or Paramedic Wilcox were not licensed or registered by the Board to prescribe or dispense dangerous drugs.

11. Respondent caused, directed, or permitted Nurse Wilcox and/or Paramedic Wilcox to furnish customers with parenteral solutions even though these solutions were not labeled with an expiration date as required by NRS 639.2806.

APPLICABLE LAW

12. It is unlawful to furnish dangerous drugs to anyone except upon the prescription of a practitioner. NRS 454.221(1). "'Furnish' means to supply by any means, by sale or otherwise." NRS 454.006.

13. It is unlawful to possess and administer dangerous drugs, including parenteral solutions, except as authorized by NRS 454.213. "Administer" means the direct application of a [dangerous drug] . . . whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject." NRS 454.191.

14. It is unlawful to dispense dangerous drugs, including parenteral solutions, except as authorized by NRS 454.215. *See also* 639.284(2). "'Dispense' means the furnishing of a dangerous drug in any amount greater than that which is necessary for the present and immediate needs of the ultimate user." NRS 454.211.

15. It is unlawful for any person to sell or dispense, or permit to be sold or dispensed, any dangerous drug, including a parenteral solution, unless the person holds the appropriate permit or

license issued by the Board and complies with the regulations adopted by the Board. NRS 639.100(1); NRS 454.321. A practitioner may not charge a patient for dispensing a dangerous drug to the patient unless the practitioner first applies for and obtains a certificate from the Board and pays the required fee. NRS 639.23505.

16. A parenteral solution which is used by a patient in his or her home may only be sold or dispensed by a practitioner if the date of expiration is on its label. NRS 639.2806.

17. With the knowledge and consent of Respondent, and/or at his direction, Nurse Wilcox and/or Paramedic Wilcox furnished, administered, and/or dispensed parenteral solutions to customers of Hangover Rescue in the manner alleged above. Nurse Wilcox and/or Paramedic Wilcox did so in situations where Respondent had not issued prescriptions for such parenteral solutions, in violation of NRS 454.221, and/or under circumstances not authorized by 454.213 and NRS 454.215.

18. Every practitioner who prescribes controlled substances in Nevada must secure and maintain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). As noted above, Respondent holds a certificate of registration issued by the Board authorizing him to prescribe controlled substances.

19. The Board may revoke or suspend the certificate of registration of any practitioner who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

20. Pursuant to NAC 639.945, a practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner: a) performs, without the required registration, any task or operation for which registration is required; b) performs his or her duties in an incompetent, unskillful, or negligent manner; c) performs or engages in any fraudulent or deceitful transaction; d) prescribes a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship; or e) dispenses a drug as a dispensing practitioner to a patient with whom the dispensing practitioner does not have a bona fide therapeutic relationship. *See* NAC 639.945(1).

21. Additionally, the Board may revoke or suspend the registration of any practitioner who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

22. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon the practitioner. The fine may not exceed $10,000 for each offense. *See* NRS 639.255(1)(f) and (3).

COUNT ONE
Unlawful Furnishing of Dangerous Drugs

23. Between January 1, 2018, and June 4, 2019, as alleged above, Respondent caused, directed, assisted, and/or permitted Nurse Wilcox and/or Paramedic Wilcox, persons then under Respondent's supervision and/or control, to store, possess, transport, sell, deliver, furnish, dispense, and/or administer parenteral solutions.

24. Nurse Wilcox and/or Paramedic Wilcox engaged in the above conduct in a manner and under circumstances not authorized by NRS 454.213 and NRS 454.215. As the medical director who supervised and/or directed their activities, Respondent violated or assisted in the violation of Nevada statutes related to dangerous drugs. Accordingly, Respondent is subject to discipline pursuant to NRS 639.210(12).

COUNT TWO
Dispensing without a Registration

25. Pursuant to NRS 639.23505, Respondent was required to obtain a registration to engage in the activity described in Count One above. Respondent did not obtain such a registration, nor did he comply with applicable statutes and regulations governing dispensing practitioners.

26. As alleged above, Respondent sold and/or dispensed dangerous drugs without the appropriate certificate issued by the Board, a violation of NRS 639.100(1). Accordingly, Respondent is subject to discipline pursuant to NRS 639.210(12) because he violated a Nevada statute related to dangerous drugs.

COUNT THREE
Dispensing without a Prescription

27. Between January 1, 2018, and June 4, 2019, as alleged above, Respondent caused, directed, assisted, and/or permitted Nurse Wilcox and/or Paramedic Wilcox, persons then under Respondent's supervision and/or control, to sell, deliver, furnish, dispense, and/or administer parenteral solutions to customers of Hangover Rescue outside of Respondent's presence and at locations remote from Respondent's office. Respondent did so without first having issued prescriptions as required by NRS 454.221.

28. By failing to issue prescriptions before selling or assisting in the sale and/or dispensing of parenteral solutions, Respondent violated or assisted in the violation of NRS 454.221. Accordingly, Respondent is subject to discipline pursuant to NRS 639.210(12) because he violated a Nevada statute related to dangerous drugs.

COUNT FOUR
Failure to Label Parenteral Solutions with Expiration Dates

29. Between January 1, 2018, and June 4, 2019, as alleged above, Respondent caused, directed, assisted, and/or permitted Nurse Wilcox and/or Paramedic Wilcox, persons then under Respondent's supervision and/or control, to sell, deliver, furnish, dispense, and/or administer parenteral solutions to customers of Hangover Rescue outside of Respondent's presence and at locations remote from Respondent's office. Respondent did so without having labeled the solutions with an expiration date as required by NRS 639.2806.

30. By failing to label parenteral solutions before causing them to be sold, furnished, and/or dispensed to Hangover Rescue's customers in their homes, hotel rooms, and/or other remote sites, Respondent violated or assisted in the violation of NRS 639.2806. Accordingly, Respondent is subject to discipline pursuant to NRS 639.210(12) because he violated a Nevada statute related to dangerous drugs.

COUNT FIVE
Engaging in Deceitful Transactions

31. Between January 1, 2018, and June 4, 2019, Respondent advertised and/or marketed Hangover Rescue as a business specializing in the provision of IV hydration treatments to people in their homes, their hotel rooms, and at other sites remote from Respondent's office. Respondent further represented to actual and prospective customers that Hangover Rescue employed a team of health care professionals who were authorized to administer such treatments to people in their homes, their hotel rooms, and/or at other remote sites.

32. By engaging in the conduct as alleged above, Respondent impliedly represented to prospective and actual customers of Hangover Rescue that he held a dispensing license and/or that he supervised all business operations, thereby ensuring that Hangover Rescue and its purported team of health care professionals were at all times compliant with Nevada law as it pertains to prescribing, storing, possessing, transporting, selling, furnishing, and/or dispensing parenteral solutions. Respondent knew or should have known that these representations were false.

33. By engaging in the conduct as alleged above, Respondent performed, was a party to, and/or engaged in "deceitful" practices or transactions within the meaning of NAC 639.945. This amounted to unprofessional conduct and/or conduct contrary to the public interest. Accordingly, pursuant to NRS 639.210(4), Respondent is subject to discipline for such conduct.

COUNT SIX
Performing Duties in an Incompetent, Unskillful, or Negligent Manner

34. Between January 1, 2018, and June 4, 2019, as alleged above, Respondent caused, directed, assisted, and/or permitted Nurse Wilcox and/or Paramedic Wilcox, persons then under Respondent's supervision and/or control, to possess, store, sell, transport, deliver, furnish, dispense, and/or administer parenteral solutions to customers of Hangover Rescue. As alleged above, Nurse Wilcox and/or Paramedic Wilcox violated numerous laws relating to dangerous drugs, including NRS 454.213, NRS 454.215, NRS 454.221(1), NRS 454.321, NRS 639.284(2), NRS 639.23505, and NRS 639.100(1).

35. By failing to properly supervise Nurse Wilcox and/or Paramedic Wilcox in connection with their possession, storage, sale, transportation, distribution, and/or administration of parenteral solutions, Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, and/or negligent manner. Pursuant to NAC 639.945 and NRS 639.210(4), Respondent's failure to supervise Nurse Wilcox and/or Paramedic Wilcox amounted to unprofessional conduct and/or conduct contrary to the public interest for which Respondent is subject to discipline.

COUNT SEVEN
Prescribing Dangerous Drugs without a Bona Fide Patient Relationship

36. Between January 1, 2018, and June 4, 2019, as alleged above, Respondent caused, directed, assisted, and/or permitted Nurse Wilcox and/or Paramedic Wilcox, persons then under Respondent's supervision and/or control, to deliver, furnish, and/or administer parenteral solutions to customers of Hangover Rescue in their homes, their hotel rooms, and/or at other sites remote from Respondent's office. To the extent that Respondent issued prescriptions for these parenteral solutions, Respondent failed to establish bona fide therapeutic relationships with the customers to whom he issued said prescriptions.

37. By failing to establish bona fide therapeutic relations with any customers to whom he issued prescriptions for parenteral solutions, Respondent engaged in unprofessional conduct and/or conduct contrary to the public interest. Accordingly, Respondent is subject to discipline pursuant to NAC 639.945 and NRS 639.210(4).

COUNT EIGHT
Dispensing Dangerous Drugs without a Bona Fide Patient Relationship

38. Between January 1, 2018, and June 4, 2019, as alleged above, Respondent caused, directed, assisted, and/or permitted Nurse Wilcox and/or Paramedic Wilcox, persons then under Respondent's supervision and/or control, to deliver, furnish, and/or administer parenteral solutions to

customers of Hangover Rescue in their homes, their hotel rooms, and at other sites remote from Respondent's office.

39. By engaging in the conduct alleged above, Respondent "dispensed" parenteral solutions within the meaning of NRS 454.211. Respondent did so without having established bona fide therapeutic relationships with one or more of the customers for whom he dispensed parenteral solutions. This amounted to unprofessional conduct and/or conduct contrary to the public interest. Accordingly, Respondent is subject to discipline pursuant to NAC 639.945 and NRS 639.210(4).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 29th day of JUNE 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAMES R. EELLS, MD,** **Certificate of Registration No. CS22639,** **Respondent.**	**CASE NO. 19-081-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 29th day of JUNE 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of July 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

James R. Eells, MD
[redacted]Smoke Ranch Rd[redacted]
Las Vegas, NV 89128

Maria Nutile, Esq.
7395 S. Pecos Rd., Ste. 103
Las Vegas, NV 89120

SHIRLEY HUNTING

FILED
AUG 09 2023
NEVADA STATE BOARD
OF PHARMACY

Maria Nutile, Esq.
Nevada Bar No.: 7847
Bridget Kelly, Esq.
Nevada Bar No.: 14388
NUTILE LAW
7395 S. Pecos Rd., Suite 103
Las Vegas, Nevada 89120
Telephone: (702) 307-4880
Facsimile: (702) 307-4881
Email: maria@nutilelaw.com
bridget@nutilelaw.com

Attorneys for James R. Eells, M.D.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. JAMES R. EELLS, M.D., Certificate of Registration No. CS22639, Respondent.	CASE NO.: 19-081-CS-S **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation ("Notice") filed in the above-titled matter before the Nevada States Board of Pharmacy (the "Board"), declares:

1. That his objections to the Notice of Intended Action and Accusation ("Notice") as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds:

A. Failure to State a Claim. As alleged, the allegations in Paragraphs 5, 6, 7, 9, 10, and 11, as reflected in Counts One through Eight, violate Dr. Eells's Sixth Amendment rights and are unconstitutionally vague because they fail to apprise the Respondent, with reasonable certainty, of the allegations against him and, thus, deprive him of the ability to prepare a defense. *United States v. Estrada-Iglesias,* 425 F. Supp. 3d 1265, 1269 (D. Nev. 2019).

Paragraphs 5, 6, 7, 9, 10, and 11 generally allege that Dr. Eells failed to adequately supervise staff, failed to maintain medical records, and allowed unauthorized persons to order, purchase, store, possess, sell, transport, deliver, furnish, dispense, and/or administer dangerous drugs. The Complaint fails to specify dates (other than a broad range of eighteen (18) months), times, locations, or patients associated with these alleged events. By failing to identify specific persons and instances on dates certain, the Notice of Intended Action and Accusation deprives Respondent of the ability to defend himself adequately.

B. False Accusations, Reckless Prosecution and Abuse of Discretion. The allegations contained in Paragraphs 7 and 9, as reflected in Counts 3, 7, and 8, are demonstrably false, as no medical records have been requested by or provided to the Board by Respondent. Petitioner knew or should have known that it did not possess any medical records, or indeed any patient names or identifiers, related to Respondent and/or Hangover Rescue. Counts 3, 7, and 8 necessarily fail in the absence of such records. Petitioner has therefore knowingly published false accusations against the Respondent, is recklessly attempting to prosecute Respondent on charges for which it does not possess (and never requested as part of its investigation) any evidence. Petitioner has abused its discretion in filing this accusation against Respondent, who must now expend resources to defend against unprovable charges, and may suffer irreparable harm to his professional reputation as the result of this action.

C. Lack of Jurisdiction. Respondent objects to the Board's jurisdiction to prosecute this matter, as (1) all allegations in this case relate to dangerous drugs, and (2) Respondent's authority to prescribe dangerous drugs derives from his licensure under NRS Chapter 630, and not from any authorization issued by the Board. See, NRS 454.00958(1), 454.213(1)(a).

D. The purpose of the foregoing paragraphs was to place the Board on notice of Respondent's legal objections to its Notice. Based on the foregoing, Respondent requests the Notice be rescinded in its entirety for good cause and with prejudice, or alternatively dismissed with prejudice. Respondent respectfully reserves the right to brief further and expand upon these objections at the appropriate juncture, if necessary.

2. That, in the event the Notice is not withdrawn or otherwise dismissed based upon the foregoing objections, in answer to the Notice, he admits, denies, and alleges as follows:

A. With regard to Paragraph 1, Respondent admits that he holds and has held Controlled Substance Registration, Certificate No. CS22639. Respondent objects to the Board's

jurisdiction to prosecute this matter as set forth above.

B. Paragraph 2 does not contain allegations against the Respondent. To the extent an answer is required, the Respondent denies the allegations in this paragraph.

C. With regard to Paragraphs 3 and 4, Respondent admits the allegations therein.

D. With regard to Paragraph 5, Respondent admits identifying himself as "medical director" of Hangover Rescue and admits Nurse Wilcox and Paramedic Wilcox were independent contractors of Hangover Rescue. Respondent cannot respond to the remaining vague and overly broad allegations without further information, as set forth in his objection above, and, thus, denies the remaining allegations contained in Paragraph 5 on that basis.

E. With regard to Paragraph 6, the allegations contained therein are overly broad and lack specificity. Respondent cannot respond to these allegations without further information, as set forth in his objection above, and, thus, denies the allegations contained in Paragraph 6 on that basis.

F. With regard to Paragraph 7, the allegations contained therein are overly broad and lack specificity. Respondent cannot respond to these allegations without further information, as set forth in his objection above, and, thus, denies the allegations contained in Paragraph 7 on that basis. Without waiving his objection, Respondent asserts a bona fide relationship was established between Respondent and each Hangover Rescue patient (estimated to be 10 or 20 patients total through its tenure of operations) via telehealth, and that a prescription was documented for each patient treated through Hangover Rescue.

G. Paragraph 8 does not contain allegations against Respondent. To the extent an answer is required, Respondent denies the allegations in these paragraphs. Respondent objects to reference to NRS 453.126 in Paragraph 8, as NRS Chapter 453 relates to controlled substances which are not at issue in this case.

H. With regard to Paragraph 9, the allegations contained therein are overly broad and lack specificity. Respondent cannot respond to these allegations without further information, as set forth in his objection above, and, thus, denies the allegations contained in Paragraph 9 on that basis. Respondent further objects to any counts arising from the allegations contained in Paragraph 9, as Respondent denies ever receiving or responding to a request for medical records from the Board, and thus there can be no evidentiary basis for the allegations

contained in Paragraph 9.

I. With regard to Paragraph 10, the allegations contained therein are overly broad and lack specificity. Respondent cannot respond to these allegations without further information, as set forth in his objection above, and, thus, denies the allegations contained in Paragraph 10 on that basis. Without waiving his objection, Respondent denies Hangover Rescue "dispensed" (as defined in NRS 454.211 and referenced in Paragraph 14 of the Notice) any dangerous drugs to any patient, and asserts that all treatments administered through Hangover Rescue were pursuant to a valid prescription in the context of a bona fide therapeutic relationship as defined under NAC 639.945(3).

J. With regard to Paragraph 11, the allegations contained therein are overly broad and lack specificity. Respondent cannot respond to these allegations without further information, as set forth in his objection above, and, thus, denies the allegations contained in Paragraph 11 on that basis.

K. Paragraph 12 does not contain allegations against Respondent. To the extent an answer is required, Respondent denies the allegations in this paragraph.

L. Paragraph 13 does not contain allegations against Respondent. To the extent an answer is required, Respondent denies the allegations in this paragraph. Respondent notes NRS 454.213(1)(c) permits a licensed registered nurse, such as Nurse Wilcox, to possess and administer dangerous drugs at the direction of a prescribing physician, or pursuant to a chart order for administration to a patient at another location.

M. Paragraphs 14-16 do not contain allegations against Respondent. To the extent an answer is required, Respondent denies the allegations in these paragraphs.

N. With regard to Paragraph 17, the allegations contained therein are overly broad and lack specificity. Respondent cannot respond to these allegations without further information, as set forth in his objection above, and, thus, denies the allegations contained in Paragraph 17 on that basis. Without waiving his objection, Respondent asserts, as above, that a bona fide relationship was established between Respondent and each Hangover Rescue patient via telehealth, and that a prescription was documented for each patient treated through Hangover Rescue.

O. With regard to Paragraph 18, Respondent admits he holds a certificate of registration to prescribe controlled substances issued by the Board. However, Respondent asserts

his authority to prescribe dangerous drugs derives from his status as a physician licensed pursuant to NRS Chapter 630. See, NRS 454.00958(1), 454.213(1)(a). Respondent objects to the Notice's references to NRS 453.226(1)(a) and 453.231(3) as irrelevant, as there has been no allegation against Respondent of any violations related to controlled substances.

P. Paragraphs 19-22 do not contain allegations against Respondent. To the extent an answer is required, Respondent denies the allegations in these paragraphs.

Q. With regard to Paragraphs 23 through 39, Respondent denies the allegations therein.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to best of my knowledge.

Dated this 9th day of August, 2023.

James Eells (Aug 9, 2023 14:00 PDT)

JAMES R. EELLS, M.D.

On behalf of Respondent:

NUTILE LAW

/s/ Bridget Kelly

Maria Nutile, Esq.
Nevada Bar No.: 7847
Bridget Kelly, Esq.
Nevada Bar No.: 14388
NUTILE LAW
7395 S. Pecos Rd., Suite 103
Las Vegas, Nevada 89120
Telephone: (702) 307-4880
Facsimile: (702) 307-4881
Email: maria@nutilelaw.com
bridget@nutilelaw.com

CERTIFICATE OF SERVICE

I hereby certify that I am an employee of NUTILE LAW, and that on this 9th day of August 2023, I caused to be filed via email an electronic copy of the foregoing Answer and Notice of Defense to each of the following at the Nevada State Board of Pharmacy:

1. Greg Zunino, Senior General Counsel, zunino@pharmacy.nv.gov;
2. Kristopher Mangosing, Asst. Board Coordinator, kmangosing@pharmacy.nv.gov.

/s/ *Bridget Kelly*
An employee of NUTILE LAW

Answer

Final Audit Report 2023-08-09

Created:	2023-08-09
By:	Bridget Kelly (Bridget@nutilelaw.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAa0rEyOFnyXnH-V8KTIFgCoLAgMtE4Umv

"Answer" History

Document created by Bridget Kelly (Bridget@nutilelaw.com)
2023-08-09 - 6:58:50 PM GMT- IP address: 216.17.28.242

Document emailed to jimreells@gmail.com for signature
2023-08-09 - 7:00:39 PM GMT

Email viewed by jimreells@gmail.com
2023-08-09 - 8:58:39 PM GMT- IP address: 174.204.10.178

Signer jimreells@gmail.com entered name at signing as james Eells
2023-08-09 - 9:00:32 PM GMT- IP address: 174.204.10.178

Document e-signed by james Eells (jimreells@gmail.com)
Signature Date: 2023-08-09 - 9:00:34 PM GMT - Time Source: server- IP address: 174.204.10.178

Agreement completed.
2023-08-09 - 9:00:34 PM GMT

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAMES R. EELLS, M.D.,** **Certificate of Registration No. CS22639,** **Respondent.**	**Case No. 19-081-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through its Board Prosecutor, Gregory L. Zunino, and Respondent James R. Eells, M.D. ("Respondent Eells"), Certificate of Registration No. CS22639, hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent Eells and this matter.

2. The Board's staff properly served Respondent Eells with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent Eells has consulted with his attorney, and he acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and that he has executed the Stipulation knowingly and voluntarily.

4. Respondent Eells acknowledges that he is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondent Eells under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent Eells has failed to comply with the provisions of the paragraphs below, Respondent Eells acknowledges that he freely and voluntarily waives his rights to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent Eells admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged against Respondent Eells in Count Two, Count Four, and Count Six of the Accusation, *to wit*:

A. Respondent Eells is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada. During the time periods discussed below, Respondent Eells was a "practitioner" as that term is defined at NRS 453.126 and NRS 639.0125.

B. Between January 1, 2018, and June 4, 2019, Respondent Eells maintained an office at 7020 Smoke Ranch Road, Suite 110, in Las Vegas, Nevada, where he operated a business under the name "Hangover Rescue." Respondent Eells advertised and/or marketed the business as a medical practice in which health care professionals deliver and administer intravenous (IV) hydration treatments to patients in their homes and/or in their hotel rooms.

C. Respondent Eells identified himself as the "medical director" of Hangover Rescue. Respondent Eells either employed or worked in partnership with Staci Wilcox, R.N. (Nurse Wilcox), a registered nurse, and Bryce Wilcox, a licensed paramedic (Paramedic Wilcox).

D. With the knowledge and consent of Respondent Eells, and/or at his direction, Nurse Wilcox and/or Paramedic Wilcox ordered, purchased, stored, possessed, sold, transported, delivered, furnished, dispensed, and/or administered IV fluids and/or injectable medications, including sodium chloride, ketorolac, famotidine, ondansetron, glutathione, and diphenhydramine. These constitute "parenteral

solutions" as that term is defined at NRS 639.0105. These are also "dangerous drugs" as that term is defined at NRS 454.201.

E. At various times between January 1, 2018, and June 4, 2019, Nurse Wilcox and/or Paramedic Wilcox delivered parenteral solutions to Hangover Rescue's customers in their homes, in their hotel rooms, or at other sites remote from Respondent's office. Upon arrival at any given site, Nurse Wilcox and/or Paramedic Wilcox administered parenteral solutions to the customer outside of Respondent Eell's presence.

F. At no time was Nurse Wilcox or Paramedic Wilcox a "practitioner" as that term is defined at NRS 453.126 and NRS 639.0125. At no time did Nurse Wilcox or Paramedic Wilcox hold a registration or license to prescribe or dispense dangerous drugs.

G. Respondent Eells caused, directed, or permitted Nurse Wilcox and/or Paramedic Wilcox to furnish customers with parenteral solutions even though Nurse Wilcox and/or Paramedic Wilcox were not licensed or registered by the Board to prescribe or dispense dangerous drugs. Respondent Eells knew or should have known that Nurse Wilcox and/or Paramedic Wilcox were not licensed or registered by the Board to prescribe or dispense dangerous drugs.

H. Respondent Eells caused, directed, or permitted Nurse Wilcox and/or Paramedic Wilcox to furnish customers with parenteral solutions even though these solutions were not labeled with an expiration date as required by NRS 639.2806.

I. Respondent Eells did not secure a registration issued by the Board pursuant to NRS 639.23505 authorizing him to dispense parenteral solutions outside of his office.

J. Respondent Eells failed to properly supervise Nurse Wilcox and Paramedic Wilcox in connection with their possession, storage, transportation, delivery, dispensing, and/or administering of parenteral solutions.

7. The Board and Respondent Eells agree that Count One, Count Three, Count Five, Count Seven, and Count Eight shall be dismissed upon approval of this Stipulation by the Board. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent Eells agree to the following:

A. Respondent Eells shall pay an administrative fine in the amount of One Thousand Five Hundred and 00/100s Dollars ($1,500.00) for the violations alleged in Count Two, Count Four, and Count Six of the Accusation. Respondent Eells shall pay this fine by cashier's check, certified check, or money order made payable to "**State of Nevada, Office of the Treasurer.**" Respondent Eells shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days after the effective date of the Board's Order as stated below.

B. Respondent Eells shall pay the sum of Five Hundred and 00/100 Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. Respondent Eells shall pay such attorney's fees and costs by issuance of a cashier's check, certified check, or money order made payable to **"Nevada State Board of Pharmacy."** Respondent Eells shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of the Board's Order as stated below.

8. Any failure by Respondent Eells to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent Eells to appear before the Board at the next regularly scheduled meeting for a show cause

hearing. If such a hearing results in a finding of a violation by Respondent Eells, the Board may impose additional discipline upon Respondent Eells not inconsistent with the provisions of NRS Chapter 639.

9. The undersigned Board Prosecutor will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 11, 2023, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent Eells or his attorney fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent Eells agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein.

AGREED:

Signed this 28 day of September 2023.

James R. Eells, M.D.
Certificate of Registration No. CS22639

Signed this 29th day of September 2023.

Gregory L. Zunino
Board Prosecutor
Nevada State Board of Pharmacy

APRROVED AS TO FORM AND CONTENT
this 22 day of September 2023.

Bridget Kelly, Esq.
Nutile Law
Attorney for Respondent James R. Eells, M.D.

DECISION AND ORDER

As to Respondent James R. Eells, M.D., Certificate of Registration No. CS22639, in Case No. 19-081-CS-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____ day of October 2023.

_____
Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DELTA DRUGS,** **Pharmacy License No. PH04105,** **Respondent.**	**Case No. 20-168-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Delta Drugs (Respondent), an out-of-state pharmacy, because Respondent is licensed by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent holds license number PH04105.

2. The Board has jurisdiction over the subject matter of this accusation because at the time of the violations alleged below Respondent was engaged in the "practice of pharmacy" as that term is defined at NRS 639.0124.

FACTUAL ALLEGATIONS

3. Respondent, a California corporation, operates a pharmacy based in Glendale, California. On or about May 17, 2019, Respondent submitted to the Board its application to conduct business in Nevada as an out-of-state pharmacy. The Board first issued a pharmacy license to Respondent on July 23, 2019.

4. Prior to July 23, 2019, Respondent was licensed to operate a pharmacy in California but not in Nevada. Between October 20, 2018, and July 22, 2019, Respondent sold and delivered dangerous drugs and/or controlled substances to consumers in Nevada. During this time frame, according to

Respondent's own dispensing records, Respondent shipped dangerous drugs and/or controlled substances into Nevada on thirty-one separate occasions.

5. As alleged above, Respondent's activity, and that of its employees, agents, and/or representatives, amounted to "dispensing" as that term is defined at NRS 639.0065.

6. Between October 20, 2018, and July 23, 2019, Respondent employed Michael Groman (Groman) as its pharmacist-in-charge. In its application for a Nevada pharmacy license, Respondent identified Groman as its managing pharmacist. Groman, now deceased, was never registered by the Board to engage in the practice of pharmacy in Nevada.

7. Sometime after July 23, 2019, Respondent employed Jerry Whittemore (Whittemore) as its pharmacist-in-charge. Whittemore cooperated with the Board's investigation of the allegations stated herein. In a written statement dated November 12, 2020, Whittemore confirmed that Respondent had dispensed dangerous drugs and/or controlled substances to patients in Nevada between October 20, 2018, and July 23, 2019.

APPLICABLE LAW

8. It is unlawful for any person to sell or dispense, or permit to be sold or dispensed, any dangerous drug or controlled substance unless the person holds the appropriate permit or license issued by the Board and complies with the regulations adopted by the Board. NRS 639.100(1).

9. Every person who dispenses dangerous drugs or controlled substances in Nevada must secure and maintain a certificate of registration from the Board based upon demonstrated expertise and training in the practice of pharmacy. NRS 639.120; NRS 639.127; NAC 639.205–.212.

10. "'Dispense' means to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery." NRS 639.0065. "'Deliver' or 'delivery' means the actual, constructive, or attempted transfer of a controlled substance or dangerous drug from one person to another, whether or not there is an agency relationship.

11. Every pharmacy located outside Nevada must be licensed by the Board before shipping any dangerous drug or controlled substance to a consumer in Nevada. NRS 639.23284; NRS 639.230–639.231. Every pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220.

12. It is unlawful for any person who is not a registered pharmacist to manage a pharmacy or dispense dangerous drugs or controlled substances. NRS 639.284. A "registered pharmacist" is a natural person registered by the Board to engage in the practice of pharmacy only as authorized by Nevada law. NRS 639.015; NRS 639.120; NRS 639.127; NAC 639.205–.212.

13. The Board may revoke or suspend the license of any pharmacy that has violated any Nevada law or regulation relating to the practice of pharmacy. NRS 639.210(12); NRS 639.230(5). The "practice of pharmacy" includes the performance or supervision of activities associated with dispensing a dangerous drug or controlled substance. NRS 639.0124.

14. In addition to or in lieu of revoking or suspending a pharmacy's license for unlawful conduct relating to the practice of pharmacy in Nevada, the Board may impose an administrative fine upon the pharmacy. NRS 639.255(1)(f). The fine may not exceed $10,000 for each offense. NRS 639.255(3).

COUNT ONE
Unlawful Practice of Pharmacy

15. Between October 20, 2018, and July 23, 2019, Respondent, acting through its employees, agents, and/or representatives, dispensed dangerous drugs and/or controlled substances to consumers in Nevada. Respondent did so without having obtained a pharmacy license as required by Nevada law.

16. Between October 20, 2018, and July 23, 2019, Respondent allowed its employees, agents, and/or representatives to dispense dangerous drugs and/or controlled substances to consumers

in Nevada even though such persons were not registered by the Board to engage in the practice of pharmacy in Nevada.

17. Respondent's conduct as alleged above violated Nevada law relating to the practice of pharmacy, including NRS 639.100(1), NRS 639.23284, NRS 639.230, and NRS 639.231.

18. Respondent's conduct as alleged above is grounds for discipline insofar as Respondent aided or abetted the unregistered practice of pharmacy in Nevada. *See* NRS 639.210(12).

19. Respondent's conduct as alleged above is grounds for discipline insofar as Respondent negligently subjected its employees, agents, and/or representatives to potential liability for the unregistered practice of pharmacy in Nevada. *See* NRS 639.210(16).

20. Respondent is subject to discipline for any of the acts or violations alleged above. *See* NRS 639.210(12) and (16).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of Respondent Delta Drugs.

DATED this 3rd day of JULY 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DELTA DRUGS,** **Pharmacy License No. PH04105,** **Respondent.**	**CASE NO. 20-168-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of JULY, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DELTA DRUGS,** **Pharmacy License No. PH04105,** **Respondent.**	**CASE NO 20-168-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR DELTA DRUGS

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this _ 6th day July of 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Delta Drugs
[redacted] Fernando Ct.
Glendale, CA 91204

KRISTOPHER MANGOSING

5F

FILED
JUL 28 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHAHIN BANAYAN, RPH,** **Certificate of Registration No. 17272,** **and,** **WALGREENS PHARMACY #10783,** **Pharmacy License No. PH02334,** **Respondents.**	**Case Nos. 20-191-RPH-S** **20-191-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Shahin Banayan ("Respondent Banayan"), because Respondent Banayan holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing him to engage in the practice of pharmacy within the state of Nevada.

2. The Board has personal jurisdiction over Respondent Walgreens Pharmacy #10783 ("Respondent Walgreens"), because Respondent Walgreens holds a license issued by the Board pursuant to NRS 639.230, authorizing Respondent Walgreens to operate a pharmacy located 6495 Decatur Boulevard in Las Vegas, Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because, at the time of the violations alleged herein, Respondent Banayan was a Nevada registered pharmacist engaged in

the practice of pharmacy at a business location operated by Respondent Walgreens in Las Vegas, Nevada.

FACTUAL ALLEGATIONS

4. In 2018 and 2019, at the time of each of the violations alleged herein, Respondent Banayan was a registered pharmacist employed by Respondent Walgreens at its pharmacy on Decatur Boulevard in Las Vegas, Nevada.

5. On May 13, 2018, while on duty at Walgreens on Decatur Boulevard, Respondent Banayan filled a prescription for patient JW (JW). The prescription had been written by JW's physician for bupropion SR, a medication used to treat depression. Respondent Banayan mistakenly filled the prescription with bupropion ER, a medication used to treat depression in some patients and/or to assist some patients to stop smoking. Upon being contacted by JW, Respondent Walgreens corrected the mistake.

6. JW had a history of filling prescriptions for bupropion SR at the Walgreens on Decatur Boulevard. In processing JW's prescription on May 13, 2018, Respondent Banayan overrode a system warning advising that bupropion ER was possibly duplicative of medications that JW was already taking. The warning should have alerted Respondent Banayan to a possible mistake involving JW's prescription.

7. On June 8, 2018, JW arrived at the Walgreens Pharmacy on Decatur Boulevard to pick up prescriptions for her son NW (NW), and prescriptions for her daughter, AW (AW). AW's physician had written her a prescription for escitalopram, a medication used to treat depression and anxiety. NW's physician had written NW prescriptions for similar medications not including escitalopram. Respondent Banayan mistakenly filled NW's prescription with escitalopram and neglected to fill AW's prescription for escitalopram.

8. When she returned home on June 8, 2018, JW noticed that her daughter AW was missing one of her medications. She later telephoned someone at Respondent Walgreens who, after

some research, discovered that AW's prescription for escitalopram had been mistakenly attributed to NW. Respondent Walgreens corrected the mistake.

9. In filling the prescription for escitalopram on June 8, 2018, Respondent Banayan overrode a system warning advising that escitalopram was possibly duplicative of medications that NW was already taking. The warning should have alerted Respondent Banayan to a possible mistake involving NW's prescription.

10. On February 12, 2019, JW's husband, JJW (JJW), arrived at the Walgreens Pharmacy on Decatur Boulevard to pick up his refill of tramadol. JJW's physician had prescribed 50 mg tablets in a quantity of 60 tablets for JJW's initial prescription and for each of his five (5) refills. Respondent Banayan refilled JJW's prescription for tramadol with a quantity of 30 tablets instead of 60 tablets. JJW did not notice the mistake until he had returned home. Respondent Walgreens corrected the mistake.

11. Respondent Banayan was the subject of prior discipline by the Board. In that case, Respondent Banayan signed a stipulation on May 31, 2016, in which he acknowledged that he had worked as a managing pharmacist for a licensed Nevada pharmacy (not Walgreens) for approximately sixty-two (62) days after his certificate of registration had expired. The Board imposed a fine and ordered Respondent Banayan to complete continuing education courses.

APPLICABLE LAW

12. The Board may revoke or suspend the registration of any pharmacist who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4). Likewise, the Board may revoke or suspend the registration of any pharmacist who has violated any provision of Nevada law relating to prescription drugs. *See* NRS 639.210(12). In lieu of revoking or suspending such a pharmacist's registration, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

13. A pharmacist's conduct is deemed unprofessional if the pharmacist fails to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or

refilling. *See* NAC 639.945(1)(i). Additionally, a pharmacist's conduct is deemed unprofessional if the pharmacist performs his or her duties in an incompetent, unskillful or negligent manner. *See* NAC 639.945(1)(i).

14. Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), pharmacies, pharmacy mangers, and/or pharmacists are responsible for the acts and omissions of the pharmacy employees under their supervision.

COUNT ONE
Unprofessional Conduct (Patient JW)

15. On or about May 13, 2018, Respondent Banayan engaged in unprofessional conduct as alleged in paragraphs 5 and 6 above. Respondent Banayan's conduct was unprofessional because: 1) he failed to strictly follow the instructions of patient JW's physician as to the filling of patient JW's prescription for bupropion SR; and 2) he performed his duties as a pharmacist in an incompetent, unskillful or negligent manner by incorrectly filling JW's prescription with bupropion ER despite a system warning that should have alerted him to the mistake.

16. For the unprofessional conduct as described above, the Board may discipline Respondent Banayan pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

17. As the owner/operator of the pharmacy at which Respondent Banayan worked, Respondent Walgreens is liable for Respondent's unprofessional conduct as described above. Accordingly, the Board may discipline Respondent Walgreens pursuant to NRS 639.210, NRS 639.255, and NAC 639.255.

COUNT TWO
Unprofessional Conduct (Patient AW)

18. On or about June 8, 2018, Respondent Banyan engaged in unprofessional conduct as alleged in paragraphs 7 and 9 above. Respondent's Banayan's conduct was unprofessional because: 1) he failed to strictly follow the instructions of patient AW's physician as to the filling of patient AW's prescription for escitalopram, attributing it instead to patient NW; and 2) he performed his duties as a

pharmacist in an incompetent, unskillful or negligent manner by incorrectly filling NW's prescription with escitalopram despite a system warning that should have alerted him to the mistake.

19. For the unprofessional conduct as described above, the Board may discipline Respondent Banayan pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

20. As the owner/operator of the pharmacy at which Respondent Banayan worked, Respondent Walgreens is liable for Respondent's unprofessional conduct as described above. Accordingly, the Board may discipline Respondent Walgreens pursuant to NRS 639.210, NRS 639.255, and NAC 639.255.

COUNT THREE
Unprofessional Conduct (Patient JJW)

21. On or about February 12, 2019, Respondent Banayan engaged in unprofessional conduct as alleged in paragraph 10 above. Respondent's Banayan's conduct was unprofessional because: 1) he failed to strictly follow the instructions of patient JJW's physician as to the filling of patient JJW's prescription for tramadol by supplying JJW with 30 tablets instead of the prescribed 60 tablets; and, 2) he performed his duties as a pharmacist in an incompetent, unskillful or negligent manner by incorrectly filling JJW's prescription with 30 tablets despite recurring prior visits by JJW, each one of which involved a supply of 60 tablets.

22. For the unprofessional conduct as described above, the Board may discipline Respondent Banayan pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

23. As the owner/operator of the pharmacy at which Respondent Banayan worked, Respondent Walgreens is liable for Respondent's unprofessional conduct as described above. Accordingly, the Board may discipline Respondent Walgreens pursuant to NRS 639.210, NRS 639.255, and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Banayan and the

pharmacy license of Respondent Walgreens.

DATED this 28th day of July 2023.

Yenh Long, Pharm.D., Deputy Executive Secretary of the
Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. SHAHIN BANAYAN, RPH, Certificate of Registration No. 17272, Respondent.	Case No. 20-191-RPH-S STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of July, 2023.

Yenh Long, Pharm.D., Deputy Executive Secretary of the
Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 2nd day of August 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Shahin Banayan, RPH
[redacted]S. Las Vegas Blvd. #2605
Las Vegas, NV 89109

Walgreens Pharmacy #10783
6495 N. Decatur Blvd.
Las Vegas, NV 89131-2960

William Stilling, Esq.
222 South Main Street, Suite 500
Salt Lake City, Utah 84101

SHIRLEY HUNTING

THOMAS C. MICHAELIDES, ESQ.
TCM LAW GROUP
Nevada Bar No. 5425
2620 Regatta Drive Suite #211
Las Vegas, Nevada 89128
Telephone : 702-462-6161
Facsimile : 702-413-6255
info@tcmlawgroup.com
Attorney for Respondent
SHAHIN BANAYAN

FILED
AUG 28 2023
NEVADA STATE BOARD
OF PHARMACY

TCM LAW GROUP
2620 Regatta Drive, Suite 211
Las Vegas, Nevada 89128
Telephone 702-426-6161

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY

Petitioner,

v.

SHAHIN BANAYAN, et al.

Respondents

Case Nos. 20-191-RPH-S
20-191-PH-S

ANSWER AND NOTICE OF DEFENSE

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to clearly state the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

None

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

TCM LAW GROUP
2620 Regatta Drive, Suite 211
Las Vegas, Nevada 89128
Telephone 702-426-6161

Count One

Respondent enters a denial as to Count One.

Respondent makes every effort to uphold the highest professional standards. In this matter, Respondent approved the filling by a technician of a prescription for bupropion SR with bupropion ER. By way of mitigation, it should be recognized that the two medications are essentially identical in ingredients and in dosage. While Respondent strives to be 100% error free, the risk to the patient in this instance was minimal or nonexistent.

To the extent that this Count is based on Respondent having overridden a system warning, it is submitted that the overriding of a private proprietary system, alone, does not constitute unprofessional conduct, and that pharmacists routinely override the system for valid reasons.

Finally, Respondent points to NRS 639.2583, which recognizes that in certain circumstances it is appropriate for a pharmacist to substitute one drug for another where (a) the second drug *"[i]s biologically equivalent to the drug prescribed by brand name, [and (b), has] the same active ingredient or ingredients of the same strength, quantity and form of dosage as the drug prescribed...."* Respondent is not suggesting that the prescription referenced in Count One fell under all of the provisions of NRS 639.2583, but simply as a matter of mitigation that the existence of

the statute indicates an acknowledgment that it can be appropriate to substitute one biologically equivalent drug for another.

Count Two

Respondent enters a denial as to Count Two.

Again, Respondent makes every effort to uphold the highest professional standards. Here, there were two members of the same family who submitted prescriptions for different drugs at the same time. Respondent recognizes the importance of making sure that each patient receives only the drugs that that individual patient has been prescribed, and that members of the same family may have different conditions, different reactions to the same drug, different drug interaction issues, etc. Not by way of excuse, but by way of mitigation, Respondent notes that he has supervised numerous technicians over many years, both before and after June 8, 2018, and that this is a singular instance in which he was ever alleged to have given a drug to one patient that had been prescribed to another patient.

Count Three

Respondent enters a denial as to Count Three.

By way of mitigation, and not by way of excuse, Respondent submits that this error was not the type of error which entailed any of the dangers to the patient that might have pertained to either Count One or Count Two. In this instant case, the patient was in no danger of either taking a different drug than had been prescribed or taking a drug that had been prescribed to another individual. Of the numerous types

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2620 Regatta Drive, Suite 211
Las Vegas, Nevada 89128
Telephone 702-426-6161

of counting errors, most occur using the quantity of thirty (30), due it being the most prescribed amount. The amount filled was also lower, rather than greater than the amount prescribed, a factor weighing in mitigation.

Conclusion

Respondent has been a pharmacist of the utmost integrity for many years. The lapses reflected in the current Accusation are not representative of his usual meticulous and conscientious approach to his responsibilities. As the pharmacist, he takes responsibility of verifying that those working under him are accurately performing their jobs. It is urged that the Board exercise leniency.

Dated this 25 day of August, 2023.

Submitted by:

TCM LAW GROUP

/s/ Thomas C. Michaelides
THOMAS C. MICHAELIDES, ESQ.
TCM LAW GROUP
Nevada Bar No. 5425
2620 Regatta Drive Suite #211
Las Vegas, Nevada 89128
Telephone : 702-462-6161
Facsimile : 702-413-6255
info@tcmlawgroup.com
Attorney for Respondent

TCM LAW GROUP
2620 Regatta Drive, Suite 211
Las Vegas, Nevada 89128
Telephone 702-426-6161

5G

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. WALGREENS PHARMACY #10783, Pharmacy License No. PH02334, Respondent.	CASE NO. 20-191-PH-S STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of July, 2023.

Yenh Long, Pharm.D., Deputy Executive Secretary of the
Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #10783, Pharmacy License No. PH02334,** **Respondent.**	**Case No. 20-191-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR WALGREENS PHARMACY #10783

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 2nd day of August 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Shahin Banayan, RPH
[redacted] S. Las Vegas Blvd. #2605
Las Vegas, NV 89109

Walgreens Pharmacy #10783
6495 N. Decatur Blvd.
Las Vegas, NV 89131-2960

William Stilling, Esq.
222 South Main Street, Suite 500
Salt Lake City, Utah 84101

SHIRLEY HUNTING

5H

FILED
JUL 28 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MONA MATAR, RPH,** **Certificate of Registration No. 20104, and,** **WALGREENS #04755,** **Pharmacy License No. PH01383,** **Respondents.**	**Case No. 22-370-RPH-S** **22-370-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Mona Matar, RPH (Matar), because Matar, at the time of the violations alleged herein, held a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing her to engage in the practice of pharmacy within the state of Nevada.

2. The Board has personal jurisdiction over Respondent Walgreens #04755 (Walgreens) because Walgreens, at the time of the violations alleged herein, held a license issued by the Board pursuant to NRS 639.230, authorizing Walgreens to operate a pharmacy located at 3480 S. Jones Boulevard in Las Vegas, Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because, at the time of the violations alleged herein, Matar was the pharmacist on duty at the Walgreens pharmacy located at 3480 S. Jones Boulevard in Las Vegas, Nevada, where she engaged in unprofessional conduct by a pharmacist.

FACTUAL ALLEGATIONS

4. Matar is a registered pharmacist authorized by the Board to engage in the practice of pharmacy.

5. On or about September 14, 2022, Matar was the pharmacist on duty at the Walgreens pharmacy located on South Jones Boulevard in Las Vegas, Nevada. While on duty, Matar fielded an adult customer's request to be vaccinated against hepatitis B.

6. Matar prepared a 10 mcg/0.5 ml dose of the Engerix B vaccine for administration by a pharmacy technician. Matar removed this pediatric dose from a refrigerator where it was stored as part of lot number YM444. Lot number YM444 consisted entirely of pediatric doses. At that time, lot number YM444 was the only Energix B remaining in Walgreens' inventory.

7. Matar placed the pediatric dose of Energix B in a bin for administration by a pharmacy technician. The technician subsequently removed the pediatric dose from the bin and injected it into the adult customer.

8. On or about September 15, 2022, a second adult customer requested to be vaccinated against hepatitis B. When a pharmacy employee advised the customer that the pharmacy had run out of adult doses of the hepatitis B vaccine, another Walgreens employee mentioned that an adult dose had been administrated to a customer one day prior. Following that conversation, the employees checked the refrigerator only to discover that lot number YM444 was the only supply of Energix B remaining in inventory.

9. After confirming that the Walgreens pharmacy had exhausted its supply of 20 mcg/ml doses of Energix B, the employees notified the pharmacy manager, Elaine Santiago, who then checked pharmacy records to identify the adult customer who had been vaccinated with the pediatric dose of Energix B. Ms. Santiago quickly identified the customer based upon the informed consent form that Matar had prepared in connection with the vaccination. Matar had noted on the form that the customer received a vaccine dose from lot number YM444.

10. Ms. Santiago telephoned the customer to advise her that she had a received a pediatric dose of the vaccine, advising her that she could return to the pharmacy for the correct dose. The customer later contacted the Board to make a complaint.

11. In response to an inquiry by Board Investigator Kenneth Scheuber, Matar explained in a written statement dated November 21, 2022, that the day of the incident had been a busy workday for her, with many patients waiting for vaccines. Mater stated that she regretted her mistake.

12. Matar was the subject of an unrelated complaint involving a similar allegation that she misfilled a prescription for Levothyroxine while employed at the QHR Pharmacy in Las Vegas, Nevada. This alleged misfill occurred on or about April 20, 2022. Pursuant to NRS 639.2895(3), Matar was separately cited for the April 20 incident.

APPLICABLE LAW

13. The Board may revoke or suspend the registration of any pharmacist who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4). In lieu of revoking or suspending such a pharmacist's registration, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

14. A pharmacist's conduct is deemed unprofessional if the pharmacist fails to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or refilling. *See* NAC 639.945(1)(i). Additionally, a pharmacist's conduct is deemed unprofessional if the pharmacist performs his or her duties in an incompetent, unskillful or negligent manner. *See* NAC 639.945(1)(i).

15. Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), pharmacies, pharmacy managers, and/or pharmacists are responsible for the acts and omissions of the pharmacy employees under their supervision.

COUNT ONE
Failure to Follow Instructions of Person Ordering Prescription

16. On or about September 14, 2022, as alleged above, Matar failed to strictly follow the instructions of an adult customer who requested to be vaccinated against hepatitis B. This constitutes unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NRS 639.255; NAC 639.945(1)(h); NAC 639.955.

17. As the owner/operator of the pharmacy at which Matar was employed on September 14, 2022, Walgreens is responsible for Matar's unprofessional conduct as alleged above. NRS 639.230(5), NRS 639.255; NAC 639.702; NAC 639.945(2); and NAC 639.955.

COUNT TWO
Performing Duties in a Negligent Manner

18. On or about September 14, 2022, as alleged above, Matar caused an adult customer to be injected with a pediatric dose of Energix B, thus necessitating a second vaccination resulting in unnecessary discomfort to the customer.

19. Matar knew or should have known that she had prepared an incorrect dose of Energix B for the adult customer. Accordingly, Matar performed her duties as a pharmacist in an incompetent, unskillful, or negligent manner. This constitutes unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4), NRS 639.255, NAC 639.945(1)(i), and NAC 639.955.

20. As alleged above, the incident on September 14, 2022, was the second of two incidents involving an alleged mistake by Matar in filling a prescription. Accordingly, the incident on September 14, 2022, warrants administrative disciplinary action and/or the imposition of a fine pursuant to NAC 639.955(1)(c).

21. As the owner/operator of the pharmacy at which Matar was employed on September 14, 2022, Walgreens is responsible for Matar's unprofessional conduct as alleged above. NRS 639.230(5), NRS 639.255; NAC 639.702; NAC 639.945(2); and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent Mona Matar and the pharmacy license of Respondent Walgreens #04755.

DATED this 28th day of July 2023.

Yenh Long, Pharm.D., Deputy Executive Secretary of the
Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MONA MATAR, RPH,** **Certificate of Registration No. 20104,** **Respondent.**	**CASE NO. 22-370-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd.
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of July, 2023.

Yenh Long, Pharm.D., Deputy Executive Secretary of the
Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MONA MATAR, RPH,** **Certificate of Registration No. 20104,** **Respondent.**	**Case No. 22-370-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

MONA MATAR, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 2nd day of August 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Mona Matar, RPH
[redacted] Timber Stand St.
Las Vegas, NV 89183

Walgreens Pharmacy #04755
3480 S. Jones Blvd.
Las Vegas, NV 89146-6709

William Stilling, Esq.
222 South Main Street, Suite 500
Salt Lake City, Utah 84101

SHIRLEY HUNTING

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #04755,** **Pharmacy License No. PH01383,** **Respondent.**	**CASE NO. 22-370-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd.
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of July, 2023.

Yenh Long, Pharm.D., Deputy Executive Secretary of the
Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #04755, Pharmacy License No. PH01383,** **Respondent.**	**CASE NO. 22-370-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR WALGREENS PHARMACY #04755

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 2nd day of August 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Mona Matar, RPH
[redacted] Timber Stand St.
Las Vegas, NV 89183

Walgreens Pharmacy #04755
3480 S. Jones Blvd.
Las Vegas, NV 89146-6709

William Stilling, Esq.
222 South Main Street, Suite 500
Salt Lake City, Utah 84101

SHIRLEY HUNTING

5J

State of Nevada Board of Pharmacy
GREGORY L. ZUNINO (4805)
Senior General Counsel – ext. 124
zunino@pharmacy.nv.gov
PETER KEEGAN (12237)
General Counsel – ext. 123
p.keegan@pharmacy.nv.gov
BRETT KANDT (5384)
General Counsel – ext. 134
b.kandt@pharmacy.nv.gov
985 Damonte Ranch Pkwy., #206
Reno, Nevada 89521
(775) 850-1440

FILED
AUG 10 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH, PT,** **Certificate of Registration No. PT18958,** **Respondent.**	**Case No. 22-041-PT-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over this matter because at the time of the events alleged herein, Respondent Justine Stanevich ("Stanevich"), held an unrenewed Nevada Pharmacy Technician Certificate of Registration No. PT18958, issued by the Board.

PRIOR DISCIPLINE

2. On April 22, 2022, the Board entered its Findings of Fact, Conclusions of Law, and Order ("Order") against Respondent Stanevich in Case No. 20-135-PT-S. Pursuant to the Board's

Order, Respondent Stanevich's Certificate of Registration No. PT18958 was revoked pursuant to NRS 639.210(11) and (12); however, the revocation was stayed, and Stanevich was placed on probation for one (1) year. The discipline was imposed for accessing a patient's confidential data in the PMP by fraudulently using another employee's credentials in violation of NRS 639.210(4) and NAC 639.945(1)(i) as well as NRS 639.210(12) and NRS 639.255.

FACTUAL ALLEGATIONS

3. On December 7, 2020, an electronic prescription for Breo Ellipta 200-25 Mcg/Inh with 11 refills was sent to Walgreens #5479 and designated by its system as prescription no. 1869680.

4. Prescription no. 1869680 was first sold on April 20, 2021, by Walgreens #5479. The first refill was sold by Walgreens #5479 on June 8, 2021.

5. Prescription no. 1869680 was then transferred to Walgreens #3843 and designated by its systems as prescription no. 2272237 and the second refill was sold on July 11, 2021.

6. Prescription no. 2272237 was then transferred to Walgreens #7841 and designated by its system as prescription no. 2385097. The third refill was sold on August 18, 2021, the fourth refill was sold on September 23, 2021, the fifth refill was sold on October 26, 2021, and the sixth refill was sold on November 26, 2021.

7. Walgreens #7841 records show a refill data entry on January 5, 2022, for "Call MD exception" at 10:22:52 p.m. The "Call MD exception" was resolved 74 seconds later with 3 refills added to prescription no. 2385097 and the seventh refill entered at 10:24:08 p.m. Walgreen's system then designated this prescription no. 2498610.

8. The data entry performed on January 5, 2022, was over one (1) year past the issue date of the original prescription.

9. Pharmaceutical technician Vanessa Calderon was signed into Walgreen's system when the 3 refills were added; however, PT Calderon had already finished her shift and left for the day. Walgreen's internal investigation determined that Respondent Stanevich was the only PT to have access

to Walgreen's system to resolve the "Call MD exception" that day.

10. Respondent Stanevich was employed by Walgreens #7841, located at 10510 Southern Highlands Parkway, Las Vegas, Nevada 89141 as a pharmaceutical technician.

11. Prescription no. 2498610 was then sold on January 11, 2022, February 9, 2022, and March 15, 2022.

12. On March 31, 2020, an electronic prescription for Albuterol Sulfate HFA 108 inhaler with 11 refills was sent to Walgreens #5311 and designated by its system as prescription no. 2781542. Prescription no. 2781542 was first sold on April 1, 2020.

13. Prescription no. 2781542 was transferred to Walgreens #5479 and designated by its system as prescription no. 1831336.

14. The issuance date of prescription no. 1831336 was changed to from March 31, 2020, to November 20, 2020. Respondent Stanevich was working at Walgreens #5479 at the time of the change to the issuance date.

15. Prescription no. 1831336 was then transferred to Walgreens #7841 and designated by its system as prescription no. 2385153.

16. Prescription no. 2385153 was then dispensed on August 18, 2021, over 1 year past the original issuance date of March 31, 2020. Respondent Stanevich was working at Walgreens #7841 when prescription no. 2385153 was filled.

17. Respondent Stanevich's employment with Walgreens was terminated on June 13, 2022, for billing fraud, for performing duties outside of the scope of a pharmaceutical technician, and for dishonesty regarding her involvement in the prescriptions for her family member.

APPLICABLE LAW

18. It is unlawful for any person to dispense any drug, poison, medicine or chemical unless the person holds the appropriate certificate, license or permit required by this NRS Chapter 639, 453, or 454, and that person complies with the regulations adopted by the Board. NRS 639.100(1).

19. No person other than a practitioner holding a license to practice his or her profession in this State may prescribe or write a prescription. NRS 639.235(1).

20. A dangerous drug may be dispensed by a registered pharmacist upon the legal prescription from a practitioner. NRS 454.215(1).

21. The following acts may only be performed by a registered pharmacist, or by a registered pharmaceutical intern acting under the direct supervision of a registered pharmacist: (i) taking new orders for prescriptions or chart orders over the phone; (ii) identifying, evaluating, and interpreting a prescription; (iii) interpreting the clinical data contained in a patient's medication system or chart; (iv) consulting with a prescribing practitioner, nurse, or other health care professional, or the authorized agent thereof; (v) determining the efficacy of a drug, a regimen, the substitution of a generic drug for a drug prescribed by brand name or the substitution of one drug therapy for another; (vi) taking responsibility for all activities of pharmaceutical technicians to ensure that those activities are performed completely, safely and without risk of harm to patients; (vii) counseling a patient or a person caring for a patient and rendering any other advice or information regarding drugs or medications; and (viii) performing any other functions which require the professional judgement of a pharmacist. NAC 639.700.

22. The Board may suspend or revoke any certificate, license, registration or permit if the holder has violated, attempted to violate, assisted or abetted in the violation, or conspired to violate, or failed to report a violation, of any provision of Nevada law relating to prescription drugs. *See* NRS 639.210(12).

23. Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to in violation of NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board pursuant to NRS 639.210(4).

24. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to in violation of NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board pursuant to NRS 639.210(4).

25. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation alleged in an accusation for which the holder is found guilty. NRS 639.255(3); NAC 639.955.

26. This Accusation constitutes a public record pursuant to NRS 622.330 and any discipline imposed by the Board shall be reported to the National Practitioner Data Bank as required by federal law. Title 42 USC § 1396r–2; 45 CFR Part 60.

COUNT ONE
Violation of State Law – Unlicensed Dispensing

27. By independently adding three (3) refills to prescription no. 2385097, a family member's prescription, without practitioner authorization, Respondent Stanevich engaged in unlicensed dispensing in violation of NRS 639.100, NRS 639.235(1), and NRS 454.215(1). Respondent Stanevich is therefore subject to discipline pursuant to NRS 639.210 and/or NAC 639.255(1)(a-f).

COUNT TWO
Violation of State – Unprofessional Conduct

28. By independently adding three (3) refills to prescription no. 2385097, a family member's prescription, without practitioner authorization, Respondent Stanevich engaged in a fraudulent or deceitful practice or transaction which constitutes unprofessional conduct or conduct contrary to the public interest pursuant to in violation of NRS 639.210(4) as defined in NAC 639.945(1)(h). Respondent Stanevich is therefore subject to discipline pursuant to NRS 639.210 and/or NAC 639.255(1)(a-f).

COUNT THREE
Violation of State – Unprofessional Conduct

29. In the alternative to Count II, by independently performing acts, including (i) taking new orders for prescriptions of chart orders over the phone; and (ii) consulting with a prescribing practitioner, nurse, or other health care professional, or authorized agent thereof; which may only be performed by a registered pharmacist or by registered pharmaceutical intern acting under the direct supervisions of a registered pharmacist, Respondent Stanevich engaged in unprofessional conduct in violation of NRS 639.210(4) as defined in NAC 639.945(1)(i). Respondent Stanevich is therefore subject to discipline pursuant to NRS 639.210 and/or NAC 639.255(1)(a-f).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 16th day of August 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH, PT,** **Certificate Of Registration No. PT18958,** **Respondent.**	**Case No. 22-041-PT-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 11, 2023, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

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You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **p.keegan@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 14th day of August 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH, PT,** **Certificate of Registration No. PT18958,** **Respondent.**	**Case No. 22-041-PT-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

JUSTINE STANEVICH, PT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of August, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Justine Stanevich
[redacted] Mandalay Springs Drive, Apt [redacted]
Las Vegas, NV 89120

Darlene Nases
DARLENE NASES

FILED
SEP 25 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH, PT,** **Certificate of Registration No. PT18958,** **Respondent.**	**Case No. 22-041-PT-S** **NEVADA STATE BOARD OF PHARMACY'S MEMORANDUM OF REASONABLE ATTORNEY'S FEES AND ACTUAL COSTS PURSUANT TO NRS 622.400**

I, Peter K. Keegan, affirm that the foregoing is a true and correct statement of the actual costs and reasonable attorney's fees incurred by the Board in the above-entitled action. Pursuant to NRS 622.400, the undersigned hereby submits the following Nevada State Board of Pharmacy staff timesheets and itemized costs, which were requested to be prepared by counsel to reflect the actual costs and reasonable attorney's fees incurred by the Nevada State Board of Pharmacy in connection with the investigation and prosecution of the above-entitled administrative action.

DATED this 26th day of September 2023.

/s/ Peter Keegan, Esq.
General Counsel
Nevada State Board of Pharmacy

Attorney Timesheet for Peter Keegan **Case No. 22-041-PT-S – Justine Stanevich**

DATE	TIME
August 3, 2023	**2.5**

Review investigative file; draft accusation; send to Board Coordination staff for emailing and mailing.

September 22, 2023	**1.0**

Prepare Exhibits and attorney fees and costs

October 10, 2023	**0.5**

Review materials and prepare for Board hearing on 10.11.2023

October 11, 2023	**0.5**

Prosecute appeal hearing before the Board.

TOTAL 4.5 hours x $63.00/hour = $283.50

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH, PT,** **Certificate of Registration No. PT18958,** **Respondent.**	**Case Nos. 20-135-PT-S** **22-041-PT-S** **DECLARATION OF** **DARLENE NASES**

I, Darlene Nases, declare under the penalty of perjury the following:

1. I am employed by the Nevada State Board of Pharmacy ("Board") as an Assistant Board Coordinator.

2. I prepared the below itemized timesheet, at the request of Peter K. Keegan, General Counsel, and pursuant to NRS 622.400, to reflect the actual costs and fees incurred by the Nevada State Board of Pharmacy in connection with my preparing, processing, and mailing, of materials required by law for a hearing before the Board in above-entitled administrative action.

DATE	TIME	ACTION/COST
8/10/23	1.0	Prepared and mailed certified and regular mail for 20-135-PT-S Order to Show and 22-041-PT-S Notice of Intended Action and Accusation.

TOTAL POSTAGE **$9.73**

TOTAL TIME **1.0 hours x $34.86/hour = $34.86**

TOTAL $44.59

Executed this 14th day of September 2023.

Darlene Nases

Darlene Nases, Assistant Board Coordinator
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH,** **Certificate of Registration No. PT18958** **Respondent.**	**Case Nos. 22-041-PT-S** **DECLARATION OF KRISTOPHER MANGOSING**

I, Kristopher Mangosing declare under the penalty of perjury the following:

1. I am employed by the Nevada State Board of Pharmacy ("Board") as an Assistant Board Coordinator.

2. I prepared the below itemized timesheet, at the request of Peter K. Keegan, General Counsel, and pursuant to NRS 622.400, to reflect the actual costs and fees incurred by the Nevada State Board of Pharmacy in connection with my preparing, processing, and mailing, of materials required by law for a hearing before the Board in above-entitled administrative action.

DATE	TIME	ACTION/COST
9/12/2023	0.25	Prepared 21-day notice for mailing.
TOTAL POSTAGE		**$8.53 X 1 = $8.53**
TOTAL TIME		**0.25 hours x $34.86/hour = $8.72**
TOTAL $94.02		

Executed this 20th day of September 2023.

Kristopher Mangosing, Assistant Board Coordinator
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH, PT,** **Certificate of Registration No. PT18958,** **Respondent.**	**Case No. 22-041-PT-S** **DECLARATION OF** **DENA MCCLISH**

I, Dena McClish declare under the penalty of perjury the following:

1. I am employed by the Nevada State Board of Pharmacy ("Board") as an Investigator.

2. I prepared the below itemized timesheet, at the request of Peter K. Keegan, General Counsel, and pursuant to NRS 622.400, to reflect the actual costs and fees incurred by the Nevada State Board of Pharmacy in connection with my investigation in the above-entitled administrative action.

Case No 22-41-PT-S **PT Stanevich**
Investigator Dena McClish

Date	Duties	Hours
3/23/2022	init review, cmplnt contact, alleg letter	1.75
3/29/2022	pharmacy contact	0.5
4/6/2022	LP contact	0.25
4/11/2022	recv'd & review docs	0.75
5/3/2022	email to walgreens	0.25
5/9/2022	2nd cmplnt contact	0.5
5/18/2022	PT statement receipt & review	0.75
5/19/2022	PIC stmt receipt & review	0.5
6/6/2022	doc review & analysis; req to pharm for more info	1.75
6/8/2022	addtl review of docs; ?;s sent to Holly on >1yr Rxs	0.75
Total hrs		**7.75**

Hourly wage		**46.41**	**359.677**
7/13/2022	follow up email	0.25	
7/18/2022	info of termination recv'd; req for more info sent	0.5	
8/17/2022	follow up email	0.25	
8/23/2022	info recvd, ROI began	2.25	
8/29/2022	ROI & clarification ? Sent	1.25	
9/28/2022	follow up email, finish ROI	0.75	
11/21/2022	review case in South; upload doc; sent to Reno review	1	
Total hrs		**6.25**	
Wage		**49.41**	**308.812**
Total hrs			
Total Investigative hours		**14.00**	
Total cost			**668.49**

Executed this 18 day of September 2023.

Dena McClish, Investigator
Nevada State Board of Pharmacy

TOTAL TIME & COST SUMMARY

Case No. 22-041-PT-S – JUSTINE STANEVICH

Attorney Peter Keegan – 4.5 hours @$63.00/hr =	**$283.50**
Board Coordinator Darlene Nases – 1.0 hours @$34.86/hr =	**$34.86**
Certified Mailing Postage	**$9.73**
Board Coordinator Kristopher Mangosing – 0.25 hours @$34.86/hr =	**$8.72**
Certified Mailing Postage	**$8.53**
Investigator Dena McClish – 7.75 hours @$46.41/hr=	**$359.68**
Investigator Dena McClish – 6.25 hours @$49.41/hr=	**$308.81**
Total	**$1,013.83**

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of September, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Justine Stanevich
[redacted]Mandalay Springs Drive Apt[redacted]
Las Vegas, NV 89120

Darlene Nases
DARLENE NASES

5K

FILED
AUG 10 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH, PT,** **Certificate of Registration No. PT18958,** **Respondent.**	**Case No. 20-135-PT-S** **ORDER TO SHOW CAUSE**

The Nevada State Board of Pharmacy ("Board") HEREBY ORDERS Respondent Justine Stanevich, PT, ("Stanevich"), Certificate of Registration No. PT18958, pursuant to NAC 639.965 – NAC 639.978, to appear before the Board on October 11, 2023, at 9:00 a.m. and show cause, if any, why Certificate of Registration No. PT18958 should not be subject to revocation.

1. On April 22, 2022, the Nevada State Board of Pharmacy ("Board") entered an its Findings of Fact, Conclusions of Law, and Order ("Order") against Respondent Justine Stanevich, PT, ("Respondent"), Certificate of Registration No. PT18958, in Case No. 20-135-PT-S.

2. Pursuant to the Board's Order, Respondent's Certificate of Registration No. PT18958 was revoked pursuant to NRS 639.210(11) and (12); however, the revocation was stayed, and Stanevich was placed on probation for one (1) year subject to the following conditions:

A. Respondent shall not have any disciplinary actions instituted against her by the Nevada State Board of Pharmacy; and

B. Respondent shall complete and submit proof of attendance to the Board staff for two (2) additional hours of continuing education, one (1) hours of ethics and one (1) hour of HIPAA training, within one-year of April 22, 2022;

C. Respondent shall attend, in-person, the disciplinary component of two (2) Nevada State Board of Pharmacy meetings within one year of April 22, 2022;

D. Respondent shall pay a fine of Five Hundred Dollars and 00/100 Cents ($500.00) to the State of Nevada; and

E. Respondent shall pay Seven Hundred Ninety-Three Dollars and 88/100 Cents ($793.88) to partially reimburse the Board for its reasonable attorney fees and recoverable costs. Payment shall be made in five (5) equal installments of One Hundred Fifty-Eight Dollars and 77/100 Cents ($158.77).

3. Respondent has failed to comply with the terms of the Board's Order. Specifically, Respondent has failed to: (1) complete the required two additional hours of continuing education; (2) attend the required two disciplinary components of the Board's meetings; (3) make timely payment of the $500.00 fine; and (4) make timely payment of the $793.88 in attorney fees and costs.

4. Additionally, on February 16, 2022, the Board received a complaint against Respondent alleging she added three (3) refills to a family member's prescription for a Breo Ellipta inhaler without authorization from the prescribing practitioner and using another Walgreen's employee's credentials. As a result of the complaint Case No. 22-041-PT-S was opened by the Board and an investigation of occurred during the Respondent's probation.

THEREFORE, IT IS HEREBY ORDERED that Respondent Justine Stanevich, PT, Certificate of Registration No. PT18958, shall appear before the Board and show cause, if any, why Certificate of Registration No. PT18958 should not be subject to revocation.

ENTERED this 16th day of August 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3); NAC 639.968.

The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 a.m. or soon thereafter. The hearing will occur at the at the Hilton Garden Inn located at 7830 S. Las Vegas Blvd, Las Vegas, Nevada 89123.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of August, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Justine Stanevich
[redacted] Mandalay Springs Drive, Apt [redacted]
Las Vegas, NV 89120

Darlene Nases
DARLENE NASES

FILED
APR 22 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. JUSTINE STANEVICH, PT Certificate of Registration No. PT18958, Respondent.	CASE NO. 20-135-PT-S FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER

This matter came before the Nevada State Board of Pharmacy ("Board") at its regularly scheduled meeting on Wednesday, April 13, 2022. Peter Keegan, Esq., prosecuted the case before the Board. Respondent Justine Stanevich, PT, ("Stanevich"), Certificate of Registration No. PT18958, appeared without counsel. The Board heard the case and, based on the evidence presented, the Board makes the following Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

The Board finds that probative evidence exists in the record to establish each of the following facts by a preponderance of the evidence:

1. Paul Howse is/was the managing pharmacist at Smith's Food and Drug Store #351 ("Smith's") located at 6130 West Tropicana Avenue, Las Vegas, Nevada 89103 during the relevant timeframe.

2. Stanevich was employed as a pharmaceutical technician at Smith's during the relevant timeframe.

3. On or about February 12, 2020, Howse, was approached by Stanevich regarding an opioid prescription for a new patient. As indicated by protocol, Howse accessed and reviewed the new patient's Prescription Monitoring Program ("PMP") history using an interface with Smith's computer system. Howse left the computer station for a moment, with Stanevich left next to the computer, to explain to the new patient at the drop-off window that he needed more information from the prescribing

practitioner. Upon Howse's return to the computer station, Howse noticed a second PMP window opened for patient P.S., who he had not checked the PMP database. Howse questioned Stanevich about the PMP inquiry on patient P.S., whereupon Stanevich admitted that she queried the PMP for patient P.S. under Howse's credentials. Stanevich stated that patient P.S. was someone personally known to her and not a patient of Smith's. Howse informed Stanevich that the PMP query was unacceptable, and against company policy and HIPAA.

4. Howse immediately reported Stanevich's PMP query to his district and division managers for Smith's. During the investigation, which included review of videotape from Howse's computer workstation, and interviews of Smith's staff working at the time, it was determined that Stanevich violated company policy, and HIPAA. Stanevich was terminated on February 18, 2020.

5. Board staff incurred at least Seven Hundred Ninety-Three Dollars and 88/100 Cents ($793.88) in attorney's fees and recoverable costs investigating and prosecuting this administrative action. The attorney's fees are reasonable based upon legal counsel's professional qualities, the nature of this administrative enforcement action, the work performed, and the result as evidenced by this Order.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

1. The Board has jurisdiction over this matter and Stanevich, because at the time of the events herein, Stanevich held a registration as a pharmaceutical technician, Certificate of Registration No. PT18958, issued by the Board.

2. The applicable law in this matter is as follows:

   A. Performing any duties as the holder of a pharmacist or pharmaceutical technician in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

B. The Board administers the PMP, which maintains a database of all transactions for controlled substances listed in schedules II, III, IV, and V which are prescribed and dispensed in Nevada. *See* NRS 453.162-.165.

C. Patient utilization reports and data in the PMP constitute Protected Health Information ("PHI") as defined in 45 CFR Part 160 and 164, Subparts A and E. The Health Insurance Portability and Accountability Act ("HIPAA") provides certain requirements regarding privacy of PHI and certain prohibitions against disclosure. 42 USC §1320d *et seq.* (HIPAA Privacy Act).

D. Patient utilization reports and all data in the PMP are also confidential and protected from unauthorized use or disclosure under state law. *See* NRS 453.164.

E. Unauthorized access, use, or disclosure of PHI carries civil and criminal penalties under federal law. *See* 42 USC § 1320d-5 and d-6.

F. Unauthorized access, use, or disclosure of information in the PMP also constitute a crime under state law. NRS 453.552(2).

G. The Board may suspend or revoke any certificate, license, registration, or permit issued if the registrant is not of good moral character, is guilty of unprofessional conduct or conduct contrary to the public interest, willfully makes to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of NRS 639, and/or violates any provision of federal or state law. NRS 639.210; NRS 639.255.

3. Based upon the testimonial and documentary evidence received at the hearing, the Board finds the Respondent guilty of the following alleged violations of law contained in the Accusation:

A. **Count Two**, by accessing patient P.S.'s confidential data in the PMP and obtaining P.S.'s utilization report, Stanevich as a registered pharmaceutical technician, without authority and fraudulently under Howse's credentials, acted in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(I)(i). Stanevich is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

B. **Count Three**, by accessing patient P.S.'s confidential data in the PMP, Stanevich violated state law protecting patients from unauthorized disclosure of PMP information under NRS 453.164(8) and is subject to discipline pursuant to NRS 639.210(12) and/or NRS 639.255.

By accessing patient P.S.'s confidential data in the PMP, Stanevich violated federal law, HIPAA Privacy Rule pursuant to 42 USC §1320d *et seq.* and is subject to discipline pursuant to NRS 639.210(11) and (12) and/or NRS 639.255.

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. The certificate of registration of Respondent Justine Stanevich, PT, Certificate of Registration No. PT18958, is hereby revoked pursuant to NRS 639.210(11) and (12). The revocation is stayed, and the Respondent is placed on probation for one (1) year subject to the following conditions:

   A. Respondent shall not have any disciplinary actions instituted against her by the Nevada State Board of Pharmacy; and

   B. Upon successful completion of probation, Respondent's Certificate of Registration PT18958 will be fully restored.

2. Respondent shall complete and submit proof of attendance to the Board staff for two (2) additional hours of continuing education, one (1) hour of ethics and one (1) hour of HIPPA training, within one-year of the effective date of this Order.

3. Respondent shall attend, in-person, the disciplinary component of two (2) Nevada State Board of Pharmacy meetings within one year of the effective date of this Order.

4. Respondent shall pay a fine of Five Hundred Dollars and 00/100 Cents ($500.00) to the State of Nevada for the above referenced violations. Payment shall be made by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within Ninety (90) days of entry of this Order.

5. Pursuant to NRS 622.400, Respondent shall pay Seven Hundred Ninety-Three Dollars and 88/100 Cents ($793.88) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter. Payment shall be made by *cashier's check*, *certified check* or *money order* made payable to the "Nevada State Board of Pharmacy" in five (5) equal installments of One Hundred Fifty-Eight Dollars and 77/100 Cents ($158.77) to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. The first payment shall be received within thirty (30) days of the effective date of this Order, with each of the four remaining payment installments due in thirty (30) day increments thereafter.

6. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 453, NRS Chapter 454, and/or NRS Chapter 639.

7. This Order constitutes a final decision in a contested case and a public record pursuant to NRS 639.255(5) and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

8. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 22nd day of April 2022.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 26th day of April 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Justine Stanevich
[redacted] Mandalay Springs Dr. Apt [redacted]
Las Vegas, NV 89120

KRISTOPHER MANGOSING

9171 9690 0935 0271 8353 15

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH, PT,** **Certificate of Registration No. PT18958,** **Respondent.**	**Case No. 20-135-PT-S** **NEVADA STATE BOARD OF PHARMACY'S MEMORANDUM OF REASONABLE ATTORNEY'S FEES AND ACTUAL COSTS PURSUANT TO NRS 622.400**

I, Peter K. Keegan, affirm that the foregoing is a true and correct statement of the actual costs and reasonable attorney's fees incurred by the Board in the above-entitled action. Pursuant to NRS 622.400, the undersigned hereby submits the following Nevada State Board of Pharmacy staff timesheets and itemized costs, which were requested to be prepared by counsel to reflect the actual costs and reasonable attorney's fees incurred by the Nevada State Board of Pharmacy in connection with the investigation and prosecution of the above-entitled administrative action.

DATED this 26th day of September 2023.

/s/ Peter Keegan, Esq.
General Counsel
Nevada State Board of Pharmacy

Attorney Timesheet for Peter Keegan **Case No. 22-135-PT-S – Justine Stanevich**

DATE	**TIME**
August 3, 2023	**1.0**

Review compliance with Findings of Fact and Conclusions of Law; draft Order to Show Cause; send to Board Coordination staff for emailing and mailing.

September 26, 2023	**1.0**

Prepare Exhibits and Memorandum of attorney fees/costs

October 10, 2023	**0.5**

Review materials and prepare for Board hearing on 10.11.2023

October 11, 2023	**0.5**

Prosecute OSC before the Board.

TOTAL 3.0 hours x $63.00/hour = $189.00

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTINE STANEVICH,** **Certificate of Registration No. PT18958** **Respondent.**	**Case Nos. 20-135-PT-S** **DECLARATION OF KRISTOPHER MANGOSING**

I, Kristopher Mangosing declare under the penalty of perjury the following:

1. I am employed by the Nevada State Board of Pharmacy ("Board") as an Assistant Board Coordinator.

2. I prepared the below itemized timesheet, at the request of Peter K. Keegan, General Counsel, and pursuant to NRS 622.400, to reflect the actual costs and fees incurred by the Nevada State Board of Pharmacy in connection with my preparing, processing, and mailing, of materials required by law for a hearing before the Board in above-entitled administrative action.

DATE	TIME	ACTION/COST
9/12/2023	0.25	Prepared 21-day notice for mailing.
TOTAL POSTAGE		**$8.53 X 1 = $8.53**
TOTAL TIME		**0.25 hours x $34.86/hour = $8.72**
TOTAL $17.25		

Executed this 26th day of September 2023.

Kristopher Mangosing, Assistant Board Coordinator
Nevada State Board of Pharmacy

TOTAL TIME & COST SUMMARY

Case No. 20-135-PT-S – JUSTINE STANEVICH

Attorney Peter Keegan – 3.0 hours @$63.00/hr =	**$189.00**
Board Coordinator Kristopher Mangosing – 0.25 hours @$34.86/hr =	**$8.72**
Certified Mailing Postage	**$8.53**
Total	**$206.25**

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 26th day of September, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Justine Stanevich
5130 Mandalay Springs Drive, Apt 201
Las Vegas, NV 89120

Darlene Nases
DARLENE NASES

FILED
SEP 26 2023
NEVADA STATE BOARD
OF PHARMACY

Justine Stanevich
[redacted] Mandalay Springs Drive, Apt [redacted]
Las Vegas, NV 89120
20-135-PT-S. Memorandum of Costs and Fees

9171 9690 0935 0279 6478 04

MAILED
9/26/23

5L

FILED
FEB 06 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #3844, Pharmacy License No. PH01123,** **KERRY S. OTERO, RPH, Certificate of Registration No. 20516, and** **MORGAN A. TOWLER, PTT, Certificate of Registration No. PT23168,** **Respondents.**	**CASE NOS. 22-096-PH-S** **22-096-RPH-S** **22-096-PTT-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Walgreens Pharmacy #3844 ("Walgreens #3844"), Pharmacy License No. PH01123, Respondent Kerry S. Otero, RPH ("Otero"), Certificate of Registration No. 20516, and Respondent Morgan A. Towler ("Towler"), Certificate of Registration No. PT23168, were licensed/registered with the Board.

FACTUAL ALLEGATIONS

2. Respondent Walgreens #3844 is located at 5011 E. Sahara Avenue, in Las Vegas, Nevada.

3. Respondent Otero was the managing pharmacist at Walgreens #3844 during the alleged events and relevant timeframes.

4. Respondent Towler was employed by Walgreens #3844 as a pharmaceutical technician in training during the alleged events and relevant timeframes.

5. On or about March 24, 2022, Respondent Otero submitted a Licensee Record of ANY Controlled Substance Loss or Theft ("Loss or Theft report") on behalf of Walgreens #3844 to the Board which reported a suspected loss on March 23, 2022, of eighty-eight (88) Oxycodone 5mg tablets, forty-five (45) Methylphenidate 5 mg tablets, and seventy (70) Oxycodone 7.5mg/325mg.

6. On or about March 30, 2022, Respondent Otero submitted a second Loss or Theft report on behalf of Walgreens #3844 to the Board containing revisions which reported a suspected employee theft discovered on March 23, 2022, and increasing the shortage counts to one hundred ninety-three (193) Oxycodone HCL acetaminophen 10/325 mg tablets, ninety-six (96) Oxycodone HCL 5 mg tablets, and sixty (60) Methylphenidate 5 mg tablets.

7. On or about March 31, 2022, Respondent Otero submitted a third Loss or Theft report on behalf of Walgreens #3844 to the Board concerning the March 23, 2022, shortage discovery. The March 31, 2022, version reported a suspected employee theft of one hundred ninety-three (193) Oxycodone HCL acetaminophen 7.5mg/325 mg tablets and ninety-six (96) Oxycodone HCL 5 mg tablets.

8. On or about May 3, 2022, Respondent Otero submitted a fourth Loss or Theft report for Walgreens #3844 to the Board concerning the March 23, 2022, shortage discovery. The May 3, 2022, version reported a suspected employee theft of one hundred ninety-three (193) Oxycodone HCL acetaminophen 7.5mg/325 mg tablets.

9. On or about May 2, 2022, Respondent Otero submitted a DEA Form-106 Report of Theft of Loss of Controlled Substances ("DEA 106") on behalf of Walgreens #3844 for the March 23, 2022, shortage discovery. The May 2, 2022, DEA Form-106 reported a suspected employee theft of one hundred ninety-three (193) Oxycodone HCL acetaminophen 10/325 mg tablets.

10. Investigation records reflect on or about February 28, 2022, Respondent Otero submitted a Loss or Theft report on behalf of Walgreens #3844 to the Board which reported a suspected large employee theft dating back to December 17, 2021, of four thousand seven (4,007) Oxycodone-acetaminophen 10/325 mg tablets and six thousand seventy-two (6,072) hydrocodone acetaminophen 10/325 mg tablets.

11. On or about February 1, 2022, and again on August 9, 2022, Krystal Bernard submitted a DEA Form-106 on behalf of Walgreens #3844 for the December 17, 2021, shortage discovery. Both the February 1, 2022, and the August 9, 2022, DEA Form-106 reported a suspected employee theft of four thousand seven (4,007) Oxycodone-acetaminophen 10/325 mg tablets and six thousand seventy-two (6,072) hydrocodone acetaminophen 10/325 mg tablets.

12. On or about July 8, 2022, Respondent Otero submitted a Loss or Theft report on behalf of Walgreens #3844 to the Board which reported a suspected employee theft on June 24, 2022, of fifty-eight (58) Dextroamp-Amphetamine 20 mg tablets, eighty-nine (89) Mixed Salt amphetamine 20 mg tablets, forty-three (43) Carisoprodol 350 mg tablets, one thousand two hundred nineteen (1,219) Carisoprodol 350 mg tablets, and two hundred twenty-nine (229) Carisoprodol 350 mg tablets.

13. On or about August 16, 2022, Michael Virtuoso submitted a DEA Form-106 on behalf of Walgreens #3844 for the June 24 2022, shortage discovery. The August 16, 2022, DEA Form-106 reported a suspected employee theft of fifty-eight (58) Dextroamp-Amphetamine 20 mg tablets, eighty-nine (89) Dextroamp-Amphetamine 20 mg, forty-three (43) Carisoprodol 350 mg tablets, one thousand two hundred nineteen (1,219) Carisoprodol 350 mg tablets, and two hundred twenty-nine (229) Carisoprodol 350 mg tablets.

14. On or about August 19, 2022, Respondent Otero submitted a Loss or Theft report on behalf of Walgreens #3844 to the Board which reported a suspected employee theft on July 26, 2022, of one hundred forty-eight (148) Alprazolam 1 mg tablets, seven hundred fifty-three (753)

Alprazolam 2 mg tablets, two hundred twelve (212) oxycodone acetaminophen 7.5/325 mg tablets, and one hundred forty-two (142) Carisoprodol 350 mg tablets.

15. On or about August 19, 2022, Respondent Otero submitted a DEA Form-106 on behalf of Walgreens #3844 for the July 26 2022, shortage discovery. The August 19, 2022, DEA Form-106 reported a suspected employee theft of one hundred forty-eight (148) Alprazolam 1 mg tablets, seven hundred fifty-three (753) Alprazolam 2 mg tablets, two hundred twelve (212) oxycodone acetaminophen 7.5/325 mg tablets, and one hundred forty-two (142) Carisoprodol 350 mg tablets.

16. In order to uncover the source(s) of the losses, Walgreens' Asset Management Team interviewed employees, reviewed months of security camera footage, reviewed controlled substances in schedule II ("CII") invoices, compared invoices to DEA 222 forms, DEA Controlled Substance Ordering System ("CSOS"), and Walgreens' inventory system AS-400. However, no invoicing or posting errors were found; therefore, the losses were attributed to internal diversion.

17. On or about August 6, 2022, Respondent Towler was interviewed by Walgreens #3844's Asset Protection Manager. During the interview, Towler admitted to taking drugs from Walgreens #3844 beginning in December 2021. Towler admitted to diverting drugs from the pharmacy, including 500 "Norcos" (Norco or hydrocodone, CII) and 500 "Percs" (Percocet or oxycodone, CII) and 120 "Somas" (Soma or carisoprodol, CIV), for financial gain. Towler's admission constitutes fraudulent and/or deceitful conduct.

18. Respondent Towler possessed and/or distributed controlled substances without a valid certificate of registration to dispense controlled substances.

19. Based upon the varying Theft or Loss reports submitted by Respondent Otero to the Board on behalf of Walgreens #3844 on March 24, 2022; March 30, 2022; March 31, 2022; and May 3, 2022; each related to the March 23, 2022, suspected employee theft, it is apparent

Walgreens #3844 and Respondent Otero failed to maintain an accurate controlled substance inventory, including perpetual inventory records.

20. Respondent Otero and Walgreens #3844 failed to report the December 17, 2021, June 24, 2022, and July 26, 2022, suspected employee thefts of controlled substances to the Board within 10 days after the date of discovery of the theft or loss, as required by Nevada law.

21. Respondent Otero and Walgreens #3844 failed to report the December 17, 2021, March 23, 2022, June 24, 2022, and July 26, 2022, suspected employee thefts of controlled substances to the DEA within the 1 day after the date of discovery of the theft or loss, as required by federal law.

22. On or about August 8, 2022, a Las Vegas Metropolitan police report was filed, a copy of Respondent Towler's admission of theft statement was included.

23. Respondent Towler was terminated from Walgreens #3844.

24. On or about September 23, 2022, Respondent Towler's Certificate of Registration No. PT23168 was summarily suspended by the Board's Executive Secretary pursuant to NRS 233B.127(3), and a notice of hearing for October 12, 2022, was served upon Towler's last known address.

25. The Board heard the matter on October 12, 2022, and Respondent Towler failed to appear, whereupon the Board found that the continuation of Towler's hearing was warranted.

APPLICABLE LAW

26. Supplying or diverting drugs which are legally sold in pharmacies constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

27. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant

to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

28. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

29. Violating, attempting to violate, assisting, or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

30. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to NRS Chapter 639 if it finds a managing pharmacist has violated any provision or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of this chapter or other state of federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision. NRS 639.210(15).

31. It is unlawful to possess and/or distribute controlled substances without a valid registration. 21 USC § 841(a), NRS 453.321, NRS 453.331(1), NRS 453.336.

32. A pharmacy shall maintain complete and accurate controlled substance records in a readily retrievable manner, including initial, biennial and perpetual inventories. 21 CFR §§ 1304.03-.21, NRS 453.246, NAC 453.475, NAC 453.485, NAC 639.485.

33. State law requires that all theft or loss of controlled substances must be reported within ten (10) days after discovery of theft or loss. NRS 453.568.

34. Federal law requires that theft or significant loss of controlled substances must be reported the next business day after discovery of theft or loss. 21 CFR § 1301.76(b).

35. "Any violation of any of the provisions of this chapter [NRS Chapter 639] by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing

pharmacist is cause for the suspension or revocation of the license of the pharmacy by the Board." NRS 639.230(5).

36. "The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty at the pharmacy are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission." NAC 639.702.

37. A pharmacy owner is responsible for violations committed by the pharmacy's employees. NAC 639.945(2).

38. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

COUNT ONE
Unprofessional Conduct- Fraudulent or Deceitful Practice
(Respondent Towler)

39. Respondent Towler engaged in fraudulent or deceitful practice when she diverted controlled substances, including Norco, Percocet, and Soma, from Walgreens #3844 as defined in NAC 639.945(1)(h), and is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT TWO
Violations of Federal and State Controlled Substances Act
(Respondent Towler)

40. Respondent Towler violated federal and state law by possessing and distributing controlled substances, including Norco, Percocet, and Soma, without the requisite registration/license in violation of 21 USC 841(a), NRS 453.321, 453.331(1), NRS 453.336, and

is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.210(11) and/or NRS 639.210(12) and/or NRS 639.255(3).

COUNT THREE
Failure to Keep Complete and Accurate Records
(Respondents Otero and Walgreens #3844)

41. As the managing pharmacist, Respondent Otero failed to keep complete and accurate controlled substance records, including perpetual inventories, as demonstrated by the four (4) different versions of Loss or Theft reports submitted to the Board for the suspected employee theft on March 23, 2022, as well as the large and delinquent Theft or Loss reports submitted to the Board on February 28, 2022, July 8, 2022, and August 19, 2022, as required by NAC 453.475, and/or NAC 639.485(2), and/or 21 CFR §§ 1304.03-.21; and is therefore subject to discipline pursuant to and/or NRS 639.210(15) and/or NRS 639.255(3).

42. Respondent Walgreens #3844 failed to keep complete and accurate records, including perpetual inventories, as demonstrated by the four (4) different versions of Loss or Theft reports submitted to the Board for the suspected employee theft on March 23, 2022, as well as the large and delinquent Theft or Loss reports submitted to the Board on February 28, 2022, July 8, 2022, and August 19, 2022, in violation of 21 CFR §§ 1304.03-.21, and/or NAC 453.475, and/or NAC 639.485(2), and is therefore subject to discipline pursuant to NAC 639.702 and/or NAC 639.945(2) and/or NRS 639.210(11) and/or NRS 639.210(12) and/or NRS 639.210(15) and/or NRS 639.255(3).

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COUNT FOUR
Managing Pharmacist Responsibility
(Respondents Walgreens #3844 and Otero)

43. As the managing pharmacist of Walgreens #3844 at the time of the violations alleged herein, Respondent Otero is responsible for those violations, including those of the pharmacy's employees pursuant to NAC 639.702, and is subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.210(12) and/or NRS639.210(15) and/or NRS 639.230(5), and/or NRS 639.255(3).

COUNT FIVE
Failure to Timely Report Theft/Losses Pursuant to Federal and State Law
(Respondent Walgreens #3844)

44. Respondent Walgreens #3844 violated 21 CFR § 1301.76(b) and/or NRS 453.568, when it failed to timely report losses or thefts of controlled substances discovered on December 17, 2021, June 24, 2022, and July 26, 2022; therefore, Walgreens #3844 is subject to discipline pursuant to NRS 639.210(12) and/or NRS 639.255(3).

COUNT SIX
Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #3844)

45. As the pharmacy where Respondents Otero, and Respondent Towler, violated the laws as alleged herein, Walgreens #3844 is responsible for those violations pursuant to NAC 639.702, and NAC 639.945(2). Respondent Walgreens #3844 is therefore subject to discipline pursuant to NRS 639.210(12), NRS 639.230(5), and/or NRS 639.255(3).

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WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license(s)/registration(s) of these Respondents.

Signed this 6th day of February 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #3844,** **Pharmacy License No. PH01123,** **Respondent.**	**CASE NO. 22-096-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, March 8, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd.
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of February 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #3844,** **Pharmacy License No. PH01123,** **Respondent.**	**CASE NO. 22-096-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of February 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR WALGREENS PHARMACY #3844

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Walgreens Pharmacy #3844
5011 E Sahara Ave.
Las Vegas, NV 89142

William Stilling, Esq.
222 South Main St., Suite 500
Salt Lake City, UT 84101

Kerry S. Otero
[redacted] Arrowhead Bluff Ave.
Las Vegas, NV 89142

Kerry S. Otero
[redacted] E Sahara Ave.
Las Vegas, NV 89142

Morgan A. Towler
[redacted]. Nellis Blvd #2090
Las Vegas, NV 89121

Darlene Nases
DARLENE NASES

5M

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KERRY S. OTERO, RPH,** **Certification of Registration No. 20516,** **Respondent.**	**CASE NO. 22-096-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, March 8, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd.
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of February 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KERRY S. OTERO, RPH,** **Certification of Registration No. 20516,** **Respondent.**	**CASE NO. 22-096-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of February 2023.

_____

KERRY S. OTERO, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Walgreens Pharmacy #3844
5011 E Sahara Ave.
Las Vegas, NV 89142

William Stilling, Esq.
222 South Main St., Suite 500
Salt Lake City, UT 84101

Kerry S. Otero
[redacted] Arrowhead Bluff Ave.
Las Vegas, NV 89142

Kerry S. Otero
[redacted] E Sahara Ave.
Las Vegas, NV 89142

Morgan A. Towler
[redacted] S. Nellis Blvd #[redacted]
Las Vegas, NV 89121

Darlene Nases

DARLENE NASES

5N

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MORGAN A. TOWLER, PTT,** **Certification of Registration No. PT23168,** **Respondent.**	**CASE NO. 22-096-PTT-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, March 8, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd.
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of February 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MORGAN A. TOWLER, PTT,** **Certification of Registration No. PT23168,** **Respondent.**	**CASE NO. 22-096-PTT-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of February 2023.

MORGAN A. TOWLER, PTT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 16th day of February 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Walgreens Pharmacy #3844
5011 E Sahara Ave.
Las Vegas, NV 89142

William Stilling, Esq.
222 South Main St., Suite 500
Salt Lake City, UT 84101

Kerry S. Otero
[redacted] Arrowhead Bluff Ave.
Las Vegas, NV 89142

Kerry S. Otero
[redacted] E Sahara Ave.
Las Vegas, NV 89142

Morgan A. Towler
[redacted] S. Nellis Blvd #[redacted]
Las Vegas, NV 89121

Darlene Nases

DARLENE NASES

FILED
SEP 23 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

In the Matter of the Investigation of: **MORGAN TOWLER, PTT,** **Certificate of Registration No. PT23168**	**CASE NO. 22-096-PTT-S** **ORDER OF SUMMARY SUSPENSION AND NOTICE OF HEARING**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), has determined that Morgan Towler's ("Towler") actions impact public health, safety or welfare which imperatively require emergency action pursuant to NRS 233B.127(3). Board staff has previously provided the Executive Secretary information, and other documentary evidence, which substantiates the preliminary findings that:

1. Towler was a pharmacy technician in training at the Walgreens Pharmacy #3844 ("Walgreens") located at 5011 W. Sahara Avenue, Las Vegas, NV 89142. Although Towler completed her hours of pharmacy technician training, she did not complete her application to be registered as a pharmacy technician.

2. On or about March 24, 2022, Walgreens reported controlled substances losses to the Board which involved 88 oxycodone HCL/acetaminophen 10/325 tablets, 70 oxycodone HCL mg tablets, and 45 methylphenidate 5 mg tablets. The Board initiated an investigation that uncovered other larger, previously unexplained losses, including a loss of 10,079 tablets of oxycodone-acetaminophen and hydrocodone-acetaminophen tablets on or about December 17, 2021.

3. On or about August 6, 2022, Towler was interviewed by Walgreens Asset Manager. Towler admitted to diverting drugs from the pharmacy, including 500 "Norcos" and 500 "Percs" and 120 "Somas". A police report was filed with the same admission of theft by Towler to sell for personal financial gain.

4. Shortly thereafter, Towler was terminated from Walgreens.

Accordingly, the Executive Secretary has reasonably determined that the summary suspension of Towler's pharmacy technician in training registration is emergently required pursuant to NRS 233B.127(3), and therefore:

ORDERS that Morgan Towler's Certificate of Registration No. PT23168 is **SUMMARILY SUSPENDED**;

IT IS FURTHER ORDERED that a hearing to determine whether the suspension may continue has been set for **Wednesday, October 12, 2022 at 9:00 am** or soon thereafter at Hilton Garden Inn, 7830 Las Vegas Boulevard South, Las Vegas, NV 89123.

IT IS SO ORDERED.

Dated this 23rd day of September, 2022.

J. David Wuest, RPH, Executive Secretary
Nevada State Board of Pharmacy

NOTICE OF HEARING

HEARING DATE, TIME, AND PLACE:

Wednesday, October 12, 2022
9:00 am or soon thereafter
Hilton Garden Inn
7830 Las Vegas Boulevard South
Las Vegas, NV 89123

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to present evidence and argument on all issues involved in your summary suspension, either personally or through counsel. NRS 233B.121; NRS 233B.127(3). Please be advised that the hearing before the Board will be open to the public pursuant to NRS 241.033 and NRS 241.034.

In addition, the Board may at its discretion, conduct a closed session to consider your character, alleged misconduct, professional competence, and/or physical or mental health. NRS 241.030. You may attend your closed session, and have counsel or other representative of your choice present during your closed session. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the suspension hearing, the Board may accept the Executive Secretary's preliminary findings as true and may proceed to consider the continuation of your summary suspension.

If warranted, the Board through Board's staff may take additional administrative action by serving an accusation against you after considering your character, alleged misconduct, professional competence, and/or physical or mental health at the suspension hearing. NRS 622A.300; NRS 639.241.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of September, 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Morgan Towler
[redacted]S. Nellis Blvd #[redacted]
Las Vegas, NV 89121

KRISTOPHER MANGOSING

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FILED
JUN 29 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **EDWARD SOLLESA VICTORIA, MD, Certificate of Registration No. CS15199,** **Respondent.**	**CASE NO. 23-113-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Edward Sollesa Victoria, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS15199, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about March 3, 2023, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case No. 22-33039-1 and imposed discipline on Respondent's License No. 12452 to practice medicine for engaging in conduct in violation of the standards of practice established by the NSBME, specifically for multiple violations of NRS 630.301(4), NRS 630.3062(1)(a) and NRS 630.3062(1)(b)(2) related to prescribing controlled substances to treat acute pain or chronic pain.

APPLICABLE LAW

3. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in conformance with the requirements of NRS 639.2391-.23914, *inclusive*, and after review of a patient's utilization report in the Prescription Monitoring Program (PMP) database in conformance with NRS 639.23507. 21 CFR § 1306.04(a); NRS 453.381(1).

4. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

5. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

6. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

7. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violation of Federal Controlled Substances Act

8. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 22-33039-1, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1306.04(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(11) and/or NRS 639.23916(3)(b).

COUNT TWO
Violations of State Law

9. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No22-33039-1, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 639.2391-.23914, *inclusive*, and/or NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b)

COUNT THREE
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

10. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 22-33039-1, and by violating 21 CFR § 1306.04(a), NRS 453.381(1), NRS 639.2391-.23914, *inclusive*, and/or NRS 639.23507, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(4) and/or NRS 639.23916(3)(b).

COUNT FOUR
Commission of Acts that Render Registration Inconsistent with the Public Interest

11. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 22-33039-1, and by violating 21 CFR § 1306.04(a), NRS 453.381(1) and/or NRS 639.2391-.23914, *inclusive*, and/or NRS 639.23507, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 24th day of JUNE 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. EDWARD SOLLESA VICTORIA, MD, Certificate of Registration No. CS15199, Respondent.	CASE NO. 23-113-CS-S STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd.
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 29th day of June, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of June 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Edward Victoria, MD
[redacted] N. Tenaya WY #[redacted]
Las Vegas, NV 89128

SHIRLEY HUNTING

FILED
AUG 24 2023
NEVADA STATE BOARD OF PHARMACY

CLARK HILL PLLC
Michael V. Cristalli, Esq. (NSBN 006266)
Brent M. Resh, Esq. (NSBN 14940)
1700 Pavilion Center Drive, Suite 500
Las Vegas, NV 89135
Telephone: (702) 862-8300
Facsimile: (702) 778-9709
Email: mcristalli@clarkhill.com
bresh@clarkhill.com
Attorneys for Respondent
EDWARD SOLLESA VICTORIA, M.D

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. EDWARD SOLLESA VICTORIA, M.D., Certificate of Registration No. CS15199, Respondent.	Case No.: 23-113-CS-S **ANSWER AND NOTICE OF DEFENSE**

Respondent Edward Sollesa Victoria, M.D., by and through counsel, hereby submits his Answer and Notice of Defense ("Answer"), in answer to the Notice of Intended Action and Accusation filed June 29, 2023 (the "Notice and Accusation"), in the above-captioned action before the Nevada State Board of Pharmacy (the "Board"). Respondent Dr. Victoria respectfully submits this Answer pursuant to NRS 639.244[1] and NRS 622A.320, declaring as follows:

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[1] **NRS 639.244 Notice of Defense: Form; effect of failure to file.**
1. The form for the Notice of Defense must be prepared and furnished by the Board and permit the respondent, by completing and signing the notice, to:
(a) Object to the accusation as being incomplete and failing to set forth clearly the charges; and
(b) Deny or admit, in part or in whole, the violations alleged.
2. The Notice of Defense must be signed by the respondent or his or her attorney under penalty of perjury. Failure to file a Notice of Defense constitutes a waiver of the respondent's right to a hearing, but the Board may grant a hearing.

1. That he objects to the Notice and Accusation pursuant to NRS 639.244(1)(a) as being incomplete and failing to set forth clearly the charges against him, on the following grounds:

a. The Notice and Accusation includes and/or recites no pertinent factual allegations regarding the charges in the Notice and Accusation.

b. The Notice and Accusation's only "factual allegation" is that a different agency (i.e., the Nevada Board of Medical Examiners) brought a different complaint (the "BME Complaint") against the Respondent.

c. The BME Complaint, along with a subsequent settlement agreement dated March 3, 2023, and order (the "Settlement") from that case, is mentioned in the Notice and Accusation, and such reference provides the only notice of the factual basis for the specific charges in the Notice and Accusation.

d. The BME Complaint is not included or attached or properly incorporated by reference in the Notice and Accusation.

e. The Notice and Accusation therefore provides inadequate notice of the factual allegations serving as the basis for the Notice and Accusation's specific charges.

2. That he, in answer to the Notice of Intended Action and Accusation pursuant to NRS 639.244(1)(b), **denies in whole** the allegations and violations alleged against him therein, excepting only to the extent that:

a. Dr. Victoria admits, pursuant to the Settlement (which was approved by the Medical Board in that case), that he "[has] admit[ted] to Counts II, III, V, VI, VIII, IX, and XII" of the BME Complaint—or "four (4) violations of NRS 630.3062(1)(a) . . . and four (4) violations of NRS 630.306(1)(b)(2)"—only and strictly as described in the BME complaint.

b. Dr. Victoria admits that, pursuant to the Settlement, he was subject to certain conditions and impositions of discipline by the Board of Medical Examiners (i.e., "Discipline"), but he denies admitting to or being Disciplined for all of the charges and all of the factual allegations included in the BME Complaint.

c. Dr. Victoria admits that on August 8, 2023, the BME notified him that he has

"fulfilled the terms of the Settlement Agreement, [and that his] Compliance file with the Nevada State Board of Medical Examiners has been closed."

d. Dr. Victoria denies that Dr. Victoria issued any prescription in violation of NRS 453.381(1).

3. That, before filing this Answer, Dr. Victoria has not waived the right to a hearing before the Board.

4. That, in filing this Answer, Dr. Victoria specifically requests and demands a hearing on this matter.

5. That Dr. Victoria asserts the following **Affirmative Defenses**:

a. The allegations contained in the Board's Accusation fail to state any actionable complaint or basis for imposing discipline.

b. The Notice and Accusation fails to meet minimum Due Process requirement for fair and adequate notice of the factual allegations supporting the charges.

c. The violations alleged against Respondent in the Board's Accusation are subject to a demand/application pursuant to NRS 233B.121(2)(d) for a more definite and detailed statement. (By this defense, Dr. Victoria specifically provides that he does not waive the right to such a demand/application even in light of this Answer.)

d. Dr. Victoria has fully complied with the Medical Board of Examiner's requirements and conditions imposed on his medical license, and that BME case is now closed.

6. That, pursuant to NRS 622A.330, though Dr. Victoria has provided this Answer, he specifically reserves the right to request a copy of all documents and other evidence intended to be presented by the Board at the hearing in support of its Accusation, as well as a list of proposed witnesses it intends to call at the hearing, if any.

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WHEREFORE, Dr. Victoria prays the Notice and Accusation be dismissed and/or that no discipline or conditions upon Dr. Victoria's license be issued.

Pursuant to NRS 639.244(2), this Answer is hereby signed by the answering Respondent's attorney.

Executed this 24th day of August, 2023.

CLARK HILL, PLLC

By */s/ Michael V. Cristalli, Esq.*
Michael V. Cristalli, Esq. (NSBN 006266)
Brent M. Resh, Esq. (NSBN 14940).
1700 South Pavilion Center Drive, Suite 500
Las Vegas, Nevada 89135
ph. (702) 862-8300; fax (702) 778-9709
email: mcristalli@clarkhill.com,
bresh@clarkhill.com
Attorneys for Respondent

VERIFICATION

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein states, are true and correct to the best of my knowledge.

DATED this 24th day of August, 2023.

/s/ Edward Sollesa Victoria, M.D.
EDWARD SOLLESA VICTORIA, M.D.

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FILED
SEP 12 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RAYMOND BRADBURY GRABER, D.D.S., Certificate of Registration No. CS27126,** **Respondent.**	**Case No. 23-340-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Raymond Bradbury Graber, D.D.S., ("Respondent") and this matter because, because at the time of the events alleged herein Respondent held a Nevada controlled substance registration, Certificate of Registration No. CS27126 issued by the Board.

FACTUAL ALLEGATIONS

2. On or about April 11, 2018, the Board initially issued Respondent Certificate of Registration to Dispense Controlled Substances, Certificate of Registration No. CS27126.

3. Respondent holds a current DEA registration which expires on September 30, 2023.

4. On or about August 27, 2022, Respondent was arrested for possession of 3.15 grams of cocaine, at or near 5650 South Carson Street, Carson City, State of Nevada.

5. On or about October 31, 2022, Respondent's Certificate of Registration No. CS27126 lapsed and was assigned non-renewed status by the Board.

6. On or about November 4, 2022, Respondent was charged for a violation of NRS 454.351, a misdemeanor, for possession of any drug which may not lawfully be introduced into interstate commerce under the Federal Food, Drug and Cosmetic Act.

7. On or about January 11, 2023, Respondent entered a guilty plea to a misdemeanor violation of NRS 454.351 and his sentencing was deferred for one year to allow for competition of a drug diversion program.

8. On or about February 15, 2023, Respondent submitted a late renewal application for Certificate of Registration No. CS27126.

9. Respondent failed to report his January 11, 2023, misdemeanor plea of guilty to a violation of NRS 454.351, within 30 days to the Board.

10. Respondent socially used cocaine prior to his arrest on August 27, 2022.

APPLICABLE LAW

11. Any person within this State who possesses, procures, obtains, produces, derives, manufactures, sells, offers for sale, gives away or otherwise furnishes any drug which may not be lawfully introduced into interstate commerce under the Federal Food, Drug and Cosmetic Act is guilty of a misdemeanor. NRS 454.351.

12. The holder of any certificate, license, or permit issued by the Board shall report to the Executive Secretary any conviction not later than 30 days after the conviction and provide any documentation of the conviction required by the Executive Secretary. The term "conviction" means a conviction for any crime, other than a misdemeanor traffic violation that does not involve the use of alcohol of a controlled substance, and includes: (a) final judgement; (b) plea of guilty or nolo contender; (c) plea pursuant to *North Carolina v. Alford*, 400 U.S. 25 (1970); or (d) guilty verdict following a bench trial or jury trial, regardless of whether a sentence is suspended or deferred, a final judgement of conviction has been entered or there are any pending appeals. Approved Regulation of the State Board of Pharmacy, LCB File No. R051-22, September 28, 2022.

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13. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.231(1)(h); NRS 453.236(1)(e) and NRS 453.241(1).

14. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

15. The Board may suspend or revoke any license or registration issued pursuant to NRS Chapter 639, and deny the application of any person for a certificate, license, registration or permit, if the holder of applicant has a substance abuse disorder. NRS 639.210(5).

16. Violating any provision of the Federal Food, Drug and Cosmetic Act is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

17. Violating, attempting to violate, assisting, or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

18. Administrative proceedings brought by the Board against a Respondent pursuant to NRS Chapter 453, to deny, suspend or revoke a registration must be initiated, conducted and concluded pursuant to the provisions of NRS 639.241 to NRS 639.257, and upon a finding of guilt against the Respondent, the Board shall suspend the right of the registrant to use his or her registration or a schedule thereof; or revoke the registration of a schedule thereof. NRS 453.241.

19. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation alleged in an accusation for which the holder is found guilty. NRS 639.255(1)(f) and (3); NAC 639.955.

20. This Accusation constitutes a public record pursuant to NRS 622.330 and any discipline imposed by the Board shall be reported to the National Practitioner Data Bank as required by federal law. Title 42 USC § 1396r–2; 45 CFR Part 60.

COUNT ONE
Failure to timely Report Conviction

21. By failing to report Respondent's guilty plea to the misdemeanor charge of NRS 454.351 within 30 days, Respondent violated Approved Regulation of the State Board of Pharmacy, LCB File No. R051-22, September 28, 2022. By failing to timely report his guilty plea, Respondent committed an act that renders his continued registration to dispense controlled substances in Nevada inconsistent with the public interest. Respondent is therefore subject to discipline pursuant to NRS 453.231(1)(h) and/or NRS 453.236(1)(e) and/or NRS 453.241(1) and/or NRS 639.255(1)(f) and (3).

COUNT TWO
Violation of the Federal Food, Drug, and Cosmetic Act

22. By pleading guilty to a violation of the Federal Food, Drug and Cosmetic Act for possession of 3.15 grams of cocaine and admitting to social use of cocaine prior to his arrest on August 27, 2022, Respondent is subject to discipline pursuant to NRS 639.210(5) and/or (11) and/or (12), and/or NRS 639.255(1)(f) and (3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 11th day of September 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RAYMOND BRADBURY GRABER, D.D.S., Certificate of Registration No. CS27126,** **Respondent.**	**Case No. 23-340-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 11, 2023, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 12th day of September 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RAYMOND BRADBURY GRABER, D.D.S., Certificate of Registration No. CS27126,** **Respondent.**	**Case No. 23-340-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

RAYMOND BRADBURY GRABER, D.D.S.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of September, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Lyn Beggs
328 California Ave. Ste 3
Reno, NV 89509

Darlene Nases
DARLENE NASES

5Q

FILED
JUL - 3 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

CRAIG PIVO, RPH,
Certificate of Registration No. 09999,

and,

GENOA HEALTHCARE LLC,
Pharmacy License No. PH03981,

Respondents.

Case Nos. 20-022-RPH-S
20-022-PH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Craig Pivo ("Respondent Pivo") because Respondent Pivo holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing him to engage in the practice of pharmacy within the state of Nevada.

2. The Board has personal jurisdiction over Respondent Genoa Healthcare LLC ("Respondent Genoa") because Respondent Genoa holds a license issued by the Board pursuant to NRS 639.230, authorizing Respondent Genoa to operate a pharmacy at 2500 W. Washinton Avenue in Las Vegas Nevada. The Board had formerly licensed Respondent Genoa to operate a pharmacy at 1901 S. Jones Boulevard in Las Vegas, Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because, at the time of the violations alleged herein, Respondent Pivo was a Nevada registered pharmacist engaged in the

practice of pharmacy at Respondent Genoa's pharmacy at 1901 S. Jones Boulevard in Las Vegas, Nevada.

FACTUAL ALLEGATIONS

4. At the time of each of the violations alleged herein, Respondent Pivo was a registered pharmacist employed by Respondent Genoa at its pharmacy on 1901 S. Jones Boulevard in Las Vegas, Nevada.

5. On March 4, 2020, while employed by Respondent Genoa, Respondent Pivo was tasked with filling a prescription for adult patient IS. The prescription had been written by the patient's healthcare provider for alprazolam, a medication used to treat anxiety.

6. Upon receiving the prescription for alprazolam, a pharmacy technician incorrectly transferred the information from the hand-written prescription to Respondent Genoa's prescription management system. The pharmacy technician who performed the data entry mistakenly attributed the prescription to patient TS, a 12-year-old boy with a history of receiving prescriptions at Respondent Genoa's pharmacy. Patient TS had a history of receiving prescriptions for various medications related to attention-deficit/hyperactivity disorder (ADHD). Those medications did not include alprazolam.

7. Adult patient IS and minor patient TS share the same last name but are not related. Respondent Pivo performed the verification of patient IS's prescription for alprazolam. Respondent Pivo failed to recognize that the pharmacy technician had incorrectly attributed the prescription to patient TS. Respondent Pivo thereafter caused a supply of 60 alprazolam tablets (1mg) to be delivered to patient TS at his home in Pahrump, Nevada. The supply arrived at patient TS's home on or about March 5, 2020. The supply of alprazolam arrived in a pill bottle with a label instructing patient TS to take the tablets twice daily.

8. Patient TS's caregivers failed to notice that alprazolam was not among the medications that TS was taking for his ADHD. TS's caregivers had recently discussed changing his medications and assumed that Respondent Genoa had delivered the correct medication. They gave TS one tablet that evening, and another tablet the following morning. TS then went to school, where his teachers

noticed that he was staggering and otherwise exhibiting symptoms of a drug overdose. TS returned home and slept for the remainder of the day.

9. On or about March 4, 2020, Respondent Pivo filled patient IS's prescription for alprazolam a second time, this time correctly attributing it to patient IS. Respondent filled the prescription under prescription number 11226, the same prescription number that was previously and incorrectly attributed to patient TS. Respondent Pivo did not contact patient TS or his caregivers to explain the mistake. Respondent voided the previous transaction so that it appeared that prescription number 11226 had only been filled once.

10. On March 26, 2020, Patient IS's health care provider contacted the Board with a complaint about the facts as alleged above. Following receipt of the complaint, Investigator Dena McClish attempted to ascertain why Respondent Genoa's drug utilization review (DUR) system had not flagged the mistakes related to prescription number 11226, and/or why the company's representatives did not disclose or self-report the mistakes after it became apparent that Respondent Pivo had twice filled prescription number 11226.

11. During her investigation, Investigator McClish interviewed Respondent Pivo, among others. In response to questions about his failure to notify TS's caregivers that he had mistakenly delivered alprazolam to TS at his home in Pahrump, Nevada, Respondent Pivo told Investigator McClish that filled prescriptions are accompanied by a toll-free telephone number that patients may call with questions.

12. When Investigator McClish inquired about Respondent Genoa's DUR system, Respondent Genoa's corporate representatives could not explain why its DUR systems had not flagged the mistakes related to prescription number 11226. A corporate representative provided Investigator McClish with written protocols and procedures that were not followed. Respondent Genoa had no record of whether Respondent Pivo offered counseling to patient TS or his caregivers.

13. In 2008, in connection with his application to renew his Nevada certificate of registration, Respondent Pivo was disciplined by the Board for having failed to disclose that he

voluntarily surrendered pharmacist licenses in California and Utah. In the 2008 case, the Board ordered Respondent to enroll in a substance abuse treatment program, among other things, as a condition of retaining his Nevada registration.

APPLICABLE LAW

14. The Board may revoke or suspend the registration of any pharmacist who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4). Likewise, the Board may revoke or suspend the registration of any pharmacist who has violated any provision of Nevada law relating to prescription drugs. *See* NRS 639.210(12). In lieu of revoking or suspending such a pharmacist's registration, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

15. A pharmacist's conduct is deemed unprofessional if the pharmacist fails to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or refilling. *See* NAC 639.945(1)(i). Additionally, a pharmacist's conduct is deemed unprofessional if the pharmacist performs his or her duties in an incompetent, unskillful or negligent manner. *See* NAC 639.945(1)(i). Finally, a pharmacist's conduct is deemed unprofessional if the pharmacist fails to confer with the person writing, making, or ordering a prescription if there is an error or omission in it which should be questioned. *See* NAC 639.945(1)(e).

16. Unless otherwise provided by law, a pharmacist must verbally provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient. Failure to provide appropriate counseling to the patient constitutes a violation of NAC 639.707(1). Pursuant to NRS 639.210(12), the Board may discipline a pharmacist who violates NAC 639.707(1)

17. Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), pharmacies, pharmacy managers, and/or pharmacists are responsible for the acts and omissions of the pharmacy employees under their supervision.

COUNT ONE
Unprofessional Conduct by a Pharmacist

18. In March of 2020, as alleged above, Respondent Pivo engaged in unprofessional conduct because he failed to strictly follow the instructions of patient IS's health care provider as to the filling of patient IS's prescription for alprazolam.

19. In March of 2020, Respondent Pivo performed his duties as a pharmacist in an incompetent, unskillful or negligent manner by causing an adult dose of alprazolam to be delivered to and ingested by minor patient TS, thus causing harm to patient TS.

20. Respondent Pivo performed his duties as a pharmacist in an incompetent, unskillful or negligent manner by delaying patient IS's receipt of his prescription medication.

21. Respondent Pivo engaged in unprofessional conduct when he failed to notify and/or confer with TS's health care provider and/or caregivers upon discovering that alprazolam was incorrectly delivered to TS at his home in Pahrump, Nevada.

22. Any one or all of the errors and/or omissions described above amounts to unprofessional conduct for which the Board may discipline Respondent Pivo pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

23. Respondent Genoa is also subject to discipline because Respondent Genoa is responsible for Respondent Pivo's unprofessional conduct as described above. NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

COUNT TWO
Supervisory Liability

24. On or about March 4, 2020, Respondent Pivo failed to adequately supervise the pharmacy technician who made the data entry mistakes described above. The pharmacy technician was under Respondent Pivo's supervision at the time. Pursuant to NAC 639.702, the pharmacy technician's errors and/or omissions may be attributed to Respondent Pivo. Accordingly, the Board may discipline Respondent Pivo pursuant to NRS 639.210(4), NRS 639.255(1), NRS 639.945(1), and NAC 639.955.

25. Respondent Genoa is also subject to discipline because Respondent Genoa is responsible for the unprofessional conduct of Respondent Pivo and/or the pharmacy technician under his supervision. NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

COUNT THREE
Violation of NAC 639.707(1)

26. On or about March 5, 2020, Respondent Pivo was the pharmacist on duty responsible for counseling patient TS's caregivers regarding the alprazolam that he had caused to be delivered to TS at his home in Pahrump, Nevada. By neglecting to telephone or otherwise contact TS's caregivers before TS ingested alprazolam, Respondent Pivo violated the provisions NAC 639.707(1). Accordingly, the Board may discipline Respondent Pivo pursuant to NRS 639.210(12), NRS 639.255(1), and NAC 639.955.

27. Respondent Genoa is also subject to discipline because Respondent Genoa is responsible for Respondent Pivo's unlawful conduct as described above. NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Pivo and the pharmacy license of Respondent Genoa.

DATED this 3rd day of JULY 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. GENOA HEALTHCARE LLC, Pharmacy License No. PH03981, Respondent.	CASE NO. 20-022-PH-S STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of July, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GENOA HEALTHCARE, LLC,** **Pharmacy License No. PH03981,** **Respondent.**	**Case No. 20-022-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

TYPE OR PRINT NAME

AUTHORIZED REPRESENTATIVE FOR GENOA HEALTHCARE, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day July of 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Genoa Healthcare, LLC
2500 W Washington Ave #103
Las Vegas, NV 89106

Craig Pivo, RPH
[redacted] Hobbyhorse Ave.
Henderson, NV 89012

Darlene Nases
DARLENE NASES

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GENOA HEALTHCARE, LLC,** **Pharmacy License No. PH03981,** **Respondent.**	**Case No. 20-022-PH-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Genoa Healthcare, LLC ("Respondent"), by and through its undersigned representative, hereby make and enter into this Stipulation and Proposed Order ("Stipulation") as to Respondent's pharmacy location operating under the authority granted by Nevada pharmacy license no. PH03981. As to that pharmacy location, the Parties stipulate and agree as follows:

1. The Board has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The undersigned representative of Respondent hereby warrants and represents that he/she has all necessary corporate power and authority to execute this Stipulation.

4. On behalf of Respondent, the undersigned representative acknowledges that he/she understands the terms of this Stipulation and that he/she has executed it knowingly and voluntarily.

5. The undersigned representative is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of the paragraphs below, Respondent hereby freely and voluntarily waives its rights to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. Without admitting to a violation of law, Respondent admits that evidence exists and that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violation alleged in Count One of the Accusation, *to wit*:

A. On March 4, 2020, while employed by Respondent as a staff pharmacist, Craig Pivo ("Pivo"), Nevada Certificate of Registration no. 09999, filled a prescription for adult patient IS. The prescription had been written by the patient's healthcare provider for alprazolam, a medication used to treat anxiety.

B. Upon receiving the prescription for alprazolam, a pharmacy technician incorrectly transferred the information from the hand-written prescription to the pharmacy's prescription management system. The pharmacy technician who performed the data entry mistakenly attributed the prescription to patient TS, a 12-year-old boy with a history of receiving prescriptions at the pharmacy. Patient TS was then awaiting a prescription for a different drug.

C. Pivo verified the above prescription and failed to recognize that the pharmacy technician had incorrectly attributed the prescription for alprazolam to patient TS. Pivo thereafter caused a supply of 60 alprazolam tablets (1mg) to be delivered to patient TS at his home. Patient TS subsequently ingested two of the tablets and experienced drowsiness and loss of balance while at school.

D. As alleged above, Pivo engaged in unprofessional conduct by failing to strictly follow the instructions of patient IS's physician, by negligently causing an incorrect prescription drug to be delivered to patient TS, and/or by failing to notify patient TS after Pivo was reasonably placed on notice of his mistake concerning the prescription.

8. The Board asserts that as Pivo's employer at the time, Respondent is vicariously liable for the unprofessional conduct of Pivo as described above. NRS 639.230(5); NAC 639.702; NAC 639.945(2), and further asserts that Respondent is subject to discipline by the Board pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955. To facilitate a resolution to this matter, Respondent does not contest these assertions.

9. In consideration of Respondent's cooperation and remedial action taken in this matter, the violations stated in Count Two and Count Three of the Accusation shall be dismissed upon the approval of this Stipulation by the Board.

10. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of One Thousand and 00/100 Dollars ($1000.00) for the violation alleged in Count One of the Accusation.

B. Respondent shall pay the sum of Five Hundred and 00/100 Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

11. Any failure by Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

12. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 11, 2023, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or its attorney fails to appear for the meeting.

13. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

14. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

15. Upon approval of this Stipulation by the Board, Respondent shall pay the fine agreed to herein by *personal, cashiers,* or *certified check* or *money order* made payable to "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days after the effective date of the Board's Order as stated below.

16. Upon approval of this Stipulation by the Board, Respondent shall pay the attorney's fees and costs agreed to herein by *personal, cashiers,* or *certified check* or *money order* made payable to **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of the Board's Order as stated below.

17. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein.

AGREED:

Signed this 22nd **day of** ~~August~~ September **2023.**

GENOA HEALTHCARE, LLC

By Robert A. Stevenson
ROBERT A. STEVENSON
Deputy General Counsel

Signed this 26th **day of September 2023.**

NEVADA STATE BOARD OF PHARMACY

GREGORY L. ZUNINO
Senior General Counsel

APRROVED AS TO FORM AND CONTENT
this 25th **day of September 2023.**

Edward Rickert
Edward Rickert, Esq.
Quarles & Brady LLP

Attorney for Respondent Genoa Health Care, LLC

DECISION AND ORDER

As to Respondent Genoa Healthcare, LLC, in Case No. 20-022-PH-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____ day of October 2023.

_____

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL C. BRINKMANN, D.V.M.,** **Certificate of Registration No. CS02213,** **Respondent.**	**Case No. 22-237-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Michael C. Brinkmann, D.V.M. ("Respondent"), held a Nevada controlled substance registration, Certificate of Registration No. CS02213, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent self-administered hydromorphone injections without a valid prescription.

3. Respondent dispensed controlled substances to Nevada patients without a valid Nevada dispensing practitioner's registration.

4. On or about October 31, 2022, Respondent executed a Form DEA-104, thereby surrendering for cause his Drug Enforcement ("DEA") Registration No. AB8900309.

5. On or about November 9, 2022, Board staff served Respondent with notice that the suspension of his DEA registration operated as an immediate suspension of his Certificate of Registration No. CS02213 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

APPLICABLE LAW

6. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. NRS 453.226(1); 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03.

7. A licensed veterinarian must hold a dispensing practitioner's registration in order to dispense controlled substances of dangerous drugs from any veterinary facility at which he or she engaged in the practice of veterinary medicine. NRS 639.100; NAC 639.7423.

8. The Board may suspend or revoke any certificate, license, registration or permit if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

9. The Board may suspend or revoke any certificate, license, registration or permit if the holder has violated, attempted to violate, assisted or abetted in the violation, or conspired to violate, or failed to report a violation, of any provision of Nevada law relating to prescription drugs. *See* NRS 639.210(12).

10. Diverting drugs which are legally sold in pharmacies constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

11. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

12. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

13. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. The Board shall register an applicant to dispense controlled substances included in schedules I to V, inclusive, unless it determines that the issuance of that registration would be inconsistent with the public interest due to failure of the applicant to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, research, or industrial channels; or the registrant has had his or her federal registration to dispense controlled substances suspended or revoked. NRS 453.231(1)(a).

15. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

16. A veterinarian, in the course of his or her professional practice only, and not for the use by a human being, may prescribe, possess and administer controlled substances, and the veterinarian may cause them to be administered by a veterinary technician under the direction and supervision of the veterinarian. NRS 453.381(2).

17. A veterinarian, in the course of his or her professional practice only, and not for use by a human being, may prescribe, possess, and administer controlled substances, and the veterinarian may cause them to be administered by a veterinary technician under the direction and supervision of the veterinarian. NRS 453.381(2).

18. It is unlawful for a person knowingly to use of be under the influence of a controlled substance except in accordance with a lawfully issued prescription. NRS 453.411(1).

19. The surrender, revocation or a suspension that has not been stayed of any certificate, license, or registration of a practitioner, as defined in NRS 453.126, 454.00958 or 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration, or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe, or dispense drugs. NRS 639.2107.

20. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation alleged in an accusation for which the holder is found guilty. NRS 639.255(3); NAC 639.955.

21. This Accusation constitutes a public record pursuant to NRS 622.330 and any discipline imposed by the Board shall be reported to the National Practitioner Data Bank as required by federal law. Title 42 USC § 1396r–2; 45 CFR Part 60.

COUNT ONE
Surrender of DEA Registration – Ineligible to Hold Controlled Substance Registration

22. By surrendering his DEA Registration, Respondent no longer qualifies to hold a certificate of registration to dispense controlled substances under federal or state law and therefore the Board is authorized to revoke or suspend Dr. Brinkmann, D.V.M.'s certificate of registration to dispense controlled substances, Certificate of Registration No. CS02213 pursuant to NRS 453.231(1)(g) and/or NRS 453.236(1)(c) and NRS 453.241(1).

COUNT TWO
Diversion/Self Administration of Controlled Substances

23. By diverting, acquiring, or obtaining possession of controlled substances for self-administrative without a prescription as alleged herein, Respondent violated, 21 U.S.C. § 843(a)(3), and/or NRS 453.331(1)(d), and/or NRS 453.381(2), and/or NRS 453.391(1), and/or NRS 453.411(1), and therefore is subject to discipline pursuant to NRS 453.231(1)(a) and/or NRS 453.236 and/or NRS 453.241 and/or NRS 639.210(12) and/or NRS 639.255.

COUNT THREE

Unprofessional Conduct - Commission of Acts that Render Registration Inconsistent with the Public Interest

24. By diverting and/or self-administering hydromorphone injections without a valid prescription, Respondent has engaged deceitful practices or transactions and/or in unprofessional conduct and conduct contrary to the public interest, as defined by NAC 639.945(1)(h),(g), and (n), which renders his continued registration to dispense controlled substances inconsistent with the public interest. Respondent's acts violated NRS 639.210(4); therefore, Respondent is subject to discipline pursuant to NRS 453.236(1); NRS 453.241(1); NRS 639.210(4); and NRS 639.255.

COUNT FOUR

Unlicensed Dispensing of Controlled Substances

25. By dispensing controlled substances without a dispensing veterinarian registration, Respondent violated NRS 639.100(1) and NAC 639. 639.7423.; therefore, Respondent is subject to discipline pursuant to NRS 639.210(12) and/or NRS 639.255.

COUNT FIVE

Unprofessional Conduct – Unlicensed Dispensing of Controlled Substances

26. By dispensing controlled substances without a dispensing veterinarian registration, Respondent has engaged in conduct contrary to the public interest as set forth in NAC 639.945(1)(k); therefore, Respondent is subject to discipline pursuant to NRS 453.236(1); NRS 453.241(1); NRS 639.210(4); and NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of this respondent.

DATED this 12th day of September 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL C. BRINKMANN, D.V.M.,** **Certificate of Registration No. CS02213,** **Respondent.**	**Case No. 22-237-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 11, 2023, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 12th day of September 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL C. BRINKMANN, D.V.M.,** **Certificate of Registration No. CS02213,** **Respondent.**	**Case No. 22-237-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

MICHAEL C. BRINKMANN, D.V.M.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of September, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Michael Brinkmann
[redacted]E Sahara Ave.
Las Vegas, NV 89104

Darlene Nases
DARLENE NASES

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MOBILITY PROSTHETIC AND ORTHOTIC SERVICES, LLC,** **License No. MP03113,** **Respondent.**	**Case No. 23-089-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.070 and NRS 639.2895 and NRS 233B.121-.126, *inclusive*, on or about March 29, 2023, a Citation and Fine was served upon Mobility Prosthetic and Orthotic Services, LLC ("Respondent"), alleging the violations of Nevada law as set forth herein.

FACTUAL ALLEGATIONS

1. On or about March 9, 2023, Respondent was issued a Medical Equipment, Device, and Gas ("MDEG") medical products provider license by the Board, License No. MP03113.

2. During its March 9, 2023, license application hearing before the Board, it was revealed that prior to obtaining its Medical Products Provider License, Respondent opened its facility on October 1, 2021, and had engaged in the sale of medical devices.

3. On or about August 30, 2023, the Board staff served Respondent with a Cease-and-Desist/Citation requiring payment of a FIVE THOUSAND DOLLAR FINE ($5,000.00) for unauthorized sale of medical devices.

4. On or about August 30, 2023, Respondent requested an appeal hearing of the Board's Citation-and-Fine.

APPLICABLE LAW

5. Any person who engages in the sale of medical devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this

State shall obtain a medical products provider license from the Board. NRS 639.100(1); NRS 639.233(1); NAC 639.693-6958 *inclusive*.

6. It is unlawful for any person to engage in wholesale distribution, sell or dispense, or permit to be disturbed at wholesale, any drug, device, poison, medicine, chemical, or to dispense, or permit to be dispensed any prescription of a practitioner unless the person holds the appropriate certificate, license, or permit required by Nevada Revised Statutes ("NRS") Chapters 639, 453, or 454 and the person complies with the regulations adopted by the Board under Nevada Administrative Code ("NAC") Chapter 639. NRS 639.100(1).

7. The Board may impose an administrative fine of not more than $5,000.00 against any person who the Board determined violated NRS 639.100(1) or NRS 639.2895(1). Each activity in which the person is engaged constitutes a separate offense for which a separate citation may be issued. NRS 639.2895(1-4).

8. Pursuant to NRS 622.400(1), a regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as part of its investigation, administrative and disciplinary proceedings against the person if the regulatory body enters a final order in which it finds that the person has violated any provision which the regulatory body has authority to enforce, any regulation adopted pursuant thereto or any order of the regulatory body.

COUNT ONE

Unlicensed Activity – Sale of Medical Devices

9. By engaging in the sale of medical devices in Nevada without a medical products provider license, Respondent violated NRS 639.100(1) and/or NRS 639.233(1) pursuant to NAC 639.693-6958 *inclusive*; therefore, Respondent is subject to discipline pursuant to NRS 639.2895(1-4), which authorizes the Board to impose upon Respondent an administrative fine of not more than $5,000.00.

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2); NRS 233B.127(3). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.127(3); NRS 622A.300(1) and (3). If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 a.m. or soon thereafter. The hearing will take place at the Hilton Garden Inn Las Vegas Strip South 7830 S. Las Vegas Blvd., Las Vegas, Nevada 89123.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. You may request and the Board may at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session. NRS 241.030 and NRS 241.033.

DATED this 12th day of September 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of September 2023, I personally served a true and correct copy of the foregoing **Statement to the Respondent and Notice of Hearing** by placing a copy in the United States Mail, postage prepaid, addressed to the following:

Mobility Prosthetic and Orthotic Services, LLC
Attn: Sekhar Mohanty, CP, BOCO, FAAOP, MBA
License No. MP03113
400 Shadow Lane, Suite 110
Las Vegas, Nevada 89106
sekhar@mobilityprosthetic.com

Darlene Nases

DARLENE NASES

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Web Page: bop.nv.gov

August 30, 2023

Via Certified Mail and Email

Mobility Prosthetic and Orthotic Services LLC
License No. MP03113
400 Shadow Lane, Suite 110
Las Vegas, NV 89106

Attn: Sekhar Mohanty, CP, BOCO, FAAOP, MBA
Email: sekhar@mobilityprosthetic.com

CITATION-AND-FINE ORDER: Case No. 23-089-S, Unlicensed Furnishing of Medical Products

Greetings:

The Nevada State Board of Pharmacy (Board) has determined that Mobility Prosthetic and Orthotic Services, LLC or one of its subsidiaries (hereafter "Mobility") was engaged in the business of furnishing prescription medical devices, gases, or equipment in Nevada without having secured a license as required by Nevada Revised Statutes (NRS) 639.233. Pursuant to NRS 639.233, any person, including a wholesaler or manufacturer of prescription medical devices must secure a Nevada license if it a) solicits or accepts orders for drugs or devices whose sale in this State is restricted by law; or b) receives, stores, or ships such products within or into Nevada.

Under Nevada law, the term "drug" is defined to include "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans." *See* NRS 639.007. The terms "manufacturer" and "wholesaler" are defined at NRS 639.009 and NRS 639.016, respectively. The term "medical products provider" is defined at Nevada Administrative Code (NAC) 639.6936. Nevada licensure is required of any person, *including* a medical products provider, who sells or ships drugs or medical devices "that are restricted by federal law to sale by or on the order of a physician to any person located within this State." *See* NRS 639.233(1) and (2); NAC 639.6942.

Mobility is engaged in the business of selling "devices" as that term is defined at 21 U.S.C. § 321(h). The product's purpose is for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Accordingly, at least some of the devices are "prescription devices" within the meaning of 21 CFR § 801.109. Some of the devices are known to be prescription only devices because of

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Mobility's Medical Products Provider Application and from Board Investigator Ken Scheuber's contact with Mobility's staff.

Because at least some of these devices are not safe to use for their intended purpose except under the supervision of a qualified medical practitioner, they must bear a label indicating that they are prescription-only devices. *See* 21 CFR § 801.109(b). The relevant facts are as follows:

- Mobility came before the Board on March 9th, 2023, requesting that the Board approve a new license application for their location at 400 Shadow Lane Suite 110 Las Vegas, NV 89106. During a discussion with Board members, it was revealed that the new location Mobility was requesting was already operating without a license. Mobility's Las Vegas location originally opened on October 1st, 2021.

- Board Investigator Ken Scheuber contacted Mobility Administrator Rebekkah Torres on March 15th, 2023, regarding the unlicensed activity revealed at the Board meeting. Ms. Torres stated that basically everything they sell requires a prescription. Mobility also revealed that they were in the business of selling prescription only medical products through their Medical Products Provider Application where they stated that they will serve patients by prescriptions.

- Under Nevada law, the fact that there is a federal restriction on sale of the drug or device by or on the order of a physician requires any person to obtain a license with the Nevada Board of Pharmacy if they 1) solicit or accept orders for drugs or devices whose sale in this State is restricted; or 2) receive, store, or ship such drugs or devices. *See* 21 U.S.C. § 353(b)(1); 21 C.F.R. § 201.100(b)(1); 21 CFR § 801.109; and NRS 639.233.

- Through Mobility's admissions at the Board meeting, Board Investigator Scheuber's conversation with a Mobility staff member, and Mobility's Medical Products Provider Application, the Board has evidence establishing that Mobility sold prescription-only medical products in the state of Nevada prior to licensure.

Accordingly, this notice shall serve as a **CITATION** pursuant to NRS 639.2895(2) for the unlicensed furnishing of medical products to persons in Nevada. Pursuant to NRS 639.2895(3), the Board has assessed an **administrative fine** against Mobility in the amount of **Five Thousand and 00/100 Dollars ($5,000.00).**

If you do not intend to contest the above fine, please pay the fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an alternative payment plan. Payment must be by *cashier's check*, *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521. Additionally, please be advised that should you fail to comply with the terms of this citation and order, your noncompliance will be reported to the National Practitioner Data Bank and referred to the Nevada Controller's Office for collection pursuant to NRS 353C.195. *See* 45 C.F.R. §§ 60.3 and 60.5.

You may contest this citation by submitting to the Board, at the Reno address listed above, a written request for a public hearing. You must submit any such request not later than 30 days after receipt of this notice. *See* NRS 639.2895(2). Additionally, please be aware that issuance of the foregoing letter does not preclude the filing of an administrative disciplinary complaint, a civil suit, or criminal charges, if deemed appropriate based upon evidence not currently available to the Board's investigative staff.

If you have any questions, please contact Nevada State Board of Pharmacy General Counsel Peter Keegan by telephone at 775-850-1440, ext. 123, or *via* email at p.keegan@pharmacy.nv.gov.

Best regards,

Nevada State Board of Pharmacy

Peter Keegan

From: Sekhar Mohanty <Sekhar@mobilityprosthetic.com>
Sent: Wednesday, August 30, 2023 11:12 AM
To: Peter Keegan
Subject: FW: 23-089-S. Citation and Fine Order - Mobility Prosthetic and Orthotic Services LLC (License No. MP03113)
Attachments: 23-089-S. Citation and Fine Order - Mobility Prosthetic and Orthotic Services LLC.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello Mr.Peter,

Thank you for your call.

As discussed, we would like to appeal this so I can present our position to the board, since we did have an Out of State License for NV Pharmacy Board for the same Business (Mobility Prosthetic and Orthotic Services LLC, Tax Id # 85 1113824) operating out of our Clinic in Kingman, Az).

We were completely unaware of the requirements to apply for a new license when we opened our Las Vegas Clinic under same entity and Tax ID in October 2021.

Please consider this as our request to appeal the citation.

Sincerely

Sekhar Mohanty,CP,BOCO,FAAOP,MBA
Clinical Director
Mobility Prosthetic and Orthotic Services
ABC Accredited Facility
714 624 3804 Mobile
Las Vegas Clinic:
400 Shadow Lane, Suite 110,Las Vegas, NV 89106
Phone 702 800 6520 Fax 702 800 6492
AZ Clinics:(Clinics in Kingman, Lake Havasu City and Bullhead City)
1921 Motor Avenue, Suite B, Kingman, AZ 86401
Phone 928 377 4180 Fax 928 277 4400
sekhar@mobilityprosthetic.com
www.mobilityprosthetic.com

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From: Darlene Nases <dnases@pharmacy.nv.gov>
Sent: Wednesday, August 30, 2023 7:50 AM
To: Sekhar Mohanty <Sekhar@mobilityprosthetic.com>
Cc: Peter Keegan <p.keegan@pharmacy.nv.gov>; Gus Vanderdonck <gvanderdonck@pharmacy.nv.gov>; Shirley Hunting <shunting@pharmacy.nv.gov>; Kristopher Mangosing <kmangosing@pharmacy.nv.gov>
Subject: 23-089-S. Citation and Fine Order - Mobility Prosthetic and Orthotic Services LLC (License No. MP03113)

Hello Sekhar Mohanty,

The **Citation and Fine Order** will be sent out via certified/regular mail today.
Please see attached courtesy copy for Case No. 23-089-S regarding Mobility Prosthetic and Orthotic Services LLC (License No. MP03113).

Regards,

Darlene Nases
Assistant Board Coordinator
Nevada State Board of Pharmacy
(775) 850-1440
dnases@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

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7

7A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada ☐ Out-of-State	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Specialty	☑ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: BioPlus Specialty Pharmacy Services, LLC

Physical Address: 3634 Maryland Parkway

City: Las Vegas State: Nevada Zip: 89169

Mailing Address (if different from physical address): P.O. Box 162088

City: Altamonte Springs State: Florida Zip: 32716

Telephone: 888-292-0744 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 833-670-2942 Contact Email: License@bioplusrx.com

Website: www.bioplusrx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Jim K. Juson

Supervising/Managing Pharmacist NV Pharmacist Registration #: NV License # 15360

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Jim K. Juson	NV Pharmacist Registration #: 15360
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you **marked YES** to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): BioPlus Parent, LLC

Corporation/Organization Name: BioPlus Specialty Pharmacy Services, LLC

Mailing Address: 220 Virginia Ave

City: Indianapolis State: Indiana Zip: 46204

Telephone: 317-488-6000 Email: License@bioplusrx.com

Contact Person Name: Kimberly Bourcier

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for BioPlus Specialty Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Mark Montgomery

Print Name of Authorized Person

Mark Montgomery

Original signature of Authorized Person (copies or stamps not accepted)

6/28/2023

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Jim K. Juson Pharmacist Registration #: 15360

Pharmacy Name: BioPlus Specialty Pharmacy Services, LLC

Initial each statement below to indicate you have read and agree with the following:

SS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

SS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

SS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

SS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

SS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jim Juson
Original signature of Managing Pharmacist (copies or stamps not accepted)

7-7-2023
Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Mark Montgomery hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for BioPlus Specialty Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Mark Montgomery
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 28th day of June, 2023

Marsha Sue Brown
Notary Public

MARSHA SUE BROWN
Notary Public - State of Florida
Commission # HH 304419
My Comm. Expires Dec 18, 2026
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Montgomery

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6/23/2023

Date

Board Use Only	Date Received: 7/17/23	Amount: 500-CK-63109386

BioPlus®
Specialty Pharmacy

Ownership

BioPlus Parent, LLC – 100% Direct Owner
220 Virginia Avenue
Indianapolis, IN 46204

Officer List

Mark Montgomery – President

Paul Edward Marchetti – Manager / Board Member

Danielle Anne Swenson - Manager / Board Member

Kathleen Susan Kiefer – Officer/Secretary

Vincent Edward Scher – Officer/Treasurer

Eric Kenneth Noble – Officer/Assistant Treasurer

Elvin Montanez – COO

Secretary of State
Statement of Information
(Limited Liability Company)

LLC-12

21-G65615

FILED

In the office of the Secretary of State
of the State of California

DEC 23, 2021

IMPORTANT — Read instructions **before completing this form.**

Filing Fee – $20.00

Copy Fees – First page $1.00; each attachment page $0.50;
Certification Fee - $5.00 plus copy fees

This Space For Office Use Only

1. Limited Liability Company Name (Enter the exact name of the LLC. If you registered in California using an alternate name, see instructions.)

BIOPLUS SPECIALTY PHARMACY SERVICES, LLC

2. 12-Digit Secretary of State File Number	3. State, Foreign Country or Place of Organization (only if formed outside of California)
202017010490	FLORIDA

4. Business Addresses

	City (no abbreviations)	State	Zip Code
a. Street Address of Principal Office - Do not list a P.O. Box 376 NORTHLAKE BLVD	ALTAMONTE SPRINGS	FL	32701
b. Mailing Address of LLC, **if different than item 4a** 376 NORTHLAKE BLVD	ALTAMONTE SPRINGS	FL	32701
c. Street Address of **California** Office, if Item 4a is not in California - Do not list a P.O. Box		CA	

5. Manager(s) or Member(s)

If no **managers** have been appointed or elected, provide the name and address of each **member**. At least one name **and** address must be listed. If the manager/member is an individual, complete Items 5a and 5c (leave Item 5b blank). If the manager/member is an entity, complete Items 5b and 5c (leave Item 5a blank). Note: The LLC cannot serve as its own manager or member. If the LLC has additional managers/members, enter the name(s) and addresses on Form LLC-12A (see instructions).

a. First Name, if an individual - Do not complete Item 5b	Middle Name	Last Name	Suffix
STEPHEN	C.	VOGT	
b. Entity Name - Do not complete Item 5a			
c. Address	City (no abbreviations)	State	Zip Code
376 NORTHLAKE BLVD	ALTAMONTE SPRINGS	FL	32701

6. Service of Process (Must provide either Individual **OR** Corporation.)

INDIVIDUAL – Complete Items 6a and 6b only. Must include agent's full name and California street address.

a. California Agent's First Name (if agent is **not** a corporation)	Middle Name	Last Name	Suffix
b. Street Address (if agent is **not** a corporation) - **Do not enter a P.O. Box**	City (no abbreviations)	State	Zip Code
		CA	

CORPORATION – Complete Item 6c only. Only include the name of the registered agent Corporation.

c. California Registered Corporate Agent's Name (if agent is a corporation) – Do not complete Item 6a or 6b

URS AGENTS INC. (C3355755)

7. Type of Business

a. Describe the type of business or services of the Limited Liability Company

SPECIALTY PHARMACEUTICALS

8. Chief Executive Officer, if elected or appointed

a. First Name	Middle Name	Last Name	Suffix
STEPHEN	C.	VOGT	
b. Address	City (no abbreviations)	State	Zip Code
376 NORTHLAKE BLVD	ALTAMONTE SPRINGS	FL	32701

9. The Information contained herein, including any attachments, is true and correct.

12/23/2021	Todd Donnelly	SENIOR VICE PRESIDENT	
Date	Type or Print Name of Person Completing the Form	Title	Signature

Return Address (Optional) (For communication from the Secretary of State related to this document, or if purchasing a copy of the filed document enter the name of a person or company and the mailing address. This information will become public when filed. SEE INSTRUCTIONS BEFORE COMPLETING.)

Name:

Company:

Address:

City/State/Zip:

BioPlus Specialty Pharmacy, LLC -

BIOPLUS SPECIALTY PHARMACY SERVICES, LLC (202017010490)

Request Certificate

Initial Filing Date	06/12/2020
Status	Active
Standing - SOS	Good
Standing - FTB	Good
Standing - Agent	Good
Standing - VCFCF	Good
Formed In	FLORIDA
Entity Type	Limited Liability Company - Out of State
Principal Address	376 NORTHLAKE BLVD ALTAMONTE SPRINGS, FL 32701
Mailing Address	376 NORTHLAKE BLVD ALTAMONTE SPRINGS, FL 32701
Statement of Info Due Date	06/30/2024
Agent	1505 Corporation 1938 URS AGENTS INC. 7801 FOLSOM BLVD, #202 SACRAMENTO, CA 95826

View History

Request Access

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler BioPlus Specialty Pharmacy Services, LLC

Pharmacy/Wholesaler License # (if applicable)

Physical Address 3634 Maryland Parkway

City Las Vegas State Nevada Zip 89169

Mailing Address (if different from physical address) P.O. Box 162088

City Altamonte Springs State Florida Zip 32716

Telephone 888-292-0744 Website www.bioplusrx.com

Licensing Company Email License@bioplusrx.com

Section 2: Personal Information

First Jim Middle K. Last Juson

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Fiddlehead Ave

City Las Vegas State NV Zip 89183

Telephone [redacted] Email jim.juson@carelon.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Colorado School of Pharmacy		9/95 to 5/98	
Address	**City**	**State**	**Zip**
12850 East Montview Blvd Mail Stop C238	Aurora	CO	80045
Diploma/Degree obtained, if any			
Bachelor of Science Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Santa Ana College		1/92 - 6/95	
Address	**City**	**State**	**Zip**
1530 W. 17th Street	Santa Ana	CA	92706
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of California Riverside		9/91- 12/91	
Address	**City**	**State**	**Zip**
900 University Ave.	Riverside	CA	92521
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Canyon High School		9/88 - 6/91	
Address	**City**	**State**	**Zip**
220 S. Imperial Highway	Anaheim	CA	92807
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/02 - present	[redacted] Fiddlehead Ave	Las Vegas	NV	89183
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
BioPlus Specialty Pharmacy Services, LLC			
Business Address	**City**	**State**	**Zip**
3634 Maryland Parkway	Las Vegas	Nevada	89169
Phone	**Title**	**Number of Employed Hours**	
888-292-0744	Pharmacy Center Manager/Pharmacist in Charge		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Elevance Health, Inc			12/20 to Present
Business Address	**City**	**State**	**Zip**
740 Peachtree St NW	Atlanta	GA	30308
Phone	**Title**	**Number of Employed Hours**	
(866) 330-1054	Pharmacist Consultant	4,880	

Description of Duties

Provide MTM services, review patient profiles, identify barriers to adherence, counsel patients

Business Name			From - To (MM/YY – MM/YY)
Optum Specialty Pharmacy			10/18 - 9/20
Business Address	**City**	**State**	**Zip**
8350 Briova Drive	Las Vegas	NV	89113
Phone	**Title**	**Number of Employed Hours**	
(855) 427-4682	Specialty Consultant Pharmacist	3,840	

Description of Duties

Conduct disease state assessments, review patient profiles, process new RX's, verify prescriptions

Business Name			From - To (MM/YY – MM/YY)
Walmart Neighborhood Market Pharmacy			10/05 - 10/18
Business Address	**City**	**State**	**Zip**
6570 E. Lake Mead Blvd	Las Vegas	NV	89156
Phone	**Title**	**Number of Employed Hours**	
(702) 437-2554	Staff Pharmacist	25,480	

Description of Duties

Counseled patients, dispensed and verified prescriptions, kept accurate pharmacy records

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			*From - To (MM/YY – MM/YY)*	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Jim K. Juson, **certify that as the designated representative for**

BioPlus Specialty Pharmacy Services, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JS I am at least 21 years of age;
3. JS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jim K. Juson
Print Name (First, Last)

Jim
Original Signature (electronic, copies or stamps not accepted)

7-7-2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jim K. Juson

Print Name (First, Last)

Jim

Original Signature (electronic, copies or stamps not accepted)

7-7-2023

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Jim Juson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jim

Original Signature

7-7-2023

Date

Subscribed and Sworn to before me this 7 day of July.

Notary Public Signature

E.A. MOORE-BARTON
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 05-97838-1
MY APPT. EXPIRES JULY 12, 2025

(Seal)

7B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-State	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Non-sterile Compounding
	☐ Location Change *	☐ Internet	☐ Sterile Compounding
	☐ Name Change*	☐ Nuclear	☐ Mail-Order Service
		☐ Other:	☐ Off-site Cognitive Services
	* If making a change, provide license #:		☐ Long Term Care
			☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Mesa Ridge Pharmacy

Physical Address: 340 Falcon Ridge Parkway, Bldg 400, Ste 403

City: Mesquite State: NV Zip: 89027

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: TBD Toll Free # (NAC 639.708, NRS 639.23286): TBD

Fax: TBD Contact Email: pharmacy@mesaridge-rx.com

Website: TBD

Nevada Business License # (if applicable) NV20232761373

Supervising/Managing Pharmacist Name (NRS 639.220): Samuel Wilde

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23475

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Ryan Wiest	NV Pharmacist Registration #: 18052
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Samuel Wilde	Credentials: Pharmacist	%: 70
Name: Travis Jackman	Credentials: Pharmacist	%: 30
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Mesa Ridge, LLC

Mailing Address: 2193 W 1420 N

City: St. George State: UT Zip: 84770

Telephone: 4356688867 Email: s.wilde@mesaridge-rx.com

Contact Person Name: Samuel Wilde

Please check type of partnership (NAC 639.214) ☐ General ☒ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner/Manager (title) for Mesa Ridge Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Samuel Wilde

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

06/16/2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Samuel Wilde hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the owner/manager (title) for Mesa Ridge Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

BRITTANY WEISS
Notary Public - State of Utah
Comm. No. 729627
My Commission Expires on
Feb 24, 2027

SUBSCRIBED AND SWORN TO
Before me, a notary public this 23 day of June, 2023

Notary Public

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Samuel Wilde Pharmacist Registration #: 23475

Pharmacy Name: Mesa Ridge Pharmacy

Initial each statement below to indicate you have read and agree with the following:

SW I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

SW I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

SW I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

SW I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

SW I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

06/16/2023
Date

Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** o **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Designated Representative Form** http://bop.nv.gov/Services/newapps/Business/ must be completed by the Designated Representative. NAC 639.5005. The requirement does not apply to: a. An applicant or a licensee that is a publicly traded corporation; b. An applicant or licensee whose pharmacy is determined by the Board to be located within a large retail store, including, without limitation, a grocery store, variety store or department store under common ownership; or c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application** http://bop.nv.gov/Services/newapps/Business/ must be completed by: a. **For Non-publicly traded -** The top 4 shareholder/stockholders. b. **For Partnerships -** All general partners; all limited partners who hold 10% or more of the interest. c. **For Sole Owner** - The owner.		✓	✓	✓
• **Sterile Compounding Questionnaire** must be completed if the pharmacy will provide sterile compounded drugs. Access form at http://bop.nv.gov/Services/newapps/Business/.	✓	✓	✓	✓
• **Submit a copy of your most recent pharmacy inspection** from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(f)	✓	✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your pharmacy** from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(a)	✓	✓	✓	✓
• **License Verification by** the regulatory board or licensing authority of the state or territory in which the pharmacy is located. You may use the License Verification form here: http://bop.nv.gov/Services/newapps/Business/. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2238(2)(g)	✓	✓	✓	✓
• **Copy of DEA Registration if handling controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)**	✓	✓	✓	✓
• **Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)**	✓	✓	✓	✓
• **Transmit Controlled Substance Prescription Data-** Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Samuel Wilde

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

06/16/2023

Date

Board Use Only	Date Received: 6/29/23	Amount: 500-CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Mesa Ridge Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 340 Falcon Ridge Parkway, Bldg 400, Ste 403

City: Mesquite State: NV Zip: 89027

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: pharmacy@mesaridge-rx.com

Section 2: Personal Information

First: Samuel Middle: Michael Last: Wilde

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] W. 1420 N.

City: St. George State: UT Zip: 84770

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Utah College of Pharmacy		06/16 - 05/2020	
Address	**City**	**State**	**Zip**
30 S. 2000 E.	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Doctorate of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Southern Utah University		08/10-05/11; 08/13-05/16	
Address	**City**	**State**	**Zip**
351 W. University Blvd.	Cedar City	UT	84720
Diploma/Degree obtained, if any			
Pre-Pharmacy Coursework			
School Name		**From - To (MM/YY – MM/YY)**	
Snow Canyon High School		08/08 - 05/10	
Address	**City**	**State**	**Zip**
1385 N. 2400 W.	St. George	UT	84770
Diploma/Degree obtained, if any			
HS Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2020 - Present	[redacted]W. 1420 N	St. George	UT	84770
06/2020-10/2020	[redacted]Blackhawk Dr.[redacted]	Santa Clara	UT	84765
07/18 - 06/2020	[redacted]E. Wildwood Dr.	Salt Lake City	UT	84121
05/16 - 07/18	[redacted] S. 1740 E. [redacted]	Salt Lake City	UT	84121
10/14 - 05/16	[redacted]Washington Meadows	Washington	UT	84780
02/14 - 10/14	[redacted]N. 100 W. [redacted]	Cedar City	UT	84720
08/13 - 02/14	[redacted]S. 900 W.	Cedar City	UT	84720
06/13 - 08/13	[redacted] Jacob Dr.	Santa Clara	UT	84765
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Intermountain - St. George Regional Hospital			06/2020 - Present
Business Address	**City**	**State**	**Zip**
1380 E. Medical Center Dr	St. George	UT	84790
Phone	**Title**		
435-251-1000	PGY1 Resident (6/20-6/21), Advanced Clinical Pharmacist - Emergency Medicine		
Description of Duties			
Research, emergency patient care, respond to code/trauma activations, medication recommendations and preparation at bedside, research and project development, order verification, outpatient antibiotic stewardship under CPA			

Business Name			From - To (MM/YY – MM/YY)
Desert Canyon Pharmacy			12/21-Present
Business Address	**City**	**State**	**Zip**
922 E Brigham Rd. #4D	St. George	UT	84790
Phone	**Title**		
435-900-1008	Pharmacist		
Description of Duties			
Prescription filling/dispensing, patient education			

Business Name			From - To (MM/YY – MM/YY)
St. George Endoscopy			01/21-Present
Business Address	**City**	**State**	**Zip**
368 E. Riverside Dr.	St. George	UT	84790
Phone	**Title**		
435-767-0404	Pharmacist		
Description of Duties			
Medication audits, medication record keeping, staff education regarding medication usage			

Business Name			From - To (MM/YY – MM/YY)
Intermountain - Primary Children's Hospital			05/16-06/2020
Business Address	**City**	**State**	**Zip**
100 N. Mario Capecchi Dr.	Salt Lake City	UT	84113
Phone	**Title**		
801-662-1000	Intern Pharmacist		
Description of Duties			
Medication preparation, delivery, medication cabinet stocking, sterile/non-sterile compounding, assist with vancomycin and anticoagulation consults			

Business Name			From - To (MM/YY – MM/YY)
Biolife Plasma Services			10/14-05/16
Business Address	**City**	**State**	**Zip**
816 N. 2860 E.	St. George	UT	84790
Phone	**Title**		
435-627-9102	Plasma Center Technician		
Description of Duties			
IV placement for plasma collection, new patient registration, patient intake (vitals)			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6/16/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Samuel Wilde

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/16/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Washington

I, Samuel Wilde, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/23/23

Date

BRITTANY WEISS
Notary Public - State of Utah
Comm. No. 729627
My Commission Expires on
Feb 24, 2027

Subscribed and Sworn to before me this 23 day of June 2023.

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Mesa Ridge Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 340 Falcon Ridge Pkwy Suite 403

City Mesquite State NV Zip 89027

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Travis Middle C Last Jackman

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Boys Pond Cir

City Santa Clara State UT Zip 84765

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	X	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Idaho State University College of Pharmacy		08/97-05/01	
Address	City	State	Zip
921 S. 8th Ave	Pocatello	ID	83209
Diploma/Degree obtained, if any			
Pharm D			

School Name		From - To (MM/YY – MM/YY)	
Ricks College		8/93-5/94, 8/96-5/97	
Address	City	State	Zip
525 S. Center St.	Rexburg	ID	83460
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Kimberly High School		8/89-5/93	
Address	City	State	Zip
885 Center St.	Kimberly	ID	83341
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/19 - current	[redacted] Boys Pond cir	Santa Clara	UT	84765
7/18 - 10/19	[redacted] E. 1175 S.	Ivins	UT	84738
3/17 - 7/18	[redacted] S. 330 W.	Ivins	UT	84738
7/08 - 3/17	[redacted] Red Mesa Cir	Santa Clara	UT	84765
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Desert Canyon Pharmacy (JWZ, LLC)			From - To (MM/YY – MM/YY): 05/21 - current
Business Address: 922 E. Brigham Rd #40	City: St. George	State: UT	Zip: 84790
Phone: 435-900-1008	Title: Owner / P.I.C.		
Description of Duties: Pharmacy owner and pharmacist in charge of a small retail pharmacy. All duties and responsibilities of an owner and PIC.			

Business Name: Fusion Specialty Pharmacy			From - To (MM/YY – MM/YY): 02/14 - 08/21
Business Address: 1100 N. Canyon View Dr. Suite C	City: Santa Clara	State: UT	Zip: 84765
Phone: 435-703-9680	Title: Owner and PIC		
Description of Duties: Same as stated above. Sold this business to my partner.			

Business Name: Lin's Pharmacy			From - To (MM/YY – MM/YY): 10/04 - 2/14
Business Address: 1120 State St.	City: Hurricane	State: UT	Zip: 84737
Phone: 435-635-4477	Title: PIC		
Description of Duties: Pharmacist in charge with responsibilities to uphold state pharmacy law and organize staff, fill prescriptions, order inventory, etc.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Travis Jackman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/14/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Washington

I, Travis Jackman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/14/2023

Date

Subscribed and Sworn to before me this 14th day of June 2023

Notary Public Signature

KODY E ROGERS
Notary Public
State of Utah
My Commission Expires 10/20/2026
COMMISSION NO. 727414

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Mesa Ridge Pharmacy

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 340 Falcon Ridge Parkway, Bldg 400, Ste 403

City: Mesquite State: NV Zip: 89027

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website:

Licensing Company Email: pharmacy@mesaridge-rx.com

Section 2: Personal Information

First: Samuel Middle: Michael Last: Wilde

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] W. 1420 N.

City: St. George State: UT Zip: 84770

Telephone: [redacted] Email: s.wilde@mesaridge-rx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Utah College of Pharmacy		08/16 - 05/2020	
Address	**City**	**State**	**Zip**
30 S. 2000 E.	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Doctorate of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Southern Utah University		08/10-05/11; 08/13-05/16	
Address	**City**	**State**	**Zip**
351 W. University Blvd.	Cedar City	UT	84720
Diploma/Degree obtained, if any			
Pre-Pharmacy Coursework			
School Name		**From - To (MM/YY – MM/YY)**	
Snow Canyon High School		08/08 - 05/10	
Address	**City**	**State**	**Zip**
1385 N. 2400 W.	St. George	UT	84770
Diploma/Degree obtained, if any			
HS Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/20 - Present	[redacted] W. 1420 N.	St. George	UT	84770
06/20-10/20	[redacted] Blackhawk Dr. [redacted]	Santa Clara	UT	84765
07/18-06/20	[redacted] E. Wildwood Dr.	Salt Lake City	UT	84121
05/16-07/18	[redacted] S. 1740 E. [redacted]	Salt Lake City	UT	84117
10/14-05/16	[redacted] Washington Meadows	Washington	UT	84780
02/14-10/14	[redacted] N. 100 W. [redacted]	Cedar City	UT	84720
08/13-02/14	[redacted] S. 900 W.	Cedar City	UT	84720
06/13-08/13	[redacted] Jacob Dr.	Santa Clara	UT	84765
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Intermountain - St. George Regional Hospital			06/20 - Present
Business Address	**City**	**State**	**Zip**
1380 E. Medical Center Dr.	St. George	UT	84790
Phone	**Title**	**Number of Employed Hours**	
435-251-1000	PGY1 Resident (06/20-06/21), EM Pharmacist	6,240	

Description of Duties
Research, emergency patient care, respond to code/trauma activations, medication recommendations and preparation at bedside, research and project development, order verification, outpatient antibiotic stewardship under CPA

Business Name			From - To (MM/YY – MM/YY)
Desert Canyon Pharmacy			12/21-Present
Business Address	**City**	**State**	**Zip**
922 E. Brigham Rd. #4D	St. George	UT	84790
Phone	**Title**	**Number of Employed Hours**	
435-900-1008	Pharmacist	106	

Description of Duties
Prescription filling/dispensing, patient education, vaccine administration

Business Name			From - To (MM/YY – MM/YY)
St. George Endoscopy			01/21-Present
Business Address	**City**	**State**	**Zip**
368 E. Riverside Dr.	St. George	UT	84790
Phone	**Title**	**Number of Employed Hours**	
435-767-0404	Pharmacist	58	

Description of Duties
Medication audits, medication record keeping, staff education regarding medication usage and storage

Business Name			From - To (MM/YY – MM/YY)
Intermountain - Primary Children's Hospital			05/16-06/20
Business Address	**City**	**State**	**Zip**
100 N. Mario Capecchi Dr.	Salt Lake City	UT	84113
Phone	**Title**	**Number of Employed Hours**	
801-662-1000	Intern Pharmacist	4,576	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

06/18/2023

Date

I, Samuel Wilde, **certify that as the designated representative for**

Mesa Ridge Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SW I am at least 21 years of age;
3. SW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Samuel Wilde

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/18/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Samuel Wilde

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/18/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Washington

I, Samuel Wilde, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/23/23

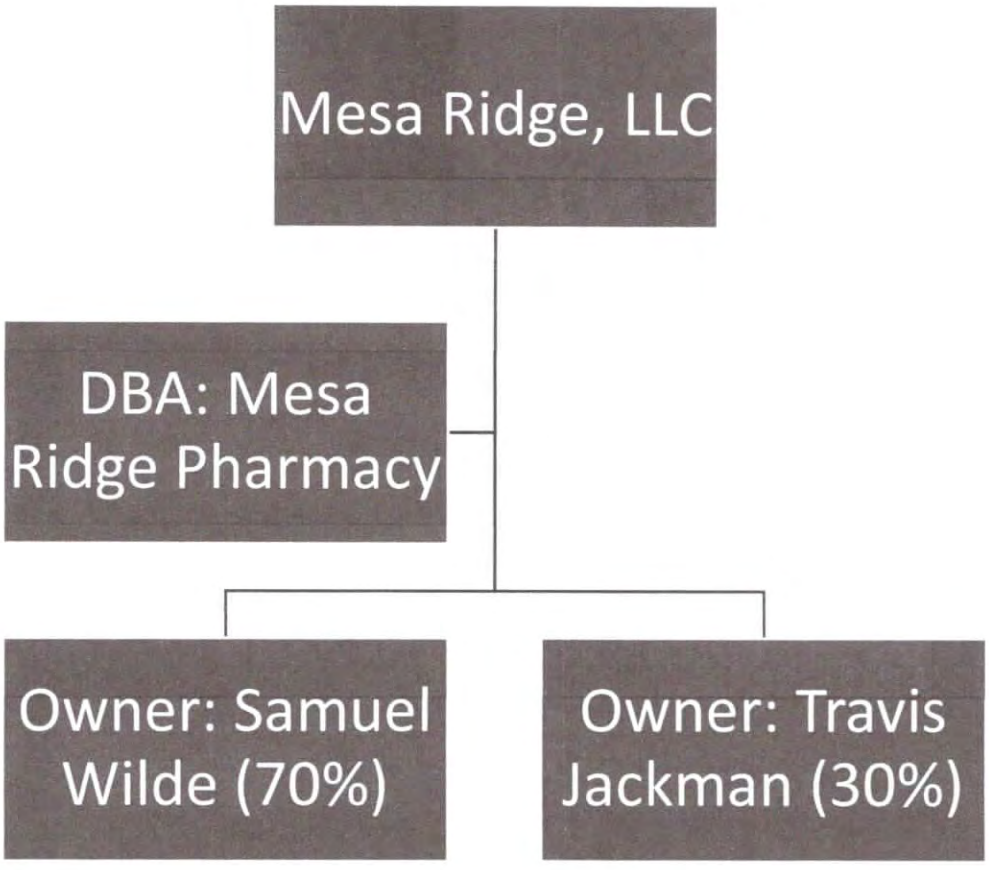
Date

BRITTANY WEISS
Notary Public - State of Utah
Comm. No. 729627
My Commission Expires on
Feb 24, 2027

Subscribed and Sworn to before me this 23 day of June 2023.

Notary Public Signature

(Seal)


Mesa Ridge, LLC
DBA: Mesa Ridge Pharmacy
Owner: Samuel Wilde (70%)
Owner: Travis Jackman (30%)

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Canyon Ridge, LLC** did, on 04/12/2023, file in this office the original Articles of Organization that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 04/12/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202304123568072
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Canyon Ridge, LLC

Nevada Business Identification # NV20232761373
Expiration Date: 04/30/2024

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 04/12/2023.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202304123568073
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Filed in the Office of	Business Number
FVAguilar	E31190262023-4
	Filing Number
	20233266256
Secretary of State	Filed On
State Of Nevada	06/14/2023 13:04:48 PM
	Number of Pages
	3

2570

Limited-Liability Company:

Certificate of Amendment (PURSUANT TO NRS 86.216, 86.221 and 86.543)

Certificate to Accompany Restated Articles or Amended and Restated Articles (PURSUANT TO NRS 86.221)

TYPE OR PRINT - USE DARK INK ONLY - DO NOT HIGHLIGHT

1. Entity Information:

Name of entity as on file with the Nevada Secretary of State :

Canyon Ridge, LLC

Entity or Nevada Business Identification Number (NVID) : **NV20232761373**

2. Restated or Amended and Restated Articles (Select one):

(If restating or amending and restating, complete section 1, 2 and 6.)

☐ **Certificate to Accompany Restated Articles or Amended and Restated Articles**

☐ Articles have been Restated

☐ Articles have been Amended and Restated

* Restated or Amended and Restated Articles must include with this filing type.

3. Type of amendment filing being completed: (Select only one box):

(If amending, complete section 1,3,5 and 6.)

☐ **Certificate of Amendment to Articles of Organization For a Nevada Limited-Liability Company Before Issuance of Member's Interest** (Pursuant to NRS 86.216)

The signers thereof are at least two-thirds of the ☐ organizers or the ☐ managers of the limited-liability company

As of the date of the certificate, no member's interest in the limited-liability company has been issued.

☑ **Certificate of Amendment to Articles of Organization For a Nevada Limited-Liability Company** (Pursuant to NRS 86.221)

The limited-liability company is managed by ☑ Managers or ☐ Members

The certificate of amendment must be signed by a manager of the company or, if management is not vested in a manager, by a member.

☐ **Amendment to Application for Registration of a Foreign Limited-Liability Company** (Pursuant to NRS Chapter 86)

Name of Foreign Limited-Liability Company if different than registered to transact business in Nevada:

If amendment is to change the name, the change taking effect: (select all that apply)

☐ The name under which Limited-Liability Company transacts business in this State

☐ Foreign Limited-Liability Company name from home jurisdiction

This form must be accompanied by appropriate fees.

FRANCISCO V. AGUILAR
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Limited-Liability Company: Certificate of Amendment (PURSUANT TO NRS 86.216, 86.221 and 86.543) Certificate to Accompany Restated Articles or Amended and Restated Articles (PURSUANT TO NRS 86.221)

4. Effective date and time: (Optional)

Date: **06/14/2023** Time:

(must not be later than 90 days after the certificate is filed)

5. Information being changed:

Changes to takes the following effect:

- ☑ The entity name has been amended.
- ☐ The registered agent has been changed. (attach Certificate of Acceptance from new registered agent)
- ☐ The purpose of the entity has been amended.
- ☐ The directors, managers or general partners have been amended.
- ☐ IRS tax language has been added.
- ☐ Articles have been added
- ☐ Articles have been deleted
- ☐ Other.

The articles have been amended as follows: (provide article numbers, if available)

Entity Name: Mesa Ridge, LLC

(attach additional page(s) if necessary)

6. Signature: (Required)

X **Samuel Wilde** — Signature of Manager, Member or Authorized Signer

Manager — Title

Please include any required or optional information in space below:
(attach additional page(s) if necessary)

This form must be accompanied by appropriate fees.

Filed in the Office of	Business Number
FVAguilar	E31190262023-4
	Filing Number
	20233266256
Secretary of State	Filed On
State Of Nevada	06/14/2023 13:04:48 PM
	Number of Pages
	3

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov

Amendment to Articles of Organization

(PURSUANT TO NRS 86.221)

USE BLACK INK ONLY - DO NOT HIGHLIGHT

ABOVE SPACE IS FOR OFFICE USE ONLY

Certificate of Amendment to Articles of Organization For a Nevada Limited-Liability Company (Pursuant to NRS 86.221)

1. Name of limited-liability company:

Canyon Ridge, LLC

2. The company is managed by: ☒ Managers **OR** ☐ Members
(check only one box)

3. The articles have been amended as follows: (provide article numbers, if available)*

1. Name. The Company's name shall be Mesa Ridge, LLC.

4. Effective date and time of filing: (optional) Date: _____ Time: _____
(must not be later than 90 days after the certificate is filed)

5. Signature (must be signed by at least one manager or by a managing member):

X _____
Signature

* 1) If amending company name, it must contain the words **"Limited-Liability Company," "Limited Company,"** or **"Limited,"** or the abbreviations **"Ltd.," "L.L.C.,"** or **"L.C.," "LLC"** or **"LC."** The word **"Company"** may be abbreviated as **"Co."**

2) If adding managers, provide names and addresses.

FILING FEE: $175.00

IMPORTANT: Failure to include any of the above information and submit with the proper fees may cause this filing to be rejected.

This form must be accompanied by appropriate fees.

8

8A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-State	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Non-sterile Compounding
	☐ Location Change *	☐ Internet	■ Sterile Compounding
	☐ Name Change*	☐ Nuclear	■ Mail-Order Service
		☐ Other:	☐ Off-site Cognitive Services
	* If making a change, provide license #:		☐ Long Term Care
			☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Pope Shenouda LLC, DBA 1st Choice Pharmacy

Physical Address: 2228 US HWY 19 N

City: Holiday State: FL Zip: 34691

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 727-934-1300 Toll Free # (NAC 639.708, NRS 639.23286): 844-565-5155

Fax: 727-934-1313 Contact Email: firstchoicepharmacy@yahoo.com

Website: www.1stchoicepharmacy.net

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Joseph Bishay ✓

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23157 ✓

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Joseph Bishay	NV Pharmacist Registration #: 23157
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?	✔	
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): _____

Corporation/Organization Name: Pope Shenouda LLC

Mailing Address: 2228 US Hwy 19 N

City: Holiday State: FL Zip: 34691

Telephone: 727-934-1300 Email: _____

Contact Person Name: George Hanna

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility – MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for Pope Shenouda LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

George Hanna

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

09/21/2022

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

George Hanna

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

09/21/2022

Date

Board Use Only	Date Received: 12-14-22	Amount: 500.00 CK-4552

ec & also

Arkansas State Board of Pharmacy

322 South Main Street, Suite 600 Little Rock, AR 72201
P: 501.682.0190 F: 501.682.0195
asbp@arkansas.gov • www.pharmacyboard.arkansas.gov
John Clay Kirtley, Pharm.D., Executive Director

March 18, 2022

George Hanna
1st Choice Pharmacy
2228 US Hwy. 19
Holiday, FL 34691

VIA CERTIFIED MAIL: 70200640000149160844
VIA STANDARD MAIL

RE: Denial Letter of Application for Out-of- State Pharmacy License

Dear Mr. Hanna:

The Arkansas State Board of Pharmacy has administratively denied your application for an out-of-state pharmacy Permit. The denial is based on your Florida and VPP inspections.

You may appeal this administrative denial of your application to a full board hearing under the Arkansas Administrative Procedures Act, Ark. Code Ann. § 25-15-201, *et seq.*, by notifying this office in writing within thirty (30) days of receipt of this letter.

If you have any questions, please contact the Board office at 501-682-0190.

Sincerely,

Luke Daniel
General Counsel

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
E-mail: bkandt@pharmacy.nv.gov • Web Page: bop.nv.gov

January 18, 2021

VIA U.S. CERTIFIED MAIL

George Hanna
Pope Shenouda LLC
d/b/a 1st Choice Pharmacy
2228 US Hwy 19 North
Holiday, FL 34691

Re: Notice of Denial - Application for Out-of-State Compounding Pharmacy License

Dear Mr. Hanna:

This constitutes notice pursuant to NRS 639.138 that the Nevada State Board of Pharmacy (Board) on January 13, 2021, denied your application pursuant to NRS 639.2328 for an out-of-state compounding pharmacy license. The Board denied your application pursuant to NRS 639.23282 due to your failure to present evidence satisfactory to the Board as to competency, qualifications and credentials. That denial was based on information and testimony presented during the hearing on the application; a copy of the audio recording of the hearing is available to you upon request.

Pursuant to NRS 639.139 you have the right to petition the Board for reconsideration of your application within thirty (30) days of receipt of this notice, and the right to submit evidence to controvert the basis for denial. To petition for reconsideration please submit the petition and all evidence in support thereof to the Board at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521.

If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

Enclosures

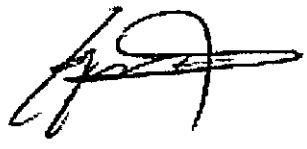
1st Choice Pharmacy

From:
George Hanna, RPh
1st Choice Pharmacy
2228 US Hwy 19 N
Holiday, FL 34691

To Whom It May Concern:

The application for licensure as a non-resident pharmacy with the state of Nevada was denied. Per the Nevada board of pharmacy, approval would be considered given additional training and competencies of the sterile compounding staff. 1st Choice Pharmacy is currently providing additional sterile compounding trainings to the compounding staff and gathering materials to submit to the Nevada Board to prove competency. Compounding staff is also completing several continuing education courses on the subject of sterile compounds. 1st Choice Pharmacy plans to re-apply to Nevada as a non-resident pharmacy in the near future with this new evidence. If you have any questions, please don't hesitate to reach out.

Regards,



George Hanna
PIC/Owner
1st Choice Pharmacy
Ph: 727-934-1300

1st Choice Pharmacy

From:
George Hanna, RPh
1st Choice Pharmacy
2228 US Hwy 19 N
Holiday, FL 34691

To Whom It May Concern:

The application for licensure as a non-resident pharmacy with the state of Arkansas was denied. Per the Arkansas board of pharmacy, approval would be considered pursuant to attendance at a board meeting and explaining certain practices. The practices that were in question are using a lyophilizer, a measurement on a certification report showing that the hazardous room went out of range for the negative pressure, and the compounding of peptides pursuant to legitimate prescriptions. 1st Choice Pharmacy is appealing this decision with Arkansas with these explanations. If you have any questions, please don't hesitate to reach out.

Regards,



George Hanna
PIC/Owner
1st Choice Pharmacy
Ph: 727-934-1300

1st Choice Pharmacy

March 24, 2022

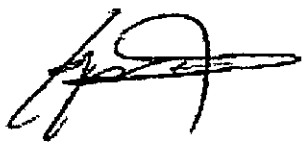
To:
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

RE: Denial Letter of Application for Out-of-State Pharmacy License

Dear Mr. Luke Daniel:

This letter serves to notify the Arkansas Board of Pharmacy that Pope Shenouda LLC dba 1st Choice Pharmacy is requesting to appeal this administrative denial of our application pursuant to the Arkansas Administrative Procedures Act, Ark. Code Ann. §25-15-201, et seq. Please let us know when the next available board hearing will be held so that we may appear in person to appeal this decision.

Regards,



George Hanna
1st Choice Pharmacy
2228 US Hwy 19 N
Holiday, FL 34691

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Pope Shenouda LLC DBA 1st Choice Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 2228 US HWY 19 N

City: Holiday State: FL Zip: 34691

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 727-934-1300 Toll Free # (NAC 639.708, NRS 639.23286): 844-565-5155

Fax: 727-934-1313 Contact Email: firstchoicepharmacy@yahoo.com

Website: www.1stchoicepharmacy.net

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Joseph Bishay

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23157

Name of Person with direct knowledge of compounding procedures: George Hanna and Joseph Bishay

Email of Person with direct knowledge of compounding procedures: george@1stchoicerx.org, joseph@1stchoicerx.org

Telephone of Person with direct knowledge of compounding procedures: 727-934-1300

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☑ Low ☑ Medium ☑ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☑ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
see attached

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
For each sterile compound:
1. Method suitability
2. Initial and end sterility and endocrine
3. Potency over time and pH
4. If oilbase no pH over time

SOP 602.4

6. What laboratory performs this additional testing?

Name: Pharmetric Lab

Address: 11880 28th St North Suite #210

City: St. Petersburg State: FL Zip: 33716

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
Visual inspection of drug production

SOP 616.1

8. How often do you perform glove fingertip and medial fill testing?
In the beginning and every 6 months

9. What is your policy if an employee fails a glove fingertip or media-fill test?
SOP 408.4
SOP 402.7

10. Describe your initial and annual training program for all personnel performing sterile compounding:
1. Training and read the SOPs
2. Hand hygiene and garbing (SOP 404)
3. Orientation, training and competency evaluation of compounding personnel (SOP 410)
4. Personal aseptic media fill testing and product verification and related forms (SOP 402)
5. Conduct of personnel in controlled array and aseptic technique overview (SOP 412)
6. Inventory storage, handling and disposal (SOP 502)
7. Use of automated

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Cleaning in the beginning of the day and the end of the day and beginning of each compound (immediately prior of each compound)
We use:
Sterile wipes
Sterile peribox (contact time 8 minutes)
Other sterile IPA

Friday- use Decon-phene

12. Who performs the sterile compounding process at your facility?
Pharmacists:George Hanna, Joseph Bishay
Pharmacist Intern: Mina Shenouda
Techs: Dayesi Hernandez, Ileana Ortega

13. Who is responsible and accountable for the sterile compounding process at your facility?
Joseph Bishay
George Hanna

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
For cold products we use warn strip or kangaroo bag

SOP 510

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)

1. What type of primary engineering controls will you be using in your facility?
Biological safety cabinet (ESCO) Class II Type A2

2. Is your BSC or CACI vented 100% to the outside?	☑ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☑ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☑ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☑ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☑ No

7. If yes, list the name of the device:

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?
Provide patients with packet (attached)

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
1. Orientation, training and competency evaluation of compounding pharmacy personnel (SOP 410)
2. Hazardous drug/ risk acknowledgment form (SOP 706.9)
3. Competency Assessments
- HP inventory receiving (SOP 700.6)
- Donning and doffing PPE for HD compounding (SOP 706)
- Hazardous drug compounding (SOP 700)
- Decontamination, cleaning and disinfection of HD environment (SOP 700)

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
see attached

2. What sterilization methods are utilized at your facility?
filtration

3. Does your facility utilize biological indicators? ☐ Yes ☐ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mina Shenouda

Name of Person who Completed the Form

Pharmacist Intern

Title

Mina Shenouda

Signature (copies or stamps not accepted)

12/8/22

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

1st Choice Compounding PHARMACY

Safe Handling of Hazardous Medicines in the Home

Some medicines need special handling because they can be hazardous (harmful) to the people giving them. This is because some studies show that people who care for patients taking these special medicines can also have changes within their own body's cells. These changes can be avoided by following certain steps. Exposure can occur from spills, splashes, breathing in the medicine's vapors or powder, and from coming in contact with the patient's vomit, urine or stool.

The medicine that needs safe handling is:

_____

The risk of danger from handling small amounts of these hazardous medicines is small, but it is a good idea to avoid exposure if possible. Here are suggestions for things you can do at home to limit exposure.

Supplies you may need

- Disposable gloves (Picture 1) – Get them from your local pharmacy or 1st Choice Compounding Pharmacy
- Disposable gown – if you are handling liquid medicines
- Household soap or detergent – any brand can be used for cleaning
- Disposable towel – in case of an accidental spill
- Two-ply, heavy duty trash bag – for used supplies
- Disposable plastic medicine cups and oral syringes – depending on what kind of medicine is being taken



Picture 1 Putting on disposable gloves.

- Needle disposal or "sharps" container – needed if you are handling injectable (given by needle or IV) medicines

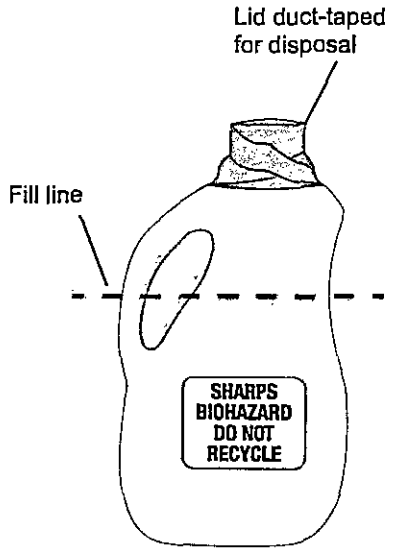
Continued...

Safety measures for handling hazardous medicines

- Wash your hands **before and after** handling hazardous medicines.
- Use disposable gloves if you are touching any type of hazardous medicine. Do not use torn or punctured gloves.
- Use disposable plastic medicine cups to move a pill from a medicine bottle.
- Throw away any used gloves, gowns, medicine cups, oral syringes, or bottles in a two-ply, heavy-duty trash bag. Tie or seal the plastic bag and place it in your household trash bag for disposal. Be sure to keep this trash out of the reach of pets and children.
- If you are pregnant or trying to become pregnant, you should not handle hazardous medicines. If you are the primary caregiver, speak to your nurse, doctor, or pharmacist about safe ways to care for the patient.

Handling hazardous medicines at home – needles and sharps

- Do not recap the used needle. Do not bend or break off the needle.
- Do not remove the needle from the syringe.
- All sharps or needles must be thrown away in a safe 'sharps container.' If you do not have a hospital-issued sharps container, use a container made of **heavy-duty plastic. This can be a laundry detergent bottle or liquid laundry softener bottle (Picture 2).** It must close with a lid that screws on tightly. Needles should not be able to poke through (puncture) the lid. The container must be leak-proof, and able to sit up and not fall over (stable).



Picture 2 Hard plastic laundry detergent bottle and fill line.

- Place the container in the middle of a full, heavy duty trash bag. You are allowed to put the trash bag out for regular trash pick-up. DO NOT put the container in the recycling.

Storing hazardous medicines

- Your pharmacist or nurse will tell you if there are any special storage instructions.
- Keep all drugs out of reach of children or pets.
- Keep hazardous medicines separate from all other medicines.
- If the medicine needs to be refrigerated, separate it from other foods. Use a separate bin in the refrigerator or place the medicine in a container.
- Keep the hazardous medicine in its original bottle or container. Do not place it in a pill box with other non-hazardous medicines.

Taking hazardous medicines

- Your physician, nurse, or pharmacist will explain to you how and when to take your medicine.
- It is important for you to take these drugs exactly as told. Do not skip a dose without discussing it with your physician.
- If you forget to take a dose, do not take double the dose the next time. Contact your physician's office or pharmacist to discuss what to do if this happens.

Accidental hazardous medicine spills

- If you are taking a hazardous medicine and it spills, wear a disposable gown and two pairs of gloves to clean up the spill. Cover the spill with a disposable towel, and then thoroughly wipe up the spill. The area should then be cleaned three times with a home cleaning product. This is to make sure that no medicine is left on the surface. All materials should be thrown away in a heavy-duty sealed trash bag and placed in a trash can that is out of reach of pets and children.
- Hazardous liquid medicines spilled on your skin may cause irritation. Wash the area well with soap and water and dry. If redness or irritation occurs within 7 days, contact your doctor.
- If the drug splashes in the eye, rinse the eye with tap water for at least 15 minutes and contact your doctor.

During clinic visits, be sure to tell the staff about any hazardous drugs you may have taken at home. If you have any other questions or concerns, ask your doctor, pharmacist, or nurse.

1. Testosterone cypionate 200mg/ml in sesame oil 5ml intramuscular
2. Testosterone enanthate 200mg/ml in sesame oil 5ml intramuscular
3. Cyanocobalamin 1200mcg/ml 10ml intramuscular
4. Nandrolone decanoate 200mg/ml 5ml intramuscular
5. Methionine/inositol/choline/cyanocobalamin 25mg/100mg/50mg/1mg /ml 10ml intramuscular
6. Methionine/inositol/choline/L-carnitine/cyanocobalamin 25mg/25mg/50mg/100mg/1mg /ml 10ml intramuscular
7. L-leucine/isoleucine/valine 10mg/10mg/5mg/ml 10ml intramuscular
8. Vitamin D3 50000 iu/ml in sesame oil 5ml intramuscular
9. Testosterone cypionate/testosterone enanthate 160mg/40mg/ml in sesame oil 5ml intramuscular
10. Ascorbic acid 550mg/ml 10ml intramuscular

High Risk Preparations

1. Testosterone cypionate 200mg/ml in sesame oil 5ml intramuscular
2. Testosterone enanthate 200mg/ml in sesame oil 5ml intramuscular
3. Testosterone cypionate/testosterone enanthate 160mg/40mg/ml in sesame oil 5ml intramuscular
4. BPC-157 15mg injection
5. Ipamorelin 15mg injection
6. Ipamorelin/sermorelin 15mg/15mg injection
7. Ipamorelin/CJC-1295 15mg/6mg injection
8. Sermorelin 15mg injection
9. Bremelanotide 20mg injection
10. Bremelanotide 2mg/ml nasal spray
11. AOD-9604 nasal spray 200mcg/0.1ml
12. AOD-9604 RDT 500mcg

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 15765
Insp # 175881

NAME	PERMIT NUMBER	DATE OF INSPECTION
POPE SHENOUDA, LLC	23208	04/28/2022
DOING BUSINESS AS 1ST CHOICE PHARMACY		
STREET ADDRESS 2228 US Hwy 19	**TELEPHONE #** 727-934-1300	**EXT**
CITY HOLIDAY	**COUNTY** PASCO	**STATE/ZIP** FL/34691

Additional Information

Business Operation Hours

M-T-W-TH-F N	Weekly Hours
Monday Y	Monday Hours 9:00 AM TO 6:30 PM
Tuesday Y	Tuesday Hours 9:00 AM TO 6:30 PM
Wednesday Y	Wednesday Hours 9:00 AM TO 6:30 PM
Thursday Y	Thursday Hours 9:00 AM TO 6:30 PM
Friday Y	Friday Hours 9:00 AM TO 6:30 PM
Saturday N	Saturday Hours 10:00 AM to 1:00 PM
Sunday N	Sunday Hours CLOSED

Registered Pharmacist / Intern / Tech

License # PS 40421	Licensee Name George Amin Hanna, PDM
License Type Registered Pharmacists	
License # RPT 68132	Licensee Name Dayesi Hernandez, Compounding technician
License Type Pharmacy Tech	
License # PSI	Licensee Name Mina Shenouda, Compounding intern
License Type Intern	
License # RPT76680	Licensee Name Natashia Medina, Data entry
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FP0721123	

License Relations

Pharmacy Affiliate

HANNA, GEORGE AMIN	License #

RX DPT MGR/COR/POR

HANNA, GEORGE AMIN	License # 40421

Special Sterile Compounding

POPE SHENOUDA LLC	License # 29868

INV 359 - Community Requirements

Signage Requirements Section

INV359 - Community Requirements

Insp # 175881

POPE SHENOUDA, LLC

File # 15765

Signage stating the hours the pharmacy department is open. [64B16-28.1081 (2) F.A.C.] *But a sign dated 6/14/21 stated "The retail department will be at the pharmacy located across the plaza"*	Yes
A sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating, "Prescription Department Closed". [64B16-28.109 F.A.C.]	N/A
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] *No patient consultation sign noted. It was posted during the inspection.*	No

Community Requirements General Section

Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	Yes
Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C] *Not signed by compounding pharmacist GH who verifies compounding in PK on dates these were signed off in PK*	No
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.].	Yes
Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.]	Yes
Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.] *Rx Return Solutions 6/21/21*	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes

Additional Community Requirements

Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.]	Yes
Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	Yes
When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.]	N/A
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.]	Yes
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.]	Yes
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]	Yes
Pharmacy licenses are current. [465.015(1)(a) F.S.]	Yes
Private consultation area available [6416-28.1035 F.A.C.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.] *There is no written offer to counsel patients of other states.*	No
Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(e) F.S.] [21CFR1306.24]; [21CFR1306.14] *Several vials such as Myers Cocktail do not contain the Federal Legend, specifically lot 04252022@5 or Magnesium Chloride/Taurine compound lot 03232022@19. These are dymo labeled drugs due to lack of extended BUD and the amount of ingredients listed. These vials were noted to have black and white labels.*	No
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality-Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(l) F.S.] *2-21-22, 11/26/21, 8/2/21, 5/4/21.*	Yes
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	Yes
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.] *Maintained in PK and Life file and formerly Prime rx.*	Yes
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approvad vendors. [893.065 F.S.]; [456.42(2) F.S.] *Mostly e-prescribed*	Yes
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11] *The pharmacy only has CIII to CV controlled substances documented on biennial inventory from 6-14-22, however has not included CII's sold to MMG Pharma LLC dba Cross Pharmacy at 2208 US Highway 19 N, Holiday. Not documented whether inventory was taken at open or close of business.*	No
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)] *CSOS with Amerisource Bergen*	Yes
Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	Yes
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.] *Pharmacy has sold one time inventory to MMG Pharma 6/14/21.*	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	Yes
Compounding records properly maintained. [64B16-28.140(4), F.A.C.] *See comments on sterile compounding Inspection.*	No
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]	Yes

INV359 - Community Requirements

Insp # 175881 POPE SHENOUDA, LLC File # 15765

Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.] *Wholesalers: Amerisource Bergen, Cardinal, River City, Masters Pharmaceutical, Medisca, PCCA, Spectrum.*	Yes
Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]	N/A
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.]	N/A
Pharmacist has a written collaborative practice agreement. [465.1865, F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent. *See SOP 510 "Packaging and Shipping of Refrigerated Drug Products"* *Reviewed Kangaroo mailer study.* *The SOP does not address shipments of medicinal drugs to other states. The pharmacy is licensed in greater than 37 states*	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy. *Pharmacy does not have a mutual agreement with Trinova, Trinova being the originating pharmacy for prescriptions for compounds.*	No
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions. *Not available during inspection*	No
The originating pharmacy is identified with pharmacy name and address on the prescription container label. *Not on label, but originating pharmacy Trinova Health stated on e-prescription.*	No
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	N/A
If a controlled substance, the word "central fill" appears on the face of the original prescription. *Original prescription sent by Trinova Health does not contain the word "Central fill" see rxC514455,*	No
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery. *This pharmacy is the central fill pharmacy who directly mails it to the patient.*	N/A

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

Remarks:

Pharmacy at this location has Life File and PK software and Prime rx. PDM states this retail establishment has been sold to MMG Pharma LLC dba Cross Pharmacy at 2208 US 19N however retail permit is still maintained at 2228 US Hwy 19, Holiday, FL for non-sterile compounding.
The closed system pharmacy PH30309 was moved to 2049 Welbilt Blvd and is operating under A&Eof Tampa Bay LLC, dba 1st Choice LTC Pharmacy, Suite A.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received e copy of the Licensee Bill of Rights.

Inspector Signature

CULLIPHER, MALA

Date:4/28/2022

Representative:

George Hanna

Date:4/28/2022

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 22731
Insp # 178092

NAME	PERMIT NUMBER	DATE OF INSPECTION
POPE SHENOUDA LLC	29868	04/28/2022
DOING BUSINESS AS		
1ST CHOICE COMPOUNDING PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
2228 2228 U. S. HWY 19 N	(727) 934-1313	
CITY	**COUNTY**	**STATE/ZIP**
HOLIDAY	PASCO	FL/34691

Additional Information

Business Operation Hours

M-T-W-TH-F N	Weekly Hours
Monday Y	Monday Hours 9 AM TO 6:30 PM
Tuesday Y	Tuesday Hours 9 AM TO 6:30 PM
Wednesday Y	Wednesday Hours 9 AM TO 6:30 PM
Thursday Y	Thursday Hours 9 AM TO 6:30 PM
Friday Y	Friday Hours 9 AM TO 6:30 PM
Saturday Y	Saturday Hours 10 AM TO 2 PM
Sunday N	Sunday Hours CLOSED

Registered Pharmacist / Intern / Tech

License # PS40421	Licensee Name George Hanna, PDM
License Type Registered Pharmacists	
License # RPT57866	Licensee Name Natasha Medina, Data Entry
License Type Pharmacy Tech	
License # PSI30754	Licensee Name Mina Shenouda Meawad Shenouda
License Type Intern	
License # RPT68132	Licensee Name Dayesi Hernandez, Sterile HD technician
License Type Pharmacy Tech	
License # RPT93349	Licensee Name Mary Hanna, Sterile Non-HD
License Type Pharmacy Tech	
License # PS54381	Licensee Name Joseph Bishay, Sterile Dispensing Pharmacist
License Type Registered Pharmacists	
License # RPT17049	Licensee Name Sean K Francisco, IT
License Type Pharmacy Tech	
License # PS61576	Licensee Name Sylvia George Abdelmessih Makar Faltous, Initial Verification Life File
License Type Registered Pharmacists	
License # RPT96882	Licensee Name Ereny Fakhry Abdelmalik, Filling technician
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FP0721123	

License Relations

Pharmacy Affiliate

INV797-Sterile Compounding

Insp # 178092 | POPE SHENOUDA LLC | File # 22731

HANNA, GEORGE AMIN	License #

RX DPT MGR/COR/POR

HANNA, GEORGE AMIN	License # 40421

Special Sterile Compounding

POPE SHENOUDA, LLC	License # 23208

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple starile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
5. Medium Risk CSP's, in absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environmenL [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	Yes
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of starile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *Pharmacy compounds Peptides in the ISO 5 HD BSC where the lyophilizer is attached. The pharmacy no longer compounds Trimix or Alprostadil stock solution based on records provided.*	Yes
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *Sterilizing filter MDI Asepticap is not capable of accomodating 5 L volume.*	Yes
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	Yes
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam] *Tuttnauer Autoclave Steam Sterilizer SN 21030347 study demonstrates temp of 121 C duration 30 mins, dry times 60 mins-validated by Pharmetric April 1, 2022.* *Pharmacy autoclaves rubber stoppers, flip caps, mop cover and foam beds (pre use) then discards mop cover. BI's are 3M Attest. Autoclave not used to terminally sterilitze CSP's.*	Yes
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat] *Dry Heat oven does have filtered forced air. Pharmacy does not terminally sterilize solutions in the dry heat oven. Oven is used to sterilize beakers with stirrers, vials.*	N/A
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	N/A
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat] *Pharmetric Dry Heat Oven validated Nov 2, 2021 with Endosafe cartridges to demonstrate a 6.1 log reduction in ET*	Yes
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	Yes

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	Yes
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	Yes
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	Yes

INV797-Sterile Compounding

Insp # 178092 | POPE SHENOUDA LLC | File # 22731

20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test] *Hercules compound has undergone method suitability-23 vials were compounded on 2-18-2022*	Yes
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	Yes

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing] *Done by Pharmetric*	Yes
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	Yes
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	Yes

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of prepering the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	Yes
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs] *Per MTA Feb 15, 2022 report, ACPH documented for negative sterile buffer room was 38*	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	Yes

INV797-Sterile Compounding

Insp # 178092 | POPE SHENOUDA LLC | File # 22731

44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs] *Using BioClean Emerald Sterile Nitrile Cleanroom Gloves rated to handle HD's.*	Yes
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs] *HD's such as Testosterone and Nandrolone compounded in the same BSC where Peptides such as Semaglutide, Sermorelin, Ipamorelin and CJC combinations are compounded. These HD's may pose a risk of contamination to the non-HD peptide where partially stoppered vials are lyophilized over several hours and then removed and crimped in the BSC. The pharmacy is decontaminating the BSC after each batch with Peridox.*	No
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	Yes
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	Yes
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs] *Critical Point*	Yes
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs] *No risk attestation for HD compounding -JB- he is currently under training.*	Yes
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	Yes

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *MTA certification Feb 15, 2022, Aug 9, 2021* *MTA Feb 2, 2021 and Aug 13, 2020 for positive pressure cleanroom,* *SEC's: Ante room ISO 8, IV buffer room ISO 7, PEC's: Air Clean Systems HLF-1432 AC6000HLF-1432 ISO 5* *Pass-through #2 ISO 8 (anteroom to non-HD buffer room), Buffer room pass through (ISO 7) Sink (ISO 8)* *HD cleanroom* *HD SEC's: ISO 7 anteroom, negative pressure IV buffer room certified as ISO 7* *HD PEC: Esco Class II A2 BSC-142292 SN 2019-142292 certified as ISO 5* *HD room has a built in Lyophilizer SP Scientific model ADP-C2-S2EL-EVA-X SN 325488 (certified as ISO 5 in Feb 2022)* *Ante room Pass through certified as ISO 7*	Yes
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Smoke studies performed in the BSC with the lyophilizer attached to the right of the hood under dynamic operational conditions but lacking a demonstration showing completely covered skin as partially stoppered vials inside BSC are transferred to the lyophilizer in the contiguous ISO 5 environment in the HD room.*	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Feb 15, 2022-Hepa Filter #1 and #2 in ante room, Hepa filter #1 for non-HD room with no leaks, HD cleanroom with 1 ante room Hepa filter and 1 IV room* *hepa filter without leaks. PEC Hepa filters also demonstrated no leaks*	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring]	Yes
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *IV Buffer room ACPH documented as 51 from Feb 15, 2022.*	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Peridox applied in pass through of non-HD IV room did not remove stain or residue in the center of the pass-through, some screws still noted to be discolored and rusted on rivets/threshold in between the ante area and buffer room. The rusty nail was fixed during the inspection as well as threshold cleaner. There is a cart with slightly rusted legs visible and somewhat comes off when wiped off. Cleanroom has ledges in this modular unit-ledges are not recommended by USP.*	No

INV797-Sterile Compounding

Insp # 178092 POPE SHENOUDA LLC File # 22731

63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Ceiling tiles sealed and caulked*	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas] *Repeater pump placed outside the hood.*	Yes

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *VAS conducted by MTA Feb 15, 2022, Aug 9, 2021.*	Yes
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] *Feb 15, 2022*	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	Yes
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *Trended by MTA for air and surface samples every 6 months*	Yes
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Pharmacy does monthly surface sampling.*	Yes
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *Policy on surface sampling states 1st choice to conduct ss with every single compound.*	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	N/A
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Daily cleaning log reviewed -demonstrates Hyp-chlor followed by Peridox RTU and SIPA, however documents show hypochlor is used, but none in cleanroom, Decon spore used. Each PEC is listed and Lyophilizer listed. Cleaning documentation -procedure does not match policy.*	No
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Mop covers from Contec and foam are sterilized using the autoclave*	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

INV797-Sterile Compounding

Insp # 178092 | POPE SHENOUDA LLC | File # 22731

85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *For months of Feb, used Peridox and SIPA, however, only documented a disinfecting agent for monthly cleaning using Decon-Ahol and IPA*	No

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Nail cleansers inside sealed brush/sponge kit*	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Non HD cleanroom-Purell Waterless Surgical Scrub, HD cleanroom: Avagard donned prior to donning sterile gloves.*	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	N/A
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	N/A
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *JB completed media fill 4/20/22 (still incubating) representing HD lyo. Inspector noted 179 media fill vials lying on the shelf in the back room incubating all 14 days at 20-25 degrees -pharmacy has these temps documented-these represent the batch for the compounding pharmacist JB who is new to the role.* *DH completed media fill 2-2-22 and 300 vials of 10ml and 8/13/21 simulating HD compounding, MH completed media fill for sterile non -HD 300 vials of 10ml, GH completed media fill simulating aqueous solutions 4/5/2022 (qty 155 vials 10ml representing non-HD Oct 8, 2021, MS completed media fill 4-22-22 and 10/15/21.*	Yes
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Documents of observational assessments for hand hygiene and garbing do not assess process for specific donning of coveralls to completely cover all exposed skin during lyophilization process.* *Documentation of written and didactic assessments available from Critical Point.*	No
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
99. Immediataly after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Temps for MEA plates not properly documented for RPT MH-these indicate they are incubated at 30-33 degrees C on test date of 11-3-21. It is not documented the plates used for GFS have L&T.*	No
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *See comments in #99.*	No

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients] *Labels do not contain Benzyl Benzoate preservative lot 04132022@15 on the label, also noted on Lipo C lot 03112022@16 Benzyl Alcohol not listed as a preservative.* *Several vials such as Myers Cocktail do not contain the Federal Legend, specifically lot 04252022@5 or Magnesium Chloride/Taurine compound lot 03232022@19. These vials were noted to have black and white labels.*	No
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes

INV797-Sterile Compounding

Insp # 178092 POPE SHENOUDA LLC File # 22731

105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	Yes
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING] *Lyophilized peptides do not have any drug information provided to the patient.*	No

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Reviewed SOP 304.7*	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING] *Documented on a QRE form*	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g] *Pharmacy has Titan Medical (name of clinic) on top left of label vials of Hercules injection compound lot 02182022@21 stored at room temperature, vials were observed in the quarantine area-LG21820 Life File records demonstrate not dispensed. Batch record reviewed demonstrates 23 vials compounded.*	No
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)] *Compounding records reviewed for Ipamorelin/Sermorelin PF 15mg/15mg Inj lot 01262022@15 shows hood as LFH1, however the drug was compounded in the BSC where the lyophilizer is attached, Bremlanotide PF 20mg Inj lot 03142022@15, batch record shows it was compounded in LFH1, however this drug was compounded in the BSC where the lyophilizer is attached. Documented theoretical yield is missing for Amino Acid #1 lot 04132022@15 -2250ml was the intended batch yield, actual yield was documented as 74 vials volume of 30ml,*	No
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

LYOPHILIZATION

INV797-Sterile Compounding

Insp # 178092 | POPE SHENOUDA LLC | File # 22731

135. Sterile products prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	Yes
136. A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.] *available for Feb 2022-performed by MTA*	Yes
137.The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.] *Contact time not adhered to based on study from Pharmetric*	No
138. The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.] *Performed by Pharmetric on stainless steel; borosilicate glass (door) of the lyophilizer on Aug 17, 2020 : Cleaning agents documented are Peridox (contact time studied 10 mins), Decon-Phene 10 mins, SIPA 10 mins.*	Yes
139. Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.] *Pharmetric conducted an evaluation on the stainless steel and borosilicate glass of the SP Scientific Lyophilizer SN SN 325488. attached to Esco HD vertical flow Class II A2 BSC on Aug 17, 2020*	Yes
140. Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.] *Procedures for use of Cleaning agents for the lyophilizer and dwell times used are not according the study done by Pharmetric lab on Aug 17, 2020 which documents a dwell time of 10 mins for Peridox and Decon Phene as well as SIPA. Infact only Hypo Chlor listed on cleaning log which has not been studied, Peridox and SIPA (no dwell times specified)* *The pharmacy has a cleaning document "Daily Cleaning Log for Controlled Sterile Compounding Environments & Adjacent Areas" which has documented daily cleaning stating "Lyophilize (if no compound inside)", and reviewed "Maintenance and check the Lyophilizer" which has documented on production days March 2022 as "Weekly Inside the ISO 5" activity of cleaning Gaskets, Trays and shelves, Door and the handle", however this latter document only states "Wipe the lyo with SIPA" for outside the lyp.*	No
141. Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.] *Pharmacy provided Intrutech Vacuum Geuge Celibration Certificate dated 10/6/21, Air Eze Scientific services did preventative maintenance for SP Scientific Freeze Dryer on 4-5-21.*	Yes
142. The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.] *Testing for chamber leaks occurs monthly and is documented.*	Yes
143.SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	Yes
144. The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.] *Documented on the batch record for lyophilized compounds.*	Yes
145. Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.] *Media fills are approximately the representative batch size for compounded peptides.*	Yes
146. Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin.[64B16-27.797(5) F.A.C.]	Yes
147. Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.] *Documented on batch record for all Peptides, specifically noted to be TSA+ and MEA+ but does not specify L&T for compound Ipamorelin/Sermorelin PF 15mg/15mg Inj lot 01262022@15, compounding technician was DH. SOP 613 "Cleaning and maintenance of a SP Scientific Lyophilizer" does not specify the TSA plates for surface sampling.-see line 15. Observed correct TSA with L&T and MEA with L&T plates in refrigerator. Incubation temps are incorrect for MEA plates used-stated to be 30-33 degrees C.*	No
148. In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product.[64B16-27.797(5) F.A.C.] *Inspector identified vials of lyophilized compound which appear to be product ejection, specifically BPC-157 Acetate lot 01102022@16. This may impact product quality attributes. Other CSP's noted to have this visual defect: Semaglutide 5mg inj (not released).* *In process criteria for rejection of different cake quality such as color, moisture, cake appearance not fully established to allow the inspector of the cake to reject or accept the end product.*	No
149. A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.] *See note above in #148- rejection criteria not established for some vials in this lot and has been released to patient.*	No
150. Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.] *On each batch record but not in SOP 613*	Yes
151. Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	Yes
152. Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	Yes
153. Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	Yes
154. Potency, radiochemical purity or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	Yes

CORRECTIVE ACTION PLAN

155. A corrective action plan is required to be submitted within 30 days for the non-compliant items listed above.	No

Remarks:

The relail pharmacy inventory is no longer at this location-medicinal drugs are missing and have been moved to Cross pharmacy. According to the PDM, the medicinal drugs were sold to MMG Pharma. The pharmacy compounds non-sterile and sterile compounds at this location.
Inspectors were informed, the pharmacy is not licensed in Texas or California but ships patient specific CSP to the physician clinic who then mails it to the patient. The pharmacy does document decontamination with cleaning agents after each batch.
Inspection conducted with Mina Shenouda, Pharmacy Intern and George Hanna, PDM and Joseph Bishay, pharmacist.
3 computer systems: PK for compounding, Life file (e-prescribed) and Prime (retail which has been discontinued).

INV797-Sterile Compounding

Insp # 178092

POPE SHENOUDA LLC

File # 22731

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature

CULLIPHER, MALA

Date:4/28/2022

Representative:

George Hanna

Date:4/28/2022

1st Choice Pharmacy

May 15th, 2022

Florida Department of Health
Division of Medical Quality Assurance
The Board of Pharmacy
4052 Bald Cypress Way, Bin #C-04
Tallahassee, FL 32399-3254

RE: State of Florida Department of Health Investigative Services INV797 – Sterile Compounding, File # 22731, Insp # 178902, Date 4/28/2022, Pharmacy Permit 20208

The State of Florida Department of Health Investigative Services, represented by Ms. Mala Cullipher, Completed an inspection on April 28th, 2022. Although no Corrective Action Plan or follow-up was requested by inspector, 1st Choice Compounding Pharmacy submits the following Corrective Actions for deficiencies that were listed on the INV797 – Sterile Compounding:

Item #	Type	Inspection Item	Inspection Notes	Facility Response/Corrective Action/Comments
45	[HAZARDOUS DRUGS AS CSPs]	Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels.	HD's such as Testosterone and Nandrolone compounded in the same BSC where Peptides such as Semaglutide, Sermorelin, Ipamorelin and CJC combinations are compounded. These HD's may pose a risk of contamination to the non-HD peptide where partially stoppered vials are lyophilized over several hours and then removed and crimped in the BSC. The pharmacy is decontaminating the BSC after each batch with Peridox.	The pharmacy, as noted by the inspector, is decontaminating the BSC after each batch using an approved operating procedure and the approved materials including Peridox RTU. Peridox RTU has been demonstrated to be an effective decontaminate when used as directed, thereby eliminating the cross-contamination risk between batches of drugs.
62	[ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]	Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants.	Peridox applied in pass through of non-HD IV room did not remove stain or residue in the center of the pass-through, some screws still noted to be discolored and rusted on rivets/threshold in between the ante area and buffer room. The rusty nail was fixed during the inspection as well as threshold cleaner. There is a cart with	All discolored rivets and screws have been coated with an oxidizer and then coated with silicone. The cart legs have also been coated with oxidizer and sealed using enamel paint. All horizontal surfaces required for structural stability and safety meet all requirements of USP, including being non-porous,

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			slightly rusted legs visible and somewhat comes off when wiped off. Cleanroom has ledges in this modular unit-ledges are not recommended by USP.	smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. As noted by inspector, recommendations are not requirements.
78	[ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel.	Daily cleaning log reviewed - demonstrates Hyp-chlor followed by Peridox RTU and SIPA, however documents show hypochlor is used, but none in cleanroom, Decon spore used. Each PEC is listed and Lyophilizer listed. Cleaning documentation - procedure does not match policy.	Policy & Procedure (SOP 304.8) has been updated to include only Sterile Water for irrigation, Peridox RTU as cleaning agents, and Sterile IPA as the disinfectant.
85	[ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]	Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly.	For months of Feb, used Peridox and SIPA, however, only documented a disinfecting agent for monthly cleaning using Decon-Ahol and IPA	Please see response to #78
95	[ENVIRONMENTAL QUALITY AND CONTROL: Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs .	Documents of observational assessments for hand hygiene and garbing do not assess process for specific donning of coveralls to completely cover all exposed skin during lyophilization process. Documentation of written and didactic assessments available from Critical Point.	Policy & Procedure SOP F-410.a - Gowning and Gloving has been updated to include measures to minimize the potential to create external contamination when garbing using sterile hoods which cover all exposed skin when using sterile goggles.

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99	[ENVIRONMENTAL QUALITY AND CONTROL: Gloved Fingertip Sampling]	Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use.	Temps for MEA plates not properly documented for RPT MH-these indicate they are incubated at 30-33 degrees C on test date of 11-3-21. It is not documented the plates used for GFS have L&T.	SOP F-202.b has been updated to reflect that all plates used for GFS contain lecithin and polysorbate 80
100	[ENVIRONMENTAL QUALITY AND CONTROL: Gloved Fingertip Sampling]	Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on	See comments in #99.	Please see the reply for #99.

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		both gloves and not per hand.		
101	[FINISHED PREPARATION RELEASE CHECKS AND TESTS: Identity and Strength Verification of Ingredients]	Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration.	Labels do not contain Benzyl Benzoate preservative lot 04132022@15 on the label, also noted on Lipo C lot 03112022@16 Benzyl Alcohol not listed as a preservative. Several vials such as Myers Cocktail do not contain the Federal Legend, specifically lot 04252022@5 or Magnesium Chloride/Taurine compound lot 03232022@19. These vials were noted to have black and white labels.	All printed dispensing labels shall be updated to include preservative content, federal legend and shall be printed in color.
108	[PATIENT OR CAREGIVER TRAINING]	Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs.	Lyophilized peptides do not have any drug information provided to the patient	Package inserts have been updated for all peptides.
117	[FAC 64B16-27.700 (3)(g]	Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility.	Pharmacy has Titan Medical (name of clinic) on top left of label vials of Hercules injection compound lot 02182022@21 stored at room temperature; vials were observed in the quarantine area-LG21820 Life File records demonstrate not dispensed. Batch record reviewed demonstrates 23 vials compounded.	All vials quarantined for disposal have been disposed of. No vials dispensed.
118	[FAC 64B16-28.140(4)]	Compounding records are properly maintained.	Compounding records reviewed for Ipamorelin/Sermorelin PF 15mg/15mg Inj lot 01262022@15 shows hood as LFH1, however the drug was compounded in the BSC where	Compounding records have been updated to reflect the correct hood. Batch Amino Acid #1 Lot 04132022@15 batch yield of 74 vials (2220mL) was within the

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			the lyophilizer is attached, Bremlanotide PF 20mg Inj lot 03142022@15, batch record shows it was compounded in LFH1, however this drug was compounded in the BSC where the lyophilizer is attached. Documented theoretical yield is missing for Amino Acid #1 lot 04132022@15 -2250ml was the intended batch yield, actual yield was documented as 74 vials volume of 30ml,	tolerance to allow for fluid retention and/or cohesion in tubing, sterilizing filter and beaker.
137	[64B16-27.797(5) F.A.C.]	The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product.	Contact time not adhered to based on study from Pharmetric	SOP 613.1updated to correct contact time.
140	[64B16-27.797(5) F.A.C.]	Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection.	Procedures for use of Cleaning agents for the lyophilizer and dwell times used are not according the study done by Pharmetric lab on Aug 17, 2020 which documents a dwell time of 10 mins for Peridox and Decon Phene as well as SIPA. Infact only Hypo Chlor listed on cleaning log which has not been studied, Peridox and SIPA (no dwell times specified) The pharmacy has a cleaning document "Daily Cleaning Log for Controlled Sterile Compounding Environments & Adjacent Areas" which has documented daily cleaning stating "Lyophilize (if no compound inside)", and reviewed "Maintenance and check the Lyophilizer" which has documented on production days March 2022 as "Weekly Inside	Please see reply for #137.

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			the ISO 5" activity of cleaning Gaskets, Trays and shelves, Door and the handle", however this latter document only states "Wipe the lyo with SIPA" for outside the lyp.	
147	[64B16-27.797(5) F.A.C.]	Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record.	Documented on batch record for all Peptides, specifically noted to be TSA+ and MEA+ but does not specify L&T for compound Ipamorelin/Sermorelin PF 15mg/15mg Inj lot 01262022@15, compounding technician was DH. SOP 613 "Cleaning and maintenance of a SP Scientific Lyophilizer" does not specify the TSA plates for surface sampling. -see line 15. Observed correct TSA with L&T and MEA with L&T plates in refrigerator. Incubation temps are incorrect for MEA plates used-stated to be 30-33 degrees C.	Please see reply for #99.
148	[64B16-27.797(5) F.A.C.]	In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product.	Inspector identified vials of lyophilized compound which appear to be product ejection, specifically BPC-157 Acetate lot 01102022@16. This may impact product quality attributes. Other CSP's noted to have this visual defect: Semaglutide 5mg inj (not released). In process criteria for rejection of different cake quality such as color, moisture, cake appearance not fully established to allow the inspector of the cake to reject or accept the end product	The lyophilized product labeled by the inspector "which appear to be product ejection" are, in fact, not product ejection but are actually just droplets from the fill process which splash and collect on the inner surface of the vial and sublimate. "Visual defects" in this case do NOT affect the product quality attributes based on potency testing and beyond use date testing. SOP 616.1 has been updated to establish criteria for rejection of different cake qualities.
149	[64B16-27.797(5) F.A.C.]	A 100% visual examination of the finished product is conducted to	See note above in #148-rejection criteria not established for some vials in this lot and has been released to patient.	Please see reply for #148.

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		determine that the product conforms to the established visual criteria and is incorporated into the batch record.		

If there are any questions or to request additional information, please do not hesitate to contact me.

Respectfully,



George Hanna
Owner/Pharmacist in Charge
1st Choice Compounding Pharmacy

2228 US HWY 19 HOLIDAY, FLORIDA 34691
PHONE: (727) 934-1300 FAX: (727)-934-1313

1st CHOICE PHARMACY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Pope Shenouda LLC dba 1st Choice Pharmacy

Physical Address 2228 US Hwy 19 N

City Holiday State FL Zip 34691

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 727-934-1300 Website 1stchoicepharmacy.net

Licensing Company Email firstchoicepharmacy@yahoo.com

Section 2: Personal Information

First Joseph Middle Kyrillos Last Bishay

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] Brighton Lake Rd

City Land O Lakes State FL Zip 34638

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Applicant's initials JB

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Florida A & M University		08/08-05/14	
Address	**City**	**State**	**Zip**
1601 S Martin Luther King Jr Blvd	Tallahassee	FL	32307
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Gaither High School		08/04-05/08	
Address	**City**	**State**	**Zip**
16200 N Dale Mabry Hwy	Tampa	FL	33618
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/20- Current	[redacted] Brighton Lake Rd	Land O Lakes	FL	34638
11/18-09/20	[redacted] Hallandale Loop Apt [redacted]	Land O Lakes	FL	34638
09/16-11/18	[redacted] Trevally Loop Apt [redacted]	Trinity	FL	34655
04/15-04/16	[redacted] Oyster Bayou Way	Clearwater	FL	33759
09/13-04/15	[redacted] Basuto Drive	Trinity	FL	34655
01/11-05/13	[redacted] Midyette rd	Tallahassee	FL	32301
08/08-01/11	[redacted] Castelview Ct Apt [redacted]	Tallahassee	FL	32301
07/90-08/08	[redacted] Dawnview Drive	Tampa	FL	33624
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
1st Choice Pharmacy			01/22-Current	
Business Address		**City**	**State**	**Zip**
2228 US HWY 19 N		Holiday	FL	34691
Phone	**Title**		**Number of Employed Hours**	
727-304-6079	Pharmacist in Charge		Approx 2,500 to date	
Description of Duties				
PIC, Oversee all day to day operations inside the pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Fusion Pharmuceuticals			10/19-12/21	
Business Address		**City**	**State**	**Zip**
28821 US HWY 19 N		Clearwater	FL	33761
Phone	**Title**		**Number of Employed Hours**	
201-240-8487	Pharmacist in Charge		4,500	
Description of Duties				
PIC, Oversaw all day to day operations in the pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
MP Pharmacy			11/18-10/19	
Business Address		**City**	**State**	**Zip**
28813 US Hwy 19 N		Clearwater	FL	33761
Phone	**Title**		**Number of Employed Hours**	
201-240-8487	Staff Pharmacist		2,000	
Description of Duties				
Managing Techs/Interns, Final verification				

Business Name			From - To (MM/YY – MM/YY)	
Tampa Family Health Centers			12/18-Current	
Business Address		**City**	**State**	**Zip**
302 W Fletcher Ave #2		Tampa	FL	33612
Phone	**Title**		**Number of Employed Hours**	
813-397-5300	PRN Pharmacist		500	
Description of Duties				
PRN Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
Benzer Pharmacy/Tampa Specialty Pharmacy			02/18-11/18	
Business Address		**City**	**State**	**Zip**
5908 Brekenridge Parkway		Tampa	FL	33610
Phone	**Title**		**Number of Employed Hours**	
813-644-7277	PRN/Staff/PIC		1,500	
Description of Duties				
Final Verification, managing techs and interns				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials JB

I, Joseph Bishay, **certify that as the designated representative for**

Pope Shenouda LLC dba 1st Choice Pharmacy,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Joseph Bishay

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials JB

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. *I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a* public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Bishay

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/07/2022

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, Jamie Kristofik, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12-7-2022

Date

Subscribed and Sworn to before me this 7th day of Dec.

Notary Public Signature

JAMIE KRISTOFIK
Notary Public
State of Florida
Comm# HH305030
Expires 8/24/2026

(Seal)

Applicant's initials JB

BISHAY, JOSEPH // TRANSCRIPT

Print

Course	Credits	Course Status	Date Completed	Lesson	Status	Score
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#15840020)	1	Completed	Jan 1, 2022 9:06 PM	The History of Compounding and USP Sterile Compounding Chapters Lesson	Completed	-
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#15840020)	1	Completed	Jan 1, 2022 9:06 PM	The History of Compounding and USP Sterile Compounding Chapters Post Test	Completed, Passed	90%
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#15840021)	2	Completed	Jan 1, 2022 10:47 PM	Primary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#15840021)	2	Completed	Jan 1, 2022 10:47 PM	Primary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	80%

(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#15840031)	2	Completed	Jan 1, 2022 11:11 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#15840031)	2	Completed	Jan 1, 2022 11:11 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	90%
(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#15840019)	1	Completed	Jan 1, 2022 11:26 PM	Personnel Competency Testing in Aseptic Manipulation Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#15840019)	1	Completed	Jan 1, 2022 11:26 PM	Personnel Competency Testing in Aseptic Manipulation Post Test	Completed, Passed	90%

(3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#15840017)	2	*Completed*	Jan 2, 2022 12:29 AM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson	*Completed*	-
(3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#15840017)	2	Completed	Jan 2, 2022 12:29 AM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test	Completed, Passed	83.32%
(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#15840028)	1	Completed	May 11, 2022 9:54 AM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson	Completed	-
(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#15840028)	1	Completed	May 11, 2022 9:54 AM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test	Completed, Passed	80%

(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#15840018)	1	Completed	Jan 2, 2022 12:39 AM	Overview of Environmental Monitoring Lesson	Completed	-
(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#15840018)	1	Completed	Jan 2, 2022 12:39 AM	Overview of Environmental Monitoring Post Test	Completed, Passed	80%
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#15840022)	0.5	Completed	Jan 2, 2022 12:50 AM	Viable Air and Surface Sampling Lesson	Completed, Passed	-
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#15840022)	0.5	Completed	Jan 2, 2022 12:50 AM	Viable Air and Surface Sampling Post Test	Completed, Passed	80%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#15840026)	1	Completed	May 3, 2022 9:06 PM	Cleaning and Disinfection of Primary Engineering Controls Lesson	Completed	-

(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#15840026)	1	Completed	May 3, 2022 9:06 PM	Cleaning and Disinfection of Primary Engineering Controls Post Test	Completed, Passed	90%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#15840025)	1	Completed	May 3, 2022 9:31 PM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#15840025)	1	Completed	May 3, 2022 9:31 PM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test	Completed, Passed	80%
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#15840014)	1	Completed	May 3, 2022 9:47 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson	Completed	-

(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#15840014)	1	Completed	May 3, 2022 9:47 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test	Completed, Passed	100%
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#15840016)	1	Completed	May 3, 2022 10:00 PM	Aseptic Technique and Conduct in Controlled Environments Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#15840016)	1	Completed	May 3, 2022 10:00 PM	Aseptic Technique and Conduct in Controlled Environments Post Test	Passed	80%
(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#15840024)	1	Completed	May 3, 2022 10:25 PM	Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson	Completed	-

(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#15840024)	1	Completed	May 3, 2022 10:25 PM	Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test	Passed	90%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#15840027)	1	Completed	May 3, 2022 10:42 PM	Hazardous Drug Introduction and Overview Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#15840027)	1	Completed	May 3, 2022 10:42 PM	Hazardous Drug Introduction and Overview Post Test	Completed, Passed	86.66%
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#15840015)	1	Completed	May 3, 2022 11:02 PM	Hazardous Drug Primary and Secondary Engineering Controls Lesson	Completed	-

(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#15840015)	1	Completed	May 3, 2022 11:02 PM	Hazardous Drug Primary and Secondary Engineering Controls Post Test	Completed, Passed	80%
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#15840023)	1	Completed	May 4, 2022 7:27 AM	Hazardous Drug Use of Personal Protective Equipment Lesson	Completed	-
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#15840023)	1	Completed	May 4, 2022 7:27 AM	Hazardous Drug Use of Personal Protective Equipment Post Test	Completed, Passed	90%

1st Choice Pharmacy is a Limited Liability Company (LLC) owned by Pope Shenouda, LLC.

This LLC has one sole 100% owner named George Hanna. His information is as follows:

George Hanna
2835 Moonbeam Way
Clearwater, FL 33759
DOB: 04/10/1981

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Pope Shenouda LLC DBA 1st Choice Pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 2228 US HWY 19 N

City: Holiday State: FL Zip: 34691

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 727-934-1300 Website: www.1stchoicepharmacy.net

Licensing Company Email: firstchoicepharmacy@yahoo.com

Section 2: Personal Information

First: George Middle: Last: Hanna

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Moonbeam Way

City: Clearwater State: FL Zip: 33759

Telephone: [redacted] Email: firstchoicepharmacy@yahoo.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Florida A & M University		2001 - 4/2005	
Address	City	State	Zip
Diploma/Degree obtained, if any			
Pharm D			

School Name		From - To (MM/YY – MM/YY)	
St Pete College		8/97 - 5/2001	
Address	City	State	Zip
Diploma/Degree obtained, if any			
AA			

School Name		From - To (MM/YY – MM/YY)	
Pinellas High School		11/95 - 5/97	
Address	City	State	Zip
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted] Moonbeam Way	Clearwater	FL	33759
From - To (MM/YY – MM/YY)	[redacted] Country Trails Dr	Safety Harbor	FL	34695
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Pope Shenouda LLC DBA 1st Choice Pharmacy				
Business Address		**City**	**State**	**Zip**
2228 US HWY 19 N		Holiday	FL	34691
Phone	**Title**			
727-934-1300	Owner/Pharmacist			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
A and E of Tampa Bay LLC DBA 1st Choice LTC Pharmacy				
Business Address		**City**	**State**	**Zip**
2049 Welbilt Blvd		Trinity	FL	34655
Phone	**Title**			
727-940-3521	Owner			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	X	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?	X	X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.	X	
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

George Hanna

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/22/2022

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, Jamie Kristofik, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/22/2022

Date

Subscribed and Sworn to before me this 22 day of Dec

Notary Public Signature

JAMIE KRISTOFIK
Notary Public
State of Florida
Comm# HH305030
Expires 8/24/2026

(Seal)

Print

Course	Credits	Course Status	Date Completed	Lesson	Status	Score
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#10142397)	1	Completed	Aug 7, 2020 12:33 PM	The History of Compounding and USP Sterile Compounding Chapters Lesson	Completed	-
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#10142397)	1	Completed	Aug 7, 2020 12:33 PM	The History of Compounding and USP Sterile Compounding Chapters Post Test	Completed, Passed	80%
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#13398761)	1	Completed	Feb 24, 2022 2:29 PM	The History of Compounding and USP Sterile Compounding Chapters Lesson	Completed	-
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#13398761)	1	Completed	Feb 24, 2022 2:29 PM	The History of Compounding and USP Sterile Compounding Chapters Post Test	Completed, Passed	90%
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#7903114)	1	Completed	Aug 8, 2019 12:11 PM	The History of Compounding and USP Sterile Compounding Chapters Lesson	Completed	-

(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#7903114)	1	Completed	Aug 8, 2019 12:11 PM	The History of Compounding and USP Sterile Compounding Chapters Post Test	Passed	80%
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#10142398)	2	Completed	Aug 7, 2020 4:42 PM	Primary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#10142398)	2	Completed	Aug 7, 2020 4:42 PM	Primary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	93.33%
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#13398762)	2	Completed	Feb 24, 2022 3:16 PM	Primary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#13398762)	2	Completed	Feb 24, 2022 3:16 PM	Primary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	93.33%

(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#7903115)	2	Completed	Aug 8, 2019 2:10 PM	Primary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#7903115)	2	Completed	Aug 8, 2019 2:10 PM	Primary Engineering Controls: Function, Use, Testing and Certification Post Test	Passed	80%
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#10142399)	2	Completed	Aug 16, 2020 3:20 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#10142399)	2	Completed	Aug 16, 2020 3:20 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	90%

(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#13398763)	2	Completed	Feb 25, 2022 12:48 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#13398763)	2	Completed	Feb 25, 2022 12:48 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	80%
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#7903116)	2	Completed	May 15, 2020 12:55 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#7903116)	2	Completed	May 15, 2020 12:55 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Post Test	Passed	80%
(3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#10142400)	2	Completed	Aug 16, 2020 10:34 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson	Completed	-

(3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#10142400)	2	Completed	Aug 16, 2020 10:34 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test	Completed, Passed	83.32%
(3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#7903117)	2	Completed	May 15, 2020 2:55 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson	Completed	-
(3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#7903117)	2	Completed	May 15, 2020 2:55 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test	Completed, Passed	83.32%
(3) Personnel Sampling Metrics - Personnel Aseptic Media Fill and Competency Evaluation (#7903118)	1	Completed	May 15, 2020 3:15 PM	Personnel Aseptic Media Fill and Competency Evaluation Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Aseptic Media Fill and Competency Evaluation (#7903118)	1	Completed	May 15, 2020 3:15 PM	Personnel Aseptic Media Fill and Competency Evaluation Post Test	Completed, Passed	80%
(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#10142401)	1	Completed	Aug 16, 2020 10:54 PM	Personnel Competency Testing in Aseptic Manipulation Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#10142401)	1	Completed	Aug 16, 2020 10:54 PM	Personnel Competency Testing in Aseptic Manipulation Post Test	Completed, Passed	100%

(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#13398765)	1	Completed	Feb 25, 2022 1:02 PM	Personnel Competency Testing in Aseptic Manipulation Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#13398765)	1	Completed	Feb 25, 2022 1:02 PM	Personnel Competency Testing in Aseptic Manipulation Post Test	Completed, Passed	80%
(3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#13398764)	2	Completed	Feb 28, 2022 1:39 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#13398764)	2	Completed	Feb 28, 2022 1:39 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test	Completed, Passed	100%
(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362473)	1	Completed	Nov 20, 2020 11:40 AM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson	Completed, Passed	-
(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362473)	1	Completed	Nov 20, 2020 11:40 AM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test	Completed, Passed	100%

(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362497)	1	Completed	Mar 10, 2022 11:52 AM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson	Completed	-
(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362497)	1	Completed	Mar 10, 2022 11:52 AM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test	Completed, Passed	90%
(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#10142406)	1	Completed	Aug 17, 2020 8:42 PM	Overview of Environmental Monitoring Lesson	Completed, Passed	-
(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#10142406)	1	Completed	Aug 17, 2020 8:42 PM	Overview of Environmental Monitoring Post Test	Completed, Passed	80%
(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#13398770)	1	Completed	Feb 28, 2022 2:23 PM	Overview of Environmental Monitoring Lesson	Completed	-
(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#13398770)	1	Completed	Feb 28, 2022 2:23 PM	Overview of Environmental Monitoring Post Test	Completed, Passed	80%
(4) Viable Facility Sampling Metrics - Surface Sampling (#7903123)	1	Completed	May 15, 2020 4:21 PM	Surface Sampling Lesson	Completed	-

(4) Viable Facility Sampling Metrics - Surface Sampling (#7903123)	1	Completed	May 15, 2020 4:21 PM	Surface Sampling Post Test	Completed, Passed	80%
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#10142402)	0.5	Completed	Aug 17, 2020 9:05 PM	Viable Air and Surface Sampling Lesson	Completed, Passed	-
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#10142402)	0.5	Completed	Aug 17, 2020 9:05 PM	Viable Air and Surface Sampling Post Test	Completed, Passed	80%
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#13398766)	0.5	Completed	Feb 28, 2022 2:45 PM	Viable Air and Surface Sampling Lesson	Completed, Passed	-
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#13398766)	0.5	Completed	Feb 28, 2022 2:45 PM	Viable Air and Surface Sampling Post Test	Completed, Passed	90%
(4) Viable Facility Sampling Metrics - Volumetric Air Sampling (#7903119)	1	Completed	May 28, 2020 9:26 PM	Volumetric Air Sampling Lesson	Completed	-
(4) Viable Facility Sampling Metrics - Volumetric Air Sampling (#7903119)	1	Completed	May 28, 2020 9:26 PM	Volumetric Air Sampling Post Test	Completed, Passed	90%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#10142408)	1	Completed	Aug 17, 2020 9:25 PM	Cleaning and Disinfection of Primary Engineering Controls Lesson	Completed	-

(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#10142408)	1	Completed	Aug 17, 2020 9:25 PM	Cleaning and Disinfection of Primary Engineering Controls Post Test	Completed, Passed	80%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#13398772)	1	Completed	Mar 1, 2022 1:20 PM	Cleaning and Disinfection of Primary Engineering Controls Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#13398772)	1	Completed	Mar 1, 2022 1:20 PM	Cleaning and Disinfection of Primary Engineering Controls Post Test	Completed, Passed	100%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#7903125)	1	Completed	May 28, 2020 9:58 PM	Cleaning and Disinfection of Primary Engineering Controls Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#7903125)	1	Completed	May 28, 2020 9:58 PM	Cleaning and Disinfection of Primary Engineering Controls Post Test	Completed, Passed	80%

(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#10142409)	1	Completed	Aug 17, 2020 9:46 PM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#10142409)	1	Completed	Aug 17, 2020 9:46 PM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test	Completed, Passed	80%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#13398773)	1	Completed	Mar 1, 2022 1:37 PM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson	Completed	-

(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#13398773)	1	Completed	Mar 1, 2022 1:37 PM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test	Completed, Passed	100%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas (#7903126)	1	Completed	May 29, 2020 9:44 AM	Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas (#7903126)	1	Completed	May 29, 2020 9:44 AM	Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas Post Test	Completed, Passed	80%
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#10142407)	1	Completed	Aug 17, 2020 11:14 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson	Completed	-

(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#10142407)	1	Completed	Aug 17, 2020 11:14 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test	Completed, Passed	90%
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#13398771)	1	Completed	Mar 1, 2022 1:53 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#13398771)	1	Completed	Mar 1, 2022 1:53 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test	Completed, Passed	100%
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#7903124)	1	Completed	May 29, 2020 10:54 AM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson	Completed	-

(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#7903124)	1	Completed	May 29, 2020 10:54 AM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test	Completed, Passed	80%
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#10142410)	1	Completed	Aug 18, 2020 12:00 AM	Aseptic Technique and Conduct in Controlled Environments Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#10142410)	1	Completed	Aug 18, 2020 12:00 AM	Aseptic Technique and Conduct in Controlled Environments Post Test	Passed	100%
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#13398774)	1	Completed	Mar 1, 2022 2:22 PM	Aseptic Technique and Conduct in Controlled Environments Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#13398774)	1	Completed	Mar 1, 2022 2:22 PM	Aseptic Technique and Conduct in Controlled Environments Post Test	Passed	80%

(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#7903127)	1	Completed	May 29, 2020 11:11 AM	Aseptic Technique and Conduct in Controlled Environments Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#7903127)	1	Completed	May 29, 2020 11:11 AM	Aseptic Technique and Conduct in Controlled Environments Post Test	Passed	100%
(6) Aseptic Technique and Related Work Practices - Sterile Compounding on Patient Units (#7903128)	1	Completed	May 29, 2020 2:00 PM	Sterile Compounding on Patient Units Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Sterile Compounding on Patient Units (#7903128)	1	Completed	May 29, 2020 2:00 PM	Sterile Compounding on Patient Units Post Test	Passed	80%
(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#10142411)	1	Completed	Aug 18, 2020 12:18 AM	Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#10142411)	1	Completed	Aug 18, 2020 12:18 AM	Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test	Passed	100%

(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#13398775)	1	Completed	Mar 3, 2022 2:56 PM	Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#13398775)	1	Completed	Mar 3, 2022 2:56 PM	Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test	Passed	90%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#10142403)	1	Completed	Aug 17, 2020 10:14 PM	Hazardous Drug Introduction and Overview Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#10142403)	1	Completed	Aug 17, 2020 10:14 PM	Hazardous Drug Introduction and Overview Post Test	Completed, Passed	100%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#13398767)	1	Completed	Mar 3, 2022 3:40 PM	Hazardous Drug Introduction and Overview Lesson	Completed	-

(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#13398767)	1	Completed	Mar 3, 2022 3:40 PM	Hazardous Drug Introduction and Overview Post Test	Completed, Passed	93.33%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#7903120)	1	Completed	Jun 1, 2020 3:37 PM	Hazardous Drug Introduction and Overview Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#7903120)	1	Completed	Jun 1, 2020 3:37 PM	Hazardous Drug Introduction and Overview Post Test	Passed	90%
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#10142405)	1	Completed	Aug 17, 2020 10:59 PM	Hazardous Drug Primary and Secondary Engineering Controls Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#10142405)	1	Completed	Aug 17, 2020 10:59 PM	Hazardous Drug Primary and Secondary Engineering Controls Post Test	Completed, Passed	80%

(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#13398769)	1	Completed	Mar 3, 2022 4:14 PM	Hazardous Drug Primary and Secondary Engineering Controls Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#13398769)	1	Completed	Mar 3, 2022 4:14 PM	Hazardous Drug Primary and Secondary Engineering Controls Post Test	Completed, Passed	90%
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Work Practice Strategies (#7903122)	2	Completed	Jun 3, 2020 1:25 PM	Hazardous Drug Work Practice Strategies Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Work Practice Strategies (#7903122)	2	Completed	Jun 3, 2020 1:25 PM	Hazardous Drug Work Practice Strategies Post Test	Passed	80%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362475)	1	Completed	Nov 20, 2020 12:13 PM	Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Lesson	Completed	-

(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362475)	1	Completed	Nov 20, 2020 12:13 PM	Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Post Test	Completed, Passed	91.66%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362499)	1	Completed	Mar 10, 2022 12:40 PM	Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362499)	1	Completed	Mar 10, 2022 12:40 PM	Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Post Test	Completed, Passed	91.66%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362474)	1	Completed	Nov 20, 2020 1:10 PM	Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Lesson	Completed	-

(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362474)	1	Completed	Nov 20, 2020 1:10 PM	Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Post Test	Completed, Passed	80%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362498)	1	Completed	Mar 10, 2022 1:08 PM	Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362498)	1	Completed	Mar 10, 2022 1:08 PM	Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Post Test	Completed, Passed	100%
(8) Requirements and Best Practices Hazardous Drug Compounding – Engineering Controls and Personal Protective Equipment (#7903121)	2	Completed	Jun 3, 2020 2:46 PM	Engineering Controls and Personal Protective Equipment Lesson	Completed	-

(8) Requirements and Best Practices Hazardous Drug Compounding – Engineering Controls and Personal Protective Equipment (#7903121)	2	Completed	Jun 3, 2020 2:46 PM	Engineering Controls and Personal Protective Equipment Post Test	Passed	90%
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#10142404)	1	Completed	Aug 17, 2020 10:36 PM	Hazardous Drug Use of Personal Protective Equipment Lesson	Completed	-
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#10142404)	1	Completed	Aug 17, 2020 10:36 PM.	Hazardous Drug Use of Personal Protective Equipment Post Test	Completed, Passed	80%
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#13398768)	1	Completed	Mar 10, 2022 10:08 AM	Hazardous Drug Use of Personal Protective Equipment Lesson	Completed	-
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#13398768)	1	Completed	Mar 10, 2022 10:08 AM	Hazardous Drug Use of Personal Protective Equipment Post Test	Completed, Passed	90%

(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#16982472)	1	Completed	Jul 27, 2022 1:05 AM	Hazardous Drug Use of Personal Protective Equipment Lesson	Completed	-
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#16982472)	1	Completed	Jul 27, 2022 1:05 AM	Hazardous Drug Use of Personal Protective Equipment Post Test	Completed, Passed	80%

(8) Requirements and Best Practices Hazardous Drug Compounding – Engineering Controls and Personal Protective Equipment (#7896620)	2	Completed	Aug 22, 2019 4:58 PM	Engineering Controls and Personal Protective Equipment Post Test	Passed	90%
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#10142389)	1	Completed	Nov 16, 2020 9:54 AM	Hazardous Drug Use of Personal Protective Equipment Lesson	Completed	-
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#10142389)	1	Completed	Nov 16, 2020 9:54 AM	Hazardous Drug Use of Personal Protective Equipment Post Test	Completed, Passed	100%
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#13398753)	1	Completed	Jan 4, 2022 11:14 PM	Hazardous Drug Use of Personal Protective Equipment Lesson	Completed	-
(8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#13398753)	1	Completed	Jan 4, 2022 11:14 PM	Hazardous Drug Use of Personal Protective Equipment Post Test	Completed, Passed	90%

(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362492)	1	Completed	Jan 4, 2022 11:47 PM	Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Post Test	Completed, Passed	80%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#16982547)	1	Completed	Jul 27, 2022 1:13 AM	Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#16982547)	1	Completed	Jul 27, 2022 1:13 AM	Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Post Test	Completed, Passed	80%
(8) Requirements and Best Practices Hazardous Drug Compounding – Engineering Controls and Personal Protective Equipment (#7896620)	2	Completed	Aug 22, 2019 4:58 PM	Engineering Controls and Personal Protective Equipment Lesson	Completed	-

(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#16982548)	1	Completed	Jul 27, 2022 1:10 AM	Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Post Test	Completed, Passed	83.33%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362468)	1	Completed	Nov 17, 2020 11:10 AM	Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362468)	1	Completed	Nov 17, 2020 11:10 AM	Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Post Test	Completed, Passed	80%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362492)	1	Completed	Jan 4, 2022 11:47 PM	Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Lesson	Completed	-

(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362469)	1	Completed	Nov 17, 2020 11:14 AM	Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Post Test	Completed, Passed	100%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362493)	1	Completed	Jan 4, 2022 11:36 PM	Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362493)	1	Completed	Jan 4, 2022 11:36 PM	Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Post Test	Completed, Passed	91.66%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#16982548)	1	Completed	Jul 27, 2022 1:10 AM	Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Lesson	Completed	-

(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#16982473)	1	Completed	Jul 27, 2022 1:03 AM	Hazardous Drug Primary and Secondary Engineering Controls Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#16982473)	1	Completed	Jul 27, 2022 1:03 AM	Hazardous Drug Primary and Secondary Engineering Controls Post Test	Completed, Passed	80%
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Work Practice Strategies (#7896621)	2	Completed	Aug 22, 2019 3:08 PM	Hazardous Drug Work Practice Strategies Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Work Practice Strategies (#7896621)	2	Completed	Aug 22, 2019 3:08 PM	Hazardous Drug Work Practice Strategies Post Test	Passed	85%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362469)	1	Completed	Nov 17, 2020 11:14 AM	Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Lesson	Completed	-

(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#10142390)	1	Completed	Nov 16, 2020 10:05 AM	Hazardous Drug Primary and Secondary Engineering Controls Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#10142390)	1	Completed	Nov 16, 2020 10:05 AM	Hazardous Drug Primary and Secondary Engineering Controls Post Test	Completed, Passed	80%
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#13398754)	1	Completed	Jan 4, 2022 11:03 PM	Hazardous Drug Primary and Secondary Engineering Controls Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#13398754)	1	Completed	Jan 4, 2022 11:03 PM	Hazardous Drug Primary and Secondary Engineering Controls Post Test	Completed, Passed	80%

(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#13398752)	1	Completed	Jan 4, 2022 10:37 PM	Hazardous Drug Introduction and Overview Post Test	Completed, Passed	80%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#16982471)	1	Completed	Jul 27, 2022 12:59 AM	Hazardous Drug Introduction and Overview Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#16982471)	1	Completed	Jul 27, 2022 12:59 AM	Hazardous Drug Introduction and Overview Post Test	Completed, Passed	86.66%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#7896619)	1	Completed	Aug 22, 2019 1:31 PM	Hazardous Drug Introduction and Overview Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#7896619)	1	Completed	Aug 22, 2019 1:31 PM	Hazardous Drug Introduction and Overview Post Test	Passed	90%

(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#16982479)	1	Completed	Jul 27, 2022 12:56 AM	Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#16982479)	1	Completed	Jul 27, 2022 12:56 AM	Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test	Passed	100%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#10142388)	1	Completed	Nov 16, 2020 10:09 AM	Hazardous Drug Introduction and Overview Lesson	Completed	-
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#10142388)	1	Completed	Nov 16, 2020 10:09 AM	Hazardous Drug Introduction and Overview Post Test	Completed, Passed	86.66%
(8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#13398752)	1	Completed	Jan 4, 2022 10:37 PM	Hazardous Drug Introduction and Overview Lesson	Completed	-

(6) Aseptic Technique and Related Work Practices - Sterile Compounding on Patient Units (#7896627)	1	Completed	Aug 21, 2019 3:44 PM	Sterile Compounding on Patient Units Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Sterile Compounding on Patient Units (#7896627)	1	Completed	Aug 21, 2019 3:44 PM	Sterile Compounding on Patient Units Post Test	Passed	90%
(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#10142396)	1	Completed	Nov 16, 2020 4:14 PM	Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#10142396)	1	Completed	Nov 16, 2020 4:14 PM	Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test	Passed	100%
(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#13398760)	1	Completed	Jan 4, 2022 10:27 PM	Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#13398760)	1	Completed	Jan 4, 2022 10:27 PM	Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test	Passed	90%

(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#13398759)	1	Completed	Jan 4, 2022 10:11 PM	Aseptic Technique and Conduct in Controlled Environments Post Test	Passed	90%
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#16982478)	1	Completed	Jul 27, 2022 12:53 AM	Aseptic Technique and Conduct in Controlled Environments Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#16982478)	1	Completed	Jul 27, 2022 12:53 AM	Aseptic Technique and Conduct in Controlled Environments Post Test	Passed	90%
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#7896626)	1	Completed	Aug 21, 2019 3:27 PM	Aseptic Technique and Conduct in Controlled Environments Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#7896626)	1	Completed	Aug 21, 2019 3:27 PM	Aseptic Technique and Conduct in Controlled Environments Post Test	Passed	80.95%

(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#7896623)	1	Completed	Aug 21, 2019 3:07 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#7896623)	1	Completed	Aug 21, 2019 3:07 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test	Passed	90%
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#10142395)	1	Completed	Nov 16, 2020 4:19 PM	Aseptic Technique and Conduct in Controlled Environments Lesson	Completed	-
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#10142395)	1	Completed	Nov 16, 2020 4:19 PM	Aseptic Technique and Conduct in Controlled Environments Post Test	Passed	100%
(6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#13398759)	1	Completed	Jan 4, 2022 10:11 PM	Aseptic Technique and Conduct in Controlled Environments Lesson	Completed	-

(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#13398756)	1	Completed	Jan 4, 2022 9:52 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#13398756)	1	Completed	Jan 4, 2022 9:52 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test	Completed, Passed	100%
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#16982475)	1	Completed	Jul 27, 2022 12:51 AM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#16982475)	1	Completed	Jul 27, 2022 12:51 AM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test	Completed, Passed	80%

(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas (#7896625)	1	Completed	Aug 21, 2019 2:19 PM	Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas (#7896625)	1	Completed	Aug 21, 2019 2:19 PM	Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas Post Test	Passed	80%
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#10142392)	1	Completed	Nov 16, 2020 4:24 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#10142392)	1	Completed	Nov 16, 2020 4:24 PM	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test	Completed, Passed	100%

(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#13398758)	1	Completed	Jan 4, 2022 1:37 AM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test	Completed, Passed	80%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#16982477)	1	Completed	Jul 27, 2022 12:48 AM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#16982477)	1	Completed	Jul 27, 2022 12:48 AM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test	Completed, Passed	90%

(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#10142394)	1	Completed	Nov 16, 2020 4:27 PM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#10142394)	1	Completed	Nov 16, 2020 4:27 PM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test	Completed, Passed	90%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#13398758)	1	Completed	Jan 4, 2022 1:37 AM	Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson	Completed	-

(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#16982476)	1	Completed	Jul 27, 2022 12:46 AM	Cleaning and Disinfection of Primary Engineering Controls Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#16982476)	1	Completed	Jul 27, 2022 12:46 AM	Cleaning and Disinfection of Primary Engineering Controls Post Test	Completed, Passed	80%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#7896624)	1	Completed	Aug 8, 2019 3:23 PM	Cleaning and Disinfection of Primary Engineering Controls Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#7896624)	1	Completed	Aug 8, 2019 3:23 PM	Cleaning and Disinfection of Primary Engineering Controls Post Test	Passed	100%

(4) Viable Facility Sampling Metrics - Volumetric Air Sampling (#7896618)	1	Completed	Aug 8, 2019 2:58 PM	Volumetric Air Sampling Lesson	Completed	-
(4) Viable Facility Sampling Metrics - Volumetric Air Sampling (#7896618)	1	Completed	Aug 8, 2019 2:58 PM	Volumetric Air Sampling Post Test	Passed	80%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#10142393)	1	Completed	Nov 16, 2020 4:36 PM	Cleaning and Disinfection of Primary Engineering Controls Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#10142393)	1	Completed	Nov 16, 2020 4:36 PM	Cleaning and Disinfection of Primary Engineering Controls Post Test	Completed, Passed	80%
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#13398757)	1	Completed	Jan 4, 2022 1:18 AM	Cleaning and Disinfection of Primary Engineering Controls Lesson	Completed	-
(5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#13398757)	1	Completed	Jan 4, 2022 1:18 AM	Cleaning and Disinfection of Primary Engineering Controls Post Test	Completed, Passed	90%

(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#16982474)	1	Completed	Jul 27, 2022 12:41 AM	Overview of Environmental Monitoring Post Test	Completed, Passed	90%
(4) Viable Facility Sampling Metrics - Surface Sampling (#7896622)	1	Completed	Aug 8, 2019 1:57 PM	Surface Sampling Lesson	Completed	-
(4) Viable Facility Sampling Metrics - Surface Sampling (#7896622)	1	Completed	Aug 8, 2019 1:57 PM	Surface Sampling Post Test	Passed	90%
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#10142387)	0.5	Completed	Nov 16, 2020 4:39 PM	Viable Air and Surface Sampling Lesson	Completed, Passed	-
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#10142387)	0.5	Completed	Nov 16, 2020 4:39 PM	Viable Air and Surface Sampling Post Test	Completed, Passed	80%
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#13398751)	0.5	Completed	Jan 3, 2022 11:14 PM	Viable Air and Surface Sampling Lesson	Completed, Passed	-
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#13398751)	0.5	Completed	Jan 3, 2022 11:14 PM	Viable Air and Surface Sampling Post Test	Completed, Passed	90%
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#16982470)	0.5	Completed	Jul 27, 2022 12:43 AM	Viable Air and Surface Sampling Lesson	Completed, Passed	-
(4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#16982470)	0.5	Completed	Jul 27, 2022 12:43 AM	Viable Air and Surface Sampling Post Test	Completed, Passed	80%

(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#16982546)	1	Completed	Jul 27, 2022 1:07 AM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson	Completed	-
(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#16982546)	1	Completed	Jul 27, 2022 1:07 AM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test	Completed, Passed	90%
(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#10142391)	1	Completed	Nov 16, 2020 4:43 PM	Overview of Environmental Monitoring Lesson	Completed, Passed	-
(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#10142391)	1	Completed	Nov 16, 2020 4:43 PM	Overview of Environmental Monitoring Post Test	Completed, Passed	90%
(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#13398755)	1	Completed	Jan 3, 2022 11:05 PM	Overview of Environmental Monitoring Lesson	Completed	-
(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#13398755)	1	Completed	Jan 3, 2022 11:05 PM	Overview of Environmental Monitoring Post Test	Completed, Passed	80%
(4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#16982474)	1	Completed	Jul 27, 2022 12:41 AM	Overview of Environmental Monitoring Lesson	Completed	-

(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362467)	1	Completed	Nov 20, 2020 4:13 PM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson	Completed, Passed	-
(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362467)	1	Completed	Nov 20, 2020 4:13 PM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test	Completed, Passed	90%
(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362491)	1	Completed	Jan 4, 2022 11:22 PM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson	Completed	-
(4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362491)	1	Completed	Jan 4, 2022 11:22 PM	Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test	Completed, Passed	80%

(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#16982469)	1	Completed	Jul 27, 2022 12:34 AM	Personnel Competency Testing in Aseptic Manipulation Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#16982469)	1	Completed	Jul 27, 2022 12:34 AM	Personnel Competency Testing in Aseptic Manipulation Post Test	Completed, Passed	90%
(3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#13398749)	2	Completed	Jan 3, 2022 10:54 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#13398749)	2	Completed	Jan 3, 2022 10:54 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test	Completed, Passed	83.32%
(3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#16982468)	2	Completed	Jul 27, 2022 12:38 AM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#16982468)	2	Completed	Jul 27, 2022 12:38 AM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test	Completed, Passed	83.32%

(3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#7896616)	2	Completed	Aug 8, 2019 12:53 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test	Passed	80%
(3) Personnel Sampling Metrics - Personnel Aseptic Media Fill and Competency Evaluation (#7896617)	1	Completed	Aug 8, 2019 1:42 PM	Personnel Aseptic Media Fill and Competency Evaluation Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Aseptic Media Fill and Competency Evaluation (#7896617)	1	Completed	Aug 8, 2019 1:42 PM	Personnel Aseptic Media Fill and Competency Evaluation Post Test	Passed	80%
(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#10142386)	1	Completed	Nov 16, 2020 4:44 PM	Personnel Competency Testing in Aseptic Manipulation Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#10142386)	1	Completed	Nov 16, 2020 4:44 PM	Personnel Competency Testing in Aseptic Manipulation Post Test	Completed, Passed	80%
(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#13398750)	1	Completed	Jan 3, 2022 9:51 PM	Personnel Competency Testing in Aseptic Manipulation Lesson	Completed	-
(3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#13398750)	1	Completed	Jan 3, 2022 9:51 PM	Personnel Competency Testing in Aseptic Manipulation Post Test	Completed, Passed	80%

(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#7896615)	2	Completed	Aug 7, 2019 1:18 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#7896615)	2	Completed	Aug 7, 2019 1:18 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Post Test	Passed	86.66%
(3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#10142385)	2	Completed	Nov 16, 2020 4:49 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson	Completed	-
(3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#10142385)	2	Completed	Nov 16, 2020 4:49 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test	Completed, Passed	83.32%
(3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#7896616)	2	Completed	Aug 8, 2019 12:53 PM	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson	Completed	-

(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#13398748)	2	Completed	Jan 3, 2022 9:40 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#13398748)	2	Completed	Jan 3, 2022 9:40 PM	Secondary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	80%
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#16982467)	2	Completed	Jul 27, 2022 12:32 AM	Secondary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#16982467)	2	Completed	Jul 27, 2022 12:32 AM	Secondary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	80%

(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#7896614)	2	Completed	Aug 7, 2019 11:56 AM	Primary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#7896614)	2	Completed	Aug 7, 2019 11:56 AM	Primary Engineering Controls: Function, Use, Testing and Certification Post Test	Passed	80%
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#10142384)	2	Completed	Nov 17, 2020 11:09 AM	Secondary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#10142384)	2	Completed	Nov 17, 2020 11:09 AM	Secondary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	100%

(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#13398747)	2	Completed	Jan 3, 2022 9:31 PM	Primary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#13398747)	2	Completed	Jan 3, 2022 9:31 PM	Primary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	86.66%
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#16982466)	2	Completed	Jul 27, 2022 12:28 AM	Primary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#16982466)	2	Completed	Jul 27, 2022 12:28 AM	Primary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	100%

(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#16982465)	1	Completed	Jul 27, 2022 12:25 AM	The History of Compounding and USP Sterile Compounding Chapters Post Test	Completed, Passed	80%
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#7896613)	1	Completed	Aug 7, 2019 8:41 AM	The History of Compounding and USP Sterile Compounding Chapters Lesson	Completed	-
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#7896613)	1	Completed	Aug 7, 2019 8:41 AM	The History of Compounding and USP Sterile Compounding Chapters Post Test	Passed	90%
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#10142383)	2	Completed	Sep 3, 2020 2:44 PM	Primary Engineering Controls: Function, Use, Testing and Certification Lesson	Completed	-
(2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#10142383)	2	Completed	Sep 3, 2020 2:44 PM	Primary Engineering Controls: Function, Use, Testing and Certification Post Test	Completed, Passed	93.33%

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Course	Credits	Course Status	Date Completed	Lesson	Status	Score
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#10142382)	1	Completed	Sep 3, 2020 2:20 PM	The History of Compounding and USP Sterile Compounding Chapters Lesson	Completed	-
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#10142382)	1	Completed	Sep 3, 2020 2:20 PM	The History of Compounding and USP Sterile Compounding Chapters Post Test	Completed, Passed	90%
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#13398746)	1	Completed	Jan 3, 2022 9:17 PM	The History of Compounding and USP Sterile Compounding Chapters Lesson	Completed	-
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#13398746)	1	Completed	Jan 3, 2022 9:17 PM	The History of Compounding and USP Sterile Compounding Chapters Post Test	Completed, Passed	90%
(1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#16982465)	1	Completed	Jul 27, 2022 12:25 AM	The History of Compounding and USP Sterile Compounding Chapters Lesson	Completed	-

State of Florida
Department of State

I certify from the records of this office that POPE SHENOUDA LLC is a limited liability company organized under the laws of the State of Florida, filed on December 10, 2007, effective December 7, 2007.

The document number of this limited liability company is L07000122168.

I further certify that said limited liability company has paid all fees due this office through December 31, 2022, that its most recent annual report was filed on April 25, 2022, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-seventh day of May, 2022



Secretary of State

Tracking Number: 9527925942CU

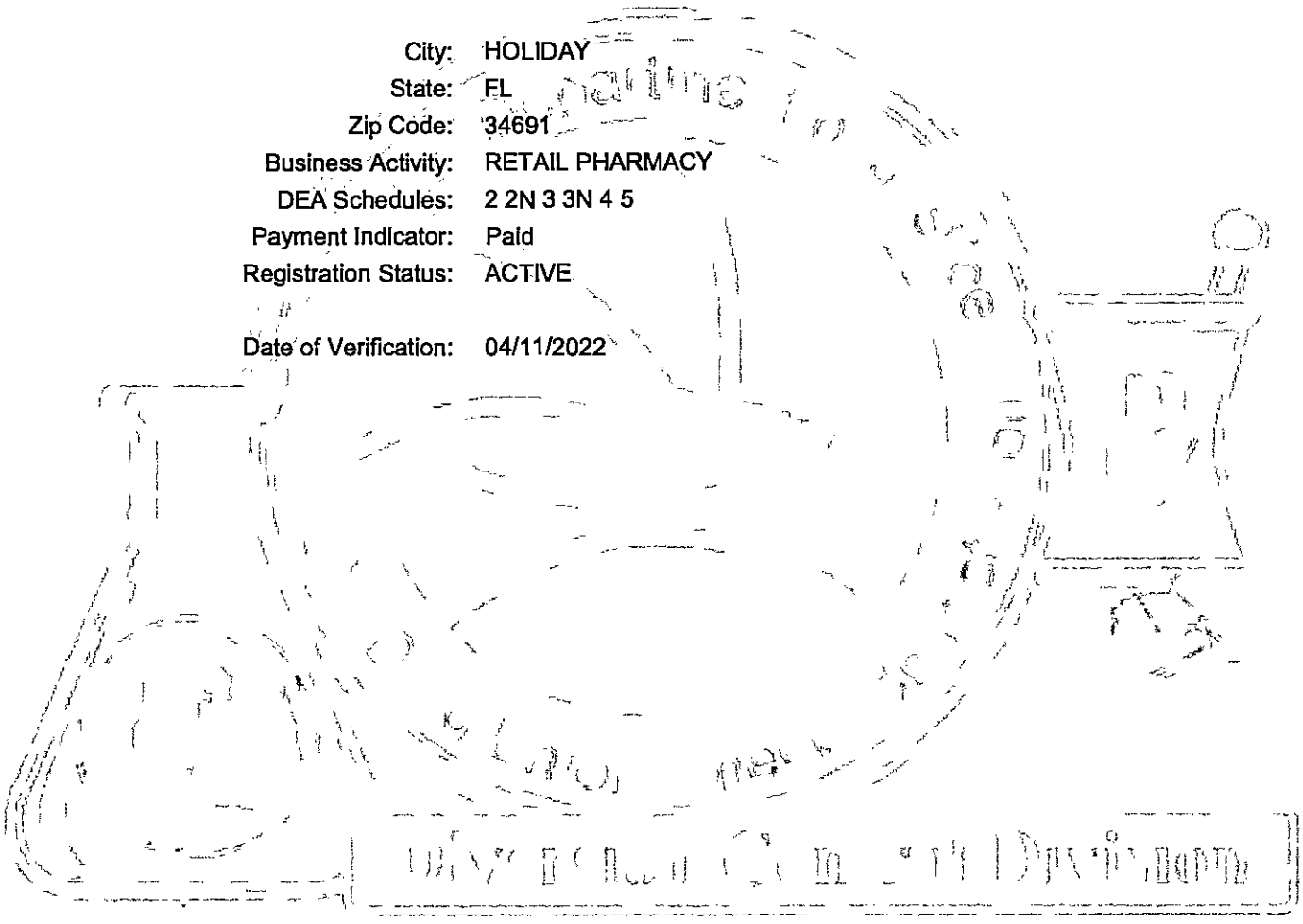
To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Registrant Verification For

POPE SHENOUDA, LLC

DEA Number:	FP0721123
Expiration Date:	03/31/2023
Additional Company Info:	1ST CHOICE PHARMACY
Registered Address:	2228 US HIGHWAY 19
City:	HOLIDAY
State:	FL
Zip Code:	34691
Business Activity:	RETAIL PHARMACY
DEA Schedules:	2 2N 3 3N 4 5
Payment Indicator:	Paid
Registration Status:	ACTIVE
Date of Verification:	04/11/2022



This Primary Source Verification was obtained from the Drug Enforcement Administration's Controlled Substance Act Registrant Database.

Drug Enforcement Administration • Diversion Control Division • 75 Morrissette Dr, Springfield, VA 22152

Department of Health

License Number: PH23208

Data As Of 11/12/2022

Profession	Pharmacy
License	PH23208
License Status	CLEAR/
Qualifications	Community PharmacySchedule II & III
License Expiration Date	2/28/2025
License Original Issue Date	02/20/2008
Address of Record	2228 US Hwy 19 HOLIDAY, FL 34691
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

8B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-State	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Non-sterile Compounding
	☐ Location Change *	☐ Internet	☒ Sterile Compounding
	☐ Name Change*	☐ Nuclear	☐ Mail-Order Service
		☐ Other:	☐ Off-site Cognitive Services
	* If making a change, provide license #:		☐ Long Term Care
			☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Strive Pharmacy

Physical Address: 1275 E. Baseline Rd ste 104

City: Gilbert State: AZ Zip: 85233

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 4806264366 Toll Free # (NAC 639.708, NRS 639.23286): 8554055993

Fax: 4806264365 Contact Email: mike@strivepharmacy.com

Website: strivepharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Matthew Montes De Oca

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23542

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Matthew Montes De Oca	NV Pharmacist Registration #: 23542
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Arizona

Parent Company (if any): _____

Corporation/Organization Name: Strive Pharmacy LLC

Mailing Address: 1275 E. Baseline Rd ste 104

City: Gilbert State: AZ Zip: 85233

Telephone: 4806264366 Email: mike@strivepharmacy.com

Contact Person Name: Michael Walker

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Strive Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Michael Walker

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

5/10/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Walker

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

4/19/23

Date

Board Use Only	Date Received: 5-11-23	Amount: 500.00 CK- 909715 3912

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Strive Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): NA

Physical Address: 1275 E Baseline Rd. ste 104

City: Gilbert State: Arizona Zip: 85233

Mailing Address (if different from physical address): NA

City: NA State: NA Zip: NA

Telephone: 4806264366 Toll Free # (NAC 639.708, NRS 639.23286): 8554055993

Fax: 4806264365 Contact Email: mike@strivepharmacy.com

Website: strivepharmacy.com

Nevada Business License # (if applicable) NA

Supervising/Managing Pharmacist Name (NRS 639.220): Matthew Montes De Oca

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23542

Name of Person with direct knowledge of compounding procedures: Matthew Montes De Oca

Email of Person with direct knowledge of compounding procedures: matt@strivepharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 775-397-5276

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ☑ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☑ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Cyclosporine 1% Opthalmic
Tacrolimus 0.03% Opthalmic
Testosterone Cypionate 25 mg/ml and 200 mg/ml MCT Inj
Estradiol Valerate 5 mg/ml Inj
Nandrolone 200 mg/ml Inj

4. Will you be utilizing beyond use dates in excess of USP-797? ☑ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

Any compounds with BUD's in excess of what USP 797 states have gone through a stability study which accesses potency, endotoxin, sterility, vial closure integrity test, pH, Particulate Matter, Method Suitability, and antimicrobial effectiveness.

6. What laboratory performs this additional testing?

Name: ARL Biopharma

Address: 840 Research Pkwy #546

City: Oklahoma City State: Oklahoma Zip: 73104

Telephone: (405) 271-1144

7. What is your procedure for visual inspection of compounded sterile products?

Visual inspection includes looking at vials under a light to check for particulate matter, we also visually verify all weights and drugs used to compound, and look at results of the filter integrity test, and 3rd party test all our products for sterility and endotoxin.

8. How often do you perform glove fingertip and medial fill testing?

We have recently changed our testing to quarterly for compounders. Our current supervisor would be due for his next GFT in November for a 6 month but at that time the USP guidelines change to annual for supervisors. Our policy will change at that time. to annual for supervisors.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

An employee may not begin compounding until all initial competencies are passed. If a continuation competency is failed a compounder will be re-educated and observed to correct any potential reason for the failure.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Quarterly Garbing competencies, GFT and Media Fills. In addition, we assure all compounding technicians shadow lead sterile technician for proper aseptic and cleaning techniques. This is represented by annual sterile techniques competencies done by direct observation of skills.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Daily Sporicidal (Peridox) on PEC and equipment inside the PEC, Floors & Work surfaces within the SEC. Washed with 70% IPA

Monthly Sporicidal (Peridox) underneath tray of PECs as well as walls, doors, ceilings, shelves/bins, and any equipment outside the PEC. Wash with 70% IPA.

12. Who performs the sterile compounding process at your facility?

Licensed Pharmacy Technicians

13. Who is responsible and accountable for the sterile compounding process at your facility?

Pharmacist-in-charge (PIC) and designated Pharmacy Managers.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Packages out of state are mailed next day air with 2 blocks of ice in winter and 3 blocks during the summer. As a new quality measure, this summer we will be executing shipping studies with temperature loggers. Also, we are looking into temp strips for all packages. Our recent stability studies showed that our products maintained potency after being subjected to 130F heat for 5 days.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)

1. What type of primary engineering controls will you be using in your facility?

Currently we have an A2 BSC (externally vented) in our hazardous buffer room and an A2 BSC (not vented as is not used for hazardous materials) and a vertical LAFW in the non-hazardous buffer room.

2. Is your BSC or CACI vented 100% to the outside?	☑ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	■ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☑ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	■ No

7. If yes, list the name of the device:

n/a

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Product leaflet goes over storage, handling and disposal of all medications.

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Quarterly Garbing competencies, GFT and Media Fills. In addition, we assure all compounding technicians shadow lead sterile technician for proper aseptic and cleaning techniques. This is represented by annual sterile techniques competencies done by direct observation of skills. Provide additional literature and SDS review of hazardous materials used during compounding.

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

Testosterone Cypionate 25 mg/ml MCT Inj, Testosterone Cypionate 100 mg/ml MCT Inj, Testosterone Cypionate 200 mg/ml MCT Inj, Estradiol Valerage 5 mg/ml Inj, MIC B12 25/50/50/1 mg/ml Inj, B Complex, SuperMIC, Semaglutide/B12 2/1, 2.5/1, and 5/1 mg/ml Inj, Tirzepatide/B12 10/1 mg/ml Inj, Glutathione 200 mg/ml Inj, Methylcobalamin 1mg/ml, 5mg/ml, and 10 mg/ml Inj, Trimix, Nandrolone 200 mg/ml Inj

2. What sterilization methods are utilized at your facility?

Filter Sterilization

3. Does your facility utilize biological indicators? ☑ Yes ☐ No

4. If yes, describe how they are utilized:

Used for depyrogenation and autoclave cycles.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Montes De Oca

Name of Person who Completed the Form

Pharmacist in Charge - Nevada

Title

MMTMJO

Signature (copies or stamps not accepted)

06/09/2023

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

List of Officers:

Name: Michael Walker

Title: Member

Address: [redacted] E Baseline Rd 104 Gilbert, AZ 85233

Percent Ownership: 55%

SSN: [redacted]

D.O.B [redacted]

Name: Nathan Hill

Title: Member

Address: [redacted] E Baseline Rd 104 Gilbert, AZ 85233

Percent Ownership: 45%

SSN: [redacted]

D.O.B [redacted]

Arizona Corporation Commission - RECEIVED: 5/1/2023
Arizona Corporation Commission - FILED: 5/1/2023

23050314158425

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

STRIVE PHARMACY LLC

ACC file number: L21888119

was incorporated under the laws of the State of Arizona on 05/22/2017, and that, according to the records of the Arizona Corporation Commission, said limited liability company is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **05/01/2023**

Douglas R. Clark, Executive Director

FILED: 5/22/2017 9:40:39 PM **DOCUMENT # 05946958**

FILE #: L21888119

DO NOT WRITE ABOVE THIS LINE: RESERVED FOR ACC USE ONLY.

ARTICLES OF ORGANIZATION

1. **ENTITY TYPE:** LIMITED LIABILITY COMPANY

2. **ENTITY NAME:** STRIVE PHARMACY LLC

3. **FILE NUMBER:** L21888119

4. **STATUTORY AGENT NAME AND ADDRESS:**

Street Address:

NATHAN HILL

[redacted]S COLT DR

GILBERT , AZ 85296

Mailing Address:

5. **ARIZONA KNOWN PLACE OF BUSINESS ADDRESS:**

[redacted]S COLT DR

GILBERT , AZ 85296

6. **DURATION:** Perpetual

7. **MANAGEMENT STRUCTURE:** **Member-Managed**

The names and addresses of all Members are:

1 **NATHAN HILL**

[redacted]S COLT DR

GILBERT, AZ 85296

2 **MICHAEL WALKER**

[redacted]S MARTINGALE RD

GILBERT, AZ 85295

ORGANIZER: Nathan Hill 5/22/2017

Arizona State Board of Pharmacy

PHARMACY INSPECTION REPORT on 05/19/2022 for Strive Pharmacy

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

DEMOGRAPHICS

AZ permit# :	AZ Permit Exp.Date :	Business Name :
Y007406	10/31/2022	Strive Pharmacy
Address :		
1275 E. Baseline Road		
Zip :	City :	State :
85233	Gilbert	AZ
Phone :	Fax :	Email :
4806264366	4806264365	info@strivepharmacy.com
Inspection Date :	PIC :	Pic License Exp Date :
05/19/2022	Michael Walker	2021-10-31T00:00:00
DEA # :	DEA # Exp. date :	Inspection Reviewed With :
FS7645748	02/29/2024	Patrick Schinzel
Reviewers License# :	Inspection type :	
S015655	Routine	
Inspection Conducted By :		
Karol Hess		

Facility Data

# Rxs/Week	RPh Hours/Week	# Rxs/Hours
1350	100	13.5

PERMITS

1	Arizona	◉S ○N/I ○V ○N/A	ARS § 32-1933(A); R4-23-606(A)
2	DEA	◉S ○N/I ○V ○N/A	ARS § 36-2522(A)(2); 21 CFR 1301.35(c)
3	Suppliers Capital Drug, PCCA, Medisca, Fagron , Spectrum, AX Pharmaceuticals, Letco, Anda	◉S ○N/I ○V ○N/A	ARS § 32-1929; R4-23-601(A); R4-23-604(A); R4-23-605(A); R4-23-607(A)

LICENSES

1	Pharmacists	◉S ○N/I ○V ○N/A	ARS § 32-1925(A); R4-23-201(A)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

2	Interns / Graduate interns	○S ○N/I ○V ◉N/A	ARS § 32-1923(B); R4-23-301(G)
3	Technicians / Trainees	◉S ○N/I ○V ○N/A	ARS § 32-1925(A); R4-23-1101(A); R4-23-1102(D); R4-23-1103(B)(2)
4	Current renewal licenses maintained	◉S ○N/I ○V ○N/A	ARS § 32-1933(B)

PHARMACY

1	Drug storage and security Keep swing door locked-extend 66" barrier around to protect front counter	○S ◉N/I ○V ○N/A	R4-23-609(G)(H)
2	Personnel and security procedures	◉S ○N/I ○V ○N/A	R4-23-610
3	Facilities	◉S ○N/I ○V ○N/A	R4-23-611(A)
4	Drug supply	◉S ○N/I ○V ○N/A	R4-23-611(B)
5	Quarantine expired drugs Return to stock cannot have more than 1 year since dispense date as beyond use date	○S ◉N/I ○V ○N/A	R4-23-611(B)(4)
6	Equipment	◉S ○N/I ○V ○N/A	R4-23-612
7	Policies and procedures	◉S ○N/I ○V ○N/A	R4-23-610(A); R4-23-611(B)

TECHNICIANS

1	Training program Trainees cannot compound-update program	○S ◉N/I ○V ○N/A	R4-23-1105(B)(D)
2	Training program - compounds Competency must be updated annually	○S ◉N/I ○V ○N/A	R4-23-1105(C)
3	Activities - trainees	◉S ○N/I ○V ○N/A	R4-23-1104(A)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

4	Activities - technicians None compounding despite policy	◉S ○N/I ○V ○N/A	R4-23-1104(A)(B)
5	Policies and procedures see above	○S ◉N/I ○V ○N/A	R4-23-1104(F)(G)

COUNSELING

1	Documentation Documentation of acceptance/denial of counsel must be done by pharmacist and document pharmacist initials/name etc.	○S ○N/I ◉V ○N/A	R4-23-402(G)(H)
2	Oral consultation	◉S ○N/I ○V ○N/A	R4-23-402(C)(D)(E)
3	Written information	◉S ○N/I ○V ○N/A	R4-23-402(C)(I)

PRESCRIPTION AUDIT

1	Prescription files prescription files must be serially numbered, filed in order dispensed	○S ◉N/I ○V ○N/A	ARS § 32-1964; ARS § 36-2525(C)(1)(2)
2	Prescription label	◉S ○N/I ○V ○N/A	ARS § 32-1968(D); ARS § 36-2525(L)
3	CII prescriptions	○S ○N/I ○V ◉N/A	ARS § 32-1968; 36-2525(A) to (G); R4-23-407(A)
4	CIII - CV prescriptions	◉S ○N/I ○V ○N/A	ARS § 32-1968; 36-2525(A)(C)(2)(H)(I); R4-23-407(A)
5	Non-controlled prescriptions If meets rule for scanned rx(front and back capabilities, electronic annotation, policy and procedures) do not need to save hard copies	◉S ○N/I ○V ○N/A	ARS § 32-1968; R4-23-407(A)
6	Transfers	◉S ○N/I ○V ○N/A	R4-23-407(D)
7	Telephone	◉S ○N/I ○V ○N/A	ARS § 32-1968(A)(5); R4-23-402(A)(1)(2)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

8	Refill authorizations	◉S ○N/I ○V ○N/A	ARS § 32-1968(A)(6); R4-23-402(A)(13); R4-23-407(E)(5)
9	Facsimile Must identify practitions locations and agent who faxed if other than practitioner	○S ◉N/I ○V ○N/A	R4-23-407(E)
10	Electronically transmitted	○S ○N/I ○V ◉N/A	R4-23-407(F); R4-23-408(H)
11	Patient information	◉S ○N/I ○V ○N/A	R4-23-402(A)(3)(4)
12	Allergies / medical conditions	○S ◉N/I ○V ○N/A	R4-23-402(A)(3)(b)
13	Brand / generic	◉S ○N/I ○V ○N/A	ARS § 32-1963.01
14	Foreign prescriptions	○S ○N/I ○V ◉N/A	ARS § 32-1969
15	Prescription blank advertising prohibited May not provide prescription blanks with any pharmacy identifying information	○S ◉N/I ○V ○N/A	R4-23-404(B); ARS § 32-1901.01(B)(25)
16	Prescription audit numbers cIII-V 4/29 Legend 5/4		

COMPUTER REQUIREMENTS

1	Security	◉S ○N/I ○V ○N/A	R4-23-408(F)
2	Log books / printout must contain pharmacist signature, printed name and initials	○S ◉N/I ○V ○N/A	R4-23-408(C)(4)
3	Reports	◉S ○N/I ○V ○N/A	R4-23-408(B)(5)(6)
4	Policies and procedures	◉S ○N/I ○V ○N/A	R4-23-408(A)

IMMUNIZATIONS

1	Certification	○S ○N/I ○V ◉N/A	ARS § 32-1974(D)(K); R4-23-411(A)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

2	Recordkeeping	○S ○N/I ○V ◉N/A	ARS § 32-1974(F)(3); R4-23-411(F)(I)
3	Reporting requirements	○S ○N/I ○V ◉N/A	ARS § 32-1974(F); R4-23-411(F)(2)
4	Current certificate maintained	○S ○N/I ○V ◉N/A	R4-23-411(C)(2)
5	Administration without a prescription	○S ○N/I ○V ◉N/A	ARS § 32-1974(A)(B); R4-23-411(A)
6	Prescription only administration	○S ○N/I ○V ◉N/A	ARS § 32-1974(C)(I); R4-23-411(A)(4); (B); (I)

MECHANICAL STORAGE / COUNTING DEVICES

1	Cell identification	○S ○N/I ○V ◉N/A	R4-23-615(A)(1)
2	Paper / electronic log	○S ○N/I ○V ◉N/A	R4-23-615(A)(2)(3)
3	Training	○S ○N/I ○V ◉N/A	R4-23-615(C)(1)(D)
4	Maintenance	○S ○N/I ○V ◉N/A	R4-23-615(C)(2)(D)
5	Accuracy validation testing	○S ○N/I ○V ◉N/A	R4-23-615(C)(3)(D)
6	Return by approval only	○S ○N/I ○V ◉N/A	R4-23-615(B)(G)
7	Policies and procedures	○S ○N/I ○V ◉N/A	R4-23-615(E)

MECHANICAL COUNTING DEVICES

1	Training	○S ○N/I ○V ◉N/A	R4-23-616(A)(1)(B)
2	Maintenance	○S ○N/I ○V ◉N/A	R4-23-616(A)(2)(B)
3	Accuracy validation testing	○S ○N/I ○V ◉N/A	R4-23-616(A)(3)(B)
4	Policies and procedures	○S ○N/I ○V ◉N/A	R4-23-616(C)

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CONTROLLED SUBSTANCE RECORDS

1	CIIs purchase / sale / disposal	○S ○N/I ○V ◉N/A	ARS § 36-2523(A); ARS § 36-2524; R4-23-601(D);R4-23-1003(A)(4)(B)
2	CIII - CVs purchase / sale / disposal	◉S ○N/I ○V ○N/A	ARS § 36-2523(A); R4-23-601(D); R4-23-612(11); R4-23-1003(A)(4)
3	Inventory Reminder-if no cIIs-document on inventory	◉S ○N/I ○V ○N/A	ARS § 36-2523(B); R4-23-1003
4	Audit	◉S ○N/I ○V ○N/A	ARS § 36-2523
5	DEA 106 Theft/Loss reporting	○S ○N/I ○V ◉N/A	R4-23-1003(A)(2); 21 CFR 1301.76(b)

MISCELLANEOUS

1	Badges - name / title	◉S ○N/I ○V ○N/A	R4-23-402(K); R4-23-671(B)(4); R4-23-1104(E)
2	Sales of drugs to practitioners	○S ○N/I ○V ◉N/A	ARS § 32-1981(7)(d); R4-23-601(D); R4-23-1003(A)(4)
3	Schedule V register	○S ○N/I ○V ◉N/A	ARS § 36-2525(J)
4	Delivery	◉S ○N/I ○V ○N/A	ARS § 32-1901.01(B)(23); R4-23-402(I)
5	CQA training / Policies and procedures	◉S ○N/I ○V ○N/A	ARS § 32-1973; R4-23-620
6	Non-controlled substances purchase / sale / disposal	◉S ○N/I ○V ○N/A	R4-23-601(D)
7	Dextromethorphan sales restrictions	○S ○N/I ○V ◉N/A	ARS 32-1978
8	Federal medication guides Must be provided with all required medicatoins	○S ◉N/I ○V ○N/A	21 CFR part 208
9	Pharmacy to pharmacy transfer of drugs (intracompany)	○S ○N/I ○V ◉N/A	R4-23-601(D); R4-23-1003(A)(4)

METHAMPHETAMINE PRECURSORS

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

1	Storage	○S ○N/I ○V ◉N/A	ARS § 32-1977(B)
2	Documentation	○S ○N/I ○V ◉N/A	ARS § 32-1977(C); 21 CFR 1314
3	Self-certification	○S ○N/I ○V ◉N/A	21 CFR 1314.35; 21 CFR 1314.40

SHARED SERVICES

1	Current resident / nonresident permit	○S ○N/I ○V ◉N/A	R4-23-621(A)
2	Same owner / written contract / common electronic file	○S ○N/I ○V ◉N/A	R4-23-621(B)
3	Notification to patients	○S ○N/I ○V ◉N/A	R4-23-621(C)
4	Maintain manual / electronic records	○S ○N/I ○V ◉N/A	R4-23-621(D)
5	Work outside pharmacy	○S ○N/I ○V ◉N/A	R4-23-621(F)
6	Policies and procedures	○S ○N/I ○V ◉N/A	R4-23-621(E)

COMPOUNDING PRACTICES (GENERAL)

1	Documentation product compounded verification of measure must be done prior to mixing, photo is ok.	○S ◉N/I ○V ○N/A	R4-23-410(C)(1)(e); R4-23-410(I)(K)
2	Patient label Label must contain statement, symbol etc. that indicates it is a compound	○S ◉N/I ○V ○N/A	R4-23-410(I)(4)
3	Beyond-use dates	◉S ○N/I ○V ○N/A	R4-23-410(I)(4)(b); R4-23-410(B)(3)(d)
4	Equipment	◉S ○N/I ○V ○N/A	R4-23-410(F)(G)
5	Product produced in excess	◉S ○N/I ○V ○N/A	R4-23-410(B)(2); R4-23-410(J)

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6	Component removed from original container Product removed from original container must be labeled with component name, manufacturer, weight/measure, lot#, BUD, transfer date	○S ◉N/I ○V ○N/A	R4-23-410(I)(6)
7	Compounds for medical practitioners	○S ○N/I ○V ◉N/A	R4-23-410(B)(3); R4-23-601(D); R4-23-1003(A)(4)
8	Patient written list must contain each component name clearly written	○S ◉N/I ○V ○N/A	R4-23-410(I)(5)
9	Protective apparel	◉S ○N/I ○V ○N/A	R4-23-410(C)(2)(c)
10	Facility	◉S ○N/I ○V ○N/A	R4-23-410(E)
11	Components for compounding/storage Reminder to verify that all containers and closures are USP compliant	◉S ○N/I ○V ○N/A	R4-23-410(B)(H)
12	Policies and procedures	◉S ○N/I ○V ○N/A	R4-23-410(D)(G)(H)(I)(K)

STERILE COMPOUNDING

1	Compounding area	◉S ○N/I ○V ○N/A	R4-23-670(A)(E)(F)
2	Equipment	◉S ○N/I ○V ○N/A	R4-23-670(B)
3	Sterile product reference	◉S ○N/I ○V ○N/A	R4-23-670(B)(6)
4	Certification hood / environment Last 11/21 next 5/22	◉S ○N/I ○V ○N/A	R4-23-670(D)(14)(g)
5	Documentation routine cleaning / maintenance	◉S ○N/I ○V ○N/A	R4-23-670(D)(14)(g)
6	Personnel protective clothing	◉S ○N/I ○V ○N/A	R4-23-670(E)(3)(F)(2)

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7	Annual / semi-annual media fill tests Every 6 months-recommend during stressful time of shirt to simulate times most likely to lose sterility	◉S ○N/I ○V ○N/A	R4-23-670(E)(4)(F)(3)
8	Documentation of product compounded	◉S ○N/I ○V ○N/A	R4-23-410(C)(1)(e), R4-23-410(I)(K)
9	Beyond-use dates	◉S ○N/I ○V ○N/A	R4-23-670(D)(14)(d), R4-23-410(B)(3)(d)
10	Process / product validation testing	◉S ○N/I ○V ○N/A	R4-23-670(D)(14)(f)
11	Policies and procedures	◉S ○N/I ○V ○N/A	R4-23-670(C)(D)

AUDIT

Date Of Inventory : 04/29/2021

Inventory Taken : Close

Date Of Audit : 05/17/2022

Name & Strength of Drug	Initial Inventory	Total Purchased	Total Accounted For	Closing Inventory	Sales (Rx & log)	Total Can Account for	Difference	Percentage
Tramadol 50mg tablet	70	0	70	70	0	70	0	0.00
Ketamine USP powder	580.1	0	580.1	523.9	47.65	571.55	-8.550000000000068	-1.47

NOTES

Violation issued:
Acceptance/denial of counseling must be documented by pharmacist with initials or signature of pharmacist.

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/permit but serves as the primary source of verification.

Name :	Strive Pharmacy
Address :	1275 E. Baseline Road 104 Gilbert AZ 85233
License No :	Y007406
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	09/14/2017
Expiration Date :	10/31/2024
Status :	OPEN
Discipline :	No

Kam Gandhi

Kam Gandhi

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 09/29/2022
Receipt
Number: 2022135984
Receipt Amount $: 480.00

Pharmacy - Independent

PERMIT NO	EXPIRES
Y007406	10/31/2024

Issued to :

Strive Pharmacy
Michael Walker
1275 E BASELINE RD 104
GILBERT, AZ 85233

Strive Pharmacy
1275 E. BASELINE ROAD 104
GILBERT, AZ 85233

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Michael Walker
LICENSE NUMBER : Y007406
EXPIRES : 10/31/2024

http://www.azpharmacy.gov

- Your license must be available for inspections during business hours.
- Permit holder(s) must display permit in the location to which it is issued.
- Please note it is your responsibility to keep this license/permit current.

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
http://www.azpharmacy.gov

602-771-ASBP (2727)
FAX: 602-771-2749

Pharmacist

LICENSE NO	EXPIRES
S021357	10/31/2023

Receipt Date: 10/27/2021
Receipt Number: 2021122130
Receipt Amount $: 180.00

Issued to : Michael Walker
3661 E CAMPBELL CT
GILBERT, AZ 85234

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Michael Walker
LICENSE NUMBER : S021357
EXPIRES : 10/31/2023

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

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Arizona State Board of Pharmacy

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Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA PHARMACIST LICENSE FOR THE INDIVIDUAL LISTED BELOW :

This document is not a license/permit but serves as the primary source of verification.

Name :	Michael Walker
License No :	S021357
Date Issued :	07/22/2015
Expiration Date :	10/31/2023
Status :	OPEN
Discipline :	No

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 04/19/2023

10007759 2/002627-1/1-0

STRIVE PHARMACY
1275 E BASELINE RD STE 104
GILBERT, AZ 85233-1224

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS7645748	02-29-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	01-22-2021

STRIVE PHARMACY
1275 E BASELINE RD STE 104
GILBERT, AZ 85233-1224

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS7645748	02-29-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	01-22-2021

STRIVE PHARMACY
1275 E BASELINE RD STE 104
GILBERT, AZ 85233-1224

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Form DEA-223 (9/2016)

Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 03/16/2023
Amount:
License #: 23542

Matthew T. Montes De Oca

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:03/16/2023
Expires:10/31/2023

Matthew T. Montes De Oca

License #
23542
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Pharmacist

License Type: Pharmacist
License #: 23542
Effective Date:03/16/2023

Expires: 10/31/2023
STATUS: Active

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Matthew T. Montes De Oca

NONTRANSFERABLE

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Strive Pharmacy

Physical Address 1275 E Baseline Rd 104

City Gilbert State AZ Zip 85233

Mailing Address (if different from physical address) 1275 E Baseline Rd 104

City Gilbert State AZ Zip 85233

Telephone 480-626-4366 Website www.strivepharmacy.com

Licensing Company Email mike@strivepharmacy.com

Section 2: Personal Information

First Matthew Middle _____ Last Montes De Oca

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] N 37th St

City Phoenix State AZ Zip 85018

Telephone [redacted] Email matt@strivepharmacy.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials MM

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pacific University		08/13 - 05/16	
Address	**City**	**State**	**Zip**
2043 College Way	Forest Grove	OR	97116
Diploma/Degree obtained, if any			
Doctorate of Pharmacology			
School Name		**From - To (MM/YY – MM/YY)**	
University of Nevada, Reno		08/10 - 05/16	
Address	**City**	**State**	**Zip**
1664 N Virginia St	Reno	NV	89557
Diploma/Degree obtained, if any			
N/A			
School Name		**From - To (MM/YY – MM/YY)**	
Elko High School		08/06 06/10	
Address	**City**	**State**	**Zip**
987 College Ave	Elko	NV	89801
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/23 - Present	[redacted] N 37th St #7	Phoenix	AZ	85018
01/22 - 01/23	[redacted] N 75th Way	Scottsdale	AZ	85251
07/21 - 01/22	[redacted] E Osborn Rd	Scottsdale	AZ	85251
11/19 - 07/21	[redacted] N 82nd St	Scottsdale	AZ	85251
06/16 - 11/19	[redacted] N 76th St Unit 11	Scottsdale	AZ	85257
06/15 06/16	[redacted] S Pacific Hwy	Medford	OR	97501
06/13 - 06/15	[redacted] SE 4th St	Hillsboro	OR	97123
08/10 - 06/13	[redacted] Canyon Meadows Dr	Reno	NV	89506
~~From - To (MM/YY – MM/YY)~~	Address	City	State	Zip
11/06 - 08/10	[redacted] Jamie Ct	Elko	NV	89801

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Strive Compounding Pharmacy				From - To (MM/YY – MM/YY): 01/21 - Present
Business Address: 1275 E Baseline Rd #104		City: Gilbert	State: AZ	Zip: 85233
Phone: 480-628-4366	Title: Pharmacy Operations Manager			Number of Employed Hours: 1,380
Description of Duties: Manage staff, Compliance, prescription workflow, Instill USP Standards				

Business Name: Walmart Pharmacy				From - To (MM/YY – MM/YY): 02/15 - 10/20
Business Address: 1606 S Signal Butte Rd		City: Mesa	State: AZ	Zip: 85209
Phone: 480-358-1122	Title: Pharmacy Manager			Number of Employed Hours: 5,440
Description of Duties: Manage staff, Compliance, prescription workflow, Balance P&L				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	X	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Montes de Oca

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4.21.23

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Matthew Montes de Oca, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4.26.23

Date

Subscribed and Sworn to before me this 26th day of April 2023

Notary Public Signature

KATIE L ABEYTA
Notary Public - Maricopa County
Arizona Commission #622169
My Commission Expires
February 1, 2026

(Seal)

Applicant's initials _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
8/24/21	12/30/21	AZ	Scottsdale	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
TR-20210137888		City of Scottsdale Police		
Reason/Charge				
DUI				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Written Explanation and Documentation Submitted During pharmacist License # 23542 application.

MM J Mlo
Original Signature (electronic, copies or stamps not accepted)

4.21.23
Date

Applicant's initials MJM

I, Matthew Montes de Oca, **certify that as the designated representative for** Strive Compounding Pharmacy, **that I am qualified as follows and will comply with the following:**

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Matthew Montes de Oca
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4.21.23
Date

Applicant's initials MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Strive Pharmacy

Physical Address: 1275 E Baseline Rd 104

City: Gilbert State: AZ Zip: 85233

Mailing Address (if different from physical address): 1275 E Baseline Rd 104

City: Gilbert State: AZ Zip: 85233

Telephone: 480-626-4366 Website: www.strivepharmacy.com

Licensing Company Email: mike@strivepharmacy.com

Section 2: Personal Information

First: Nathan Middle: _____ Last: Hill

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] E Baseline Rd [redacted]

City: Gilbert State: AZ Zip: 85233

Telephone: [redacted] Email: nate@strivepharmacy.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Applicant's initials NH

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		City	State	Zip	From - To (MM/YY – MM/YY)
Viewmont High School					09/03 - 5/05
Address: 120 W 1000 N		Bountiful	UT	84010	
Diploma/Degree obtained, if any: Diploma					
School Name: University of Utah					From - To (MM/YY – MM/YY): 02/08 - 05/13
Address: 201 President's Circle		City: Salt Lake City	State: Ut.	Zip: 84112	
Diploma/Degree obtained, if any: Bachelor of Science Business Administration					
School Name					From - To (MM/YY – MM/YY)
Address		City	State	Zip	
Diploma/Degree obtained, if any					
School Name					From - To (MM/YY – MM/YY)
Address		City	State	Zip	
Diploma/Degree obtained, if any					
School Name					From - To (MM/YY – MM/YY)
Address		City	State	Zip	
Diploma/Degree obtained, if any					

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/17 - Present	[redacted] S. Annie Lane	Gilbert	AZ	85296
10/16 - 10/17	[redacted] S. Colt Lane	Gilbert	AZ	85296
05/15 - 10/16	[redacted] W Willow Green Way	Farmington	Ut	84025
09/13 - 05/15	[redacted] S Main St	Bountiful	Ut	84010
10/09 - 09/13	[redacted] W Grand Ave	Salt Lake City	UT	84103

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Strive Pharmacy			07/18 - Present	
Business Address		**City**	**State**	**Zip**
1275 E Baseline rd Ste 104		Gilbert	AZ	85233
Phone	**Title**			
480-626-4366	Co-Founder / CEO			
Description of Duties				
founder & CEO. All things business related				

Business Name			From - To (MM/YY – MM/YY)	
Daiichi Sankyo			09/16 - 05/18	
Business Address		**City**	**State**	**Zip**
211 Mt. Airy Rd.		Basking Ridge	NJ	07920
Phone	**Title**			
908 992 6400	Specialty Sales Rep			
Description of Duties				
Pharmaceutical Sales representative				

Business Name			From - To (MM/YY – MM/YY)	
Scoreboard Sports			11/15 - 05/16	
Business Address		**City**	**State**	**Zip**
445 N 700 W Ste 105		North Salt Lake	Ut	84054
Phone	**Title**			
877-407-3500	Team Sales Representative			
Description of Duties				
Sold brand name apparel to corporations, schools & teams. B2B				

Business Name			From - To (MM/YY – MM/YY)	
Vivint			05/10 - 11/15	
Business Address		**City**	**State**	**Zip**
4931 N 300 W		Provo	Ut	84604
Phone	**Title**			
801-506-6182	Sales Representative			
Description of Duties				
Sold home security & home automation. B2C				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials NH

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

04/21/23
Date

Applicant's initials NH

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Hill

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/21/23

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Nathan Hill, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/26/23

Date

Subscribed and Sworn to before me this 26th day of April 2023

Notary Public Signature

KATIE L ABEYTA
Notary Public - Maricopa County
Arizona Commission #622169
My Commission Expires
February 1, 2026

(Seal)

Applicant's initials _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Strive Pharmacy

Physical Address: 1275 E Baseline Rd 104

City: Gilbert State: AZ Zip: 85233

Mailing Address (if different from physical address): 1275 E Baseline Rd 104

City: Gilbert State: AZ Zip: 85233

Telephone: 480-626-4366 Website: www.strivepharmacy.com

Licensing Company Email: mike@strivepharmacy.com

Section 2: Personal Information

First: Michael Middle: Last: Walker

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] E Baseline Rd [redacted]

City: Gilbert State: AZ Zip: 85233

Telephone: 480-626-4366 Email: mike@strivepharmacy.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Applicant's initials MW

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Viewmont High School		08/02 - 05/05	
Address	**City**	**State**	**Zip**
120 W 1000 N.	Bountiful	Ut	84010
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
University of Utah		08/09 - 05/12	
Address	**City**	**State**	**Zip**
201 Presidents' cir	Salt Lake City	Ut	84112
Diploma/Degree obtained, if any			
Bachelor of Science			
School Name		**From - To (MM/YY – MM/YY)**	
Midwestern University		06/12 - 05/15	
Address	**City**	**State**	**Zip**
19555 N. 59th Ave	Glendale	AZ	85308
Diploma/Degree obtained, if any			
Doctor of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	NA			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials MW

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Strive Pharmacy			07/18 – current	
Business Address		**City**	**State**	**Zip**
1275 E. Baseline Rd Ste 104		Gilbert	AZ	85233
Phone	**Title**			
8019138796	Pharmacist in Charge			
Description of Duties				
manage pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Saraya Gilbert Pharmacy			10/15 – 03/18	
Business Address		**City**	**State**	**Zip**
3570 S. Val Vista Dr #108		Gilbert	AZ	85297
Phone	**Title**			
4808870244	Pharmacist in charge			
Description of Duties				
manage pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials _____

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Applicant's initials MW

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/19/23

Date

Applicant's initials WW

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Walker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/19/23

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Michael Walker, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/19/23

Date

Subscribed and Sworn to before me this 19th day of April 2023

Notary Public Signature

KATIE L ABEYTA
Notary Public - Maricopa County
Arizona Commission #622169
My Commission Expires
February 1, 2026

(Seal)

Applicant's initials

9

Robert Seik, PharmD, Owner
Partell Pharmacy
5835 S Eastern Ave, STE 101
Las Vegas, NV 89119
(702) 791-3800

CC: Noah E. Jussim
Hinshaw & Culbertson, LLP

May 2, 2023

SCANNED
MAY 8 2023
BY:

Nevada Board of Pharmacy
Attn: Greg Zunino, Senior General Counsel
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

RE: Status of Sterile Compounding Questionnaire Submission
Partell Pharmacy Sterile Compounding

Dear Mr. Zunino and Members of the Nevada Board of Pharmacy,

As requested, a Sterile Compounding Questionnaire (SCQ) was tendered to the NVBOP on February 3, 2023. Receipt of said SCQ was confirmed by NVBOP counsel Paul Edwards when directly queried by Jeff Lang, PIC, in early March, 2023. A subsequent tracked follow-up written request for confirmation of receipt of the SCQ was sent and received by the NVBOP on March 6, 2023. (See attached.)

Due to an apparent delay in response by the NVBOP, I am writing to again request an update on the current status of our SCQ submission to the NVBOP. To date, Partell Pharmacy has received neither written updates nor requests for additional pertinent information that may have basis. Please know that Partell Pharmacy's sterile compounding lab has undergone extensive remodel and upgrades and we plan to reopen our sterile product compounding laboratory very soon.

We have been informed by NVBOP staff that "approval" of the SCQ is required before we can engage in sterile product compounding. However, we cannot find any pertinent statutes or regulations which require a separate approval or license for sterile compounding from the NVBOP. Absent any conflict of interest within the NVBOP, we find no regulation or statute that requires a public meeting for discussion, approval, or dissent of our existing pharmacy's sterile product compounding operation given our active Nevada pharmacy license.

Partell Pharmacy employs a highly competent staff, trained and experienced in sterile product compounding. Previous conversations with Board counsel noted that the company would submit a request before resuming sterile product compounding. As the owner, I do not recall making a commitment to notify the Board before restarting sterile product compounding, nor

does current management. PIC Jeff Lang manages the pharmacy and will oversee the sterile product compounding laboratory. Mr. Lang is trained in sterile product compounding. During previous conversations with staff Board, comments were made about the delay in reopening Partell Pharmacy's sterile product compounding laboratory from the time the company's previous PIC was employed. While an explanation is not required by any statute or regulation, we are willing to inform the Board that the delay in reopening the laboratory is related mostly to the previous PIC's unwillingness to train for sterile product compounding. The delay was also impacted by Covid-19, which caused a scarcity of necessary equipment, materials, and contractor services necessary for our desired changes to the lab. The lab is now complete.

Partell Pharmacy takes its obligations as a compounding pharmacy seriously and is committed to operating in full compliance with all applicable Nevada laws and regulations. We believe that we have provided all necessary information to the Board and have taken all necessary steps to ensure the safety and quality of our compounding practices. Furthermore, the original sterile compounding questionnaire was submitted February 3, 2023 and the Board has had ample time to review it and respond.

Finally, we kindly request that Board counsel confirm there is no regulation or statute that gives the Board the right to decline approval of Partell Pharmacy's sterile product compounding operation. We also request that the Board respond to this letter within five days of receipt. We appreciate your attention to this matter and look forward to your prompt response.

Sincerely,

Robert Seik, PharmD – Owner
Partell Pharmacy

Jeff Lang, PharmD
Pharmacist-In-Charge

STEFANI MORRIS
Notary Public, State of Nevada
Appointment No. 21-6315-01
My Appt. Expires Apr 6, 2025

CC: Noah E. Jussim
Hinshaw & Culbertson, LLP

PS for Mr. Zunino: Be aware that one member of the NVBOP, Gener Tejero, has a conflict of interest in regard to Partell Pharmacy's resumption of sterile product compounding as it may compete with his company, Solutions Specialty Pharmacy.

Enc.
Sterile Compounding Questionnaire

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Partell Specialty Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): PHN02028

Physical Address: 5835 South Eastern Ave, Suite 101

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-791-3800 Toll Free # (NAC 639.708, NRS 639.23286): 888-490-5534

Fax: 702-791-3630 Contact Email: info@partellpharmacy.com

Website: partellpharmacy.com

Nevada Business License # (if applicable) NV20061661768

Supervising/Managing Pharmacist Name (NRS 639.220): David Whitehouse

Supervising/Managing Pharmacist NV Pharmacist Registration #: 13635

Name of Person with direct knowledge of compounding procedures: David Whitehouse

Email of Person with direct knowledge of compounding procedures: dwhitehouse@partellpharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 702-791-3800

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☑ Low ☑ Medium ☑ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☑ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Methylcobalamin
M.I.C
Glutathione
Tri-Mix
Ascorbic Acid
Myer's Cocktail
NAD+
BPC-157
Semaglutide/B6
GHK-Cu
Epithalon
DSIP
PT-141
AOD 9604
TA1
MOTS-C

Tirzepatide

Selank

*****Testosterone (projected for future use based on capabilities)**

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☑ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
N/A

6. What laboratory performs this additional testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
Please see attached (SOP 06-06.01)

8. How often do you perform glove fingertip and media fill testing?
Initially and every 6 months thereafter.

9. What is your policy if an employee fails a glove fingertip or media-fill test?
Please see attached SOP (03-08C.01)

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initially - Pharmacists and Techs complete "Achieving Best Practices: Sterile Compounding" 3 day live course presenterd by Medisca and or PCCA 4 day Sterile Comnpounding course.

Annually - Pharmacists and Techs complete a sterile compounding training course (ex. "Compound Sterile Preparations " by ASHP

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Please see attached SOP (02-04.01, and 02-04C.01)

12. Who performs the sterile compounding process at your facility?
Pharmacists: David Whitehouse and Chris Peters
Te\chnician: Keith Bullo

13. Who is responsible and accountable for the sterile compounding process at your facility?
David Whitehouse

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Please see attached SOP (08-10.01)

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? EdgeGARD EG-637A; SteriGARD SG503A-HE Manufacturer: Baker		
2. Is your BSC or CACI vented 100% to the outside?	☑ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☑ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☑ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☑ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☑ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? Pharmacists are required to counsel all new patients on proper use, handling, and disposal of hazardous drugs. An electronic counseling log is maintained on the premises.		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? Pharmacists and Techs attend live training such as "Achieving Best Practices: Sterile Compounding" 3 day live course presenterd by Medisca and or PCCA 4 day Sterile Comnpounding course Each employee must then pass the finger tip test and media fill testing criteria prior to compounding.		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
Injections made from non-sterile APIs:

Methocobalamin
M.I.C
Glutathione
Tri-Mix
Ascorb c Acid
Myer's Cocktail
NAD+

2. What sterilization methods are utilized at your facility?
Filter Sterilization

3. Does your fac lity utilize biological indicators? ☐ Yes ☒ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DAVID WHITEHOUSE
Name of Person who Completed the Form

PHARMACIST IN CHARGE
Title

David White
Signature (copies or stamps not accepted)

9/26/23
Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Partell Specialty Pharmacy
5835 S Eastern Ave Ste 101
Las Vegas, NV 89119-3031

06-06.01 07/23 Compounded Sterile Preparation Inspection

Revision History:

I Initiated: 07/23
II Revised:
A

Scope:

I This Policy and Procedure applies to all facility operations.

Policy:

I This procedure will outline the process of visual inspection for both in-process and final check of the Compounded Sterile Preparation (CSP).

Personnel:

I It is the responsibility of the Pharmacist-in-Charge or designee to complete this procedure.

Frequency:

I This procedure will be performed with every CSP.

Equipment / Supplies / References:

I Appropriate lighting
II Lighted white and/or black background

Procedure:

I Visual inspections of compounded sterile preparations shall include but not be limited to:
- A Accuracy of correct identities and amounts of ingredients.
- B Aseptic compounding techniques
- C Sterilization techniques
- D Container integrity
- E Phase separation
- F Appropriate coloring
- G Appropriate volume
- H Container-closure integrity
- I Packaging
- J Labeling
- K Expected physical appearance.

II Where possible, while swirling, the end product shall be inspected against lighted white or black background, or both, for evidence of visible particulates and other foreign matter.
III All compounded sterile preparations that are intended to be solutions shall be visually examined for the presence of particulate matter, and not dispensed for administration if such matter is present.
IV In case of any unusual observances, the compounded sterile preparation shall be quarantined and reported to the Pharmacist-in-Charge or designee.
V The Pharmacist-in-Charge or designee must make a determination to the integrity and quality of the preparation.
VI If necessary, the complete disposal of the preparation must be done according to proper procedure and logged in accordingly.

Partell Specialty Pharmacy
5835 S Eastern Ave Ste 101
Las Vegas, NV 89119-3031

03-08C.01 07/23 Gloved Fingertip Sampling Action Report

Employee Name (if applicable):			Date:
Type of Unit:		**Number of CFU**	**Date Sampled:**
□ Gloved Fingertip Sampling (GFS)	□ Left or □ Right Hand		
Complete the following actions and document additional information in the space provided:			
1. PIC or designee notified?			□ Yes □ No
2. Employee removed from compounding operations. (Check N/A if VAS/SS)			□ Yes □ No □ N/A
3. Correct procedure followed for preparation?			□ Yes □ No
4. Incubated Plates/MFUs have not been exposed/leaking during incubation?			□ Yes □ No
5. Certification of PEC associated with units reviewed?			□ Yes □ No
6. Historical viable air sampling of location reviewed?			□ Yes □ No
7. Procedures reviewed (check all that apply): □ Hand Hygiene/Garbing □ Aseptic Technique □ Facility Cleaning □ Other: _____			□ Yes □ No □ N/A
8. Area cleaned?			□ Yes □ No □ N/A
9. Re:est: □ GFS □ MFU □ VAS □ SS		Date:	□ Yes □ No
10. Subsequent to positive □ GFS □ MFU □ SS, employee successfully completes each of the following (place original form in employee record and attach copy to this form):			
	a. Competency assessment for Hand Hygiene and Garbing.		□ Yes □ No □ N/A
	b. Competency assessment for Aseptic Technique.		□ Yes □ No □ N/A
Use the space below to document additional pertinent information (signature required):_____			
Check if microbiological analysis performed □ VAS (mandatory) □ GFS □ MFU □ SS			
Results attached?			□ Yes □ No □ N/A
Based on the results of the microbiological analysis, have additional actions been taken?			□ Yes □ No
If Yes Description of actions taken:_____			
Action Completed by:			Date:
PIC or designee review:			Date:

partell PHARMACY	**Partell Specialty Pharmacy** **5835 S Eastern Ave Ste 101** **Las Vegas, NV 89119-3031**

02-04.01 07/23 Sterile Hazardous Drug and Non-Hazardous Drug Compounding Area Cleaning

Revision History:

I Initiated: 07/23
II Revised:
A

Scope:

I This Policy and Procedure applies to all sterile facility operations.

Purpose:

I To describe, standardize and define the process by which the controlled environments (ISO Class 5, 7, and 8) and the general preparation area are cleaned, disinfected, and maintained in a manner that ensures an environment suitable for compounding sterile preparations.
II To describe, standardize and define the additional processes by which Hazardous Drugs (HDs) are deactivated and decontaminated in the HD preparation area(s).
III To describe, standardize, and define the additional processes by which Sterile Highly Potent and Highly Allergic Drugs are decontaminated in the HD preparation area(s).

Responsibility:

I The Pharmacist-in-Charge or designee is accountable for this P&P being followed.

Policy:

I This policy defines the non-Hazardous Drug cleaning and disinfection of the ISO Class 7 buffer rooms, ISO Class 7/8 ante-areas, Segregated Compounding Areas (SCAs) as well as the associatec Primary Engineering Controls (PECs) such as but not limited to Laminar A r Flow Hocds and Compounding Aseptic Isolators (CAIs).
II This policy defines the Hazardous Drug (HD) cleaning, deactivation, decontamination and disinfection of HD ISO Class 7 buffer rooms, HD ISO Class 7/8 ante-areas, Containment-Segregated Compounding Areas (C-SCAs) as well as Containment-Primary Engineering Controls (C-PECs) such as but not limited to Biological Safety Cabinets (BSCs) and Compounding Aseptic Containment Isolators (CACIs).
III This policy defines the Highly Potent and Highly Allergic drug decontamination of the associated Primary Engineering Controls (PECs) such as but not limited to Laminar Air Flow Hoods and Compounding Aseptic Isolators (CAIs).
IV The facility leadership will designate an appropriate cleaning agent(s) based upon careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.
V Sterile water (sterile water for injection or irrigation) must be used to dilute disinfectant solutions if they will be used inside of the ISO Class 5 areas. Though these areas are not sterile and the buckets/wipes used are not sterile, use of sterile water to dilute disinfectants reduces pyrogens and potential bioburden.
VI The facility leadership will designate an appropriate HD deactivation agent and HD decontamination agent for each HD being utilized in Policy and Procedure 10-20 Hazardous Drug (HD_ Inventory Management.
VII Though the preparation area is not an ISO "classed" environment it is must be kept clean and orderly and is included in the cleaning schedule in this policy.
VIII Ideally, cleaning of the general compounding area (buffer area/clean room and ante-area) should occur at the end of compounding day to prevent any component residue from sitting

overnight and promoting bacterial growth.

IX If cleaning occurs at the start of the compounding day, adequate time must be given to allow all cleaned surfaces to dry PRIOR to starting any compounding activity.

X If any compounding occurs during after-hours conditions (on-call situation), additional cleaning may occur at the start of the next business day.

XI Cleaning and disinfection of the controlled environments will not be performed while compounding is taking place.

XII Facility compounding personnel must ensure that cleaning is being performed properly and by personnel who have been adequately trained on this policy as well as on Hand Hygiene and Garbing.

XIII Facility compounding personnel must also ensure that cleaning in the HD area is being performed properly and by personnel who have been adequately trained on this policy as well as on Hazardous Hand Hygiene and Garbing.

XIV Cleaning of the buffer area/clean room, segregated compounding area, and ante-area may be performed by trained custodial/housekeeping personnel.

XV Custodial/housekeeping personnel may not clean ISO Class 5 PECs.

XVI All personnel who perform cleaning and disinfecting functions in the non-HD areas must successfully complete both of the following and in this order:

- A Competency Assessment: Hand Hygiene and Garbing
- B Competency Assessment: Cleaning and Disinfecting

XVII All personnel who perform cleaning, deactivation, decontamination and disinfecting functions in the HD area must also successfully complete the following and in this order:

- A Competency Assessment: Hazardous Drug Hand Hygiene and Garbing
- B Competency Assessment: Hazardous Drug Aseptic Technique
- C Competency Assessment: Hazardous Drug Cleaning, Deactivation, Decontamination and Disinfecting
- D Hazardous Drug Risk Acknowledgement Form

XVIII Cleaning equipment and supplies

- A Shall be stored in a designated area to ensure segregation from compounding supplies.
- B Materials used (wipers, sponges, mops, etc.) must be non-shedding and preferable composed of synthetic micro fibers.
- C Materials used must be dedicated to use in particular areas (buffer area/clean room, ante-area/room, segregated compounding area, etc.) and will not be moved from these areas except for disposal.
- D Floor mops may be used in both the buffer area/clean room and the ante-area/room as long as they are used in that order.
- E Ideally all cleaning tools are to be discarded after one use.
- F For any reusable cleaning equipment:
  1. Hang mops vertically to promote drying when not in use
  2. Buckets must be inverted and allowed to dry.
  3. Manufacturer's instructions on the product used must be followed to ensure that the effectiveness of the device is maintained and that repeated use does not add to the bioburden of the areas cleaned.

XIX Since disinfectant solutions are irritants and can damage the skin and eyes, the Personal Protective Gowning and Gloving must be followed which stipulates safety glasses must be worn when compounding and during cleaning of ceiling and walls.

XX Material Safety Data Sheets must be readily available for reference in the facility for all disinfectants used in the cleaning and disinfecting process.

XXI Tacky Mats:

A Must be placed at the entrance to controlled areas within the compounding area to remove debris from personnel and equipment as they enter these areas.

B The PIC or designee will determine the location of the tacky mats depending on workflow and room configuration.

C Tacky mats must be changed frequently as they become soiled. Frequency of the mat change is determined by organizational policy but no less frequently than daily and change may be required more frequently depending on need.

XXII Any compounding equipment (i.e., automated compounders, devices, or pumps) placed into ISO Class 5 PECs are subject to the same cleaning requirements as the LAFW and BSC itself.

XXIII If any equipment or device used to compound sterile preparations is removed from the ISO Class 5 buffer area/clean room, it must be properly cleaned and disinfected prior to being placed back into service within that environment.

Note: There is no scientific basis at the time of this policy writing to suggest that alternation of cleaning agents is necessary. The possibility of producing germicidal resistant microorganisms does not apply to cleaning of controlled environments.

General Information:

I Environmental contact is a major source of microbial contamination of CSPs, therefore scrupulous attention to cleaning and disinfecting of the areas used for sterile compounding is required to reduce and minimize this potential source of CSP contamination.

II The cleaning sequence will be from the cleanest environment progressing to the dirtiest. The PECs will be cleaned first, the SEC area second, the buffer area third, ante-area fourth and the non-classes prep areas.

III Proper HD deactivation and decontamination will limit exposure to HDs in the compounding environment.

Applicable Documents:

I	05-C1	Orientation, Training and Competency Evaluation of Compounding Personnel
II	05-C2	Aseptic Technique Overview
III	05-C3	Universal Precautions
IV	05-04	Hand Hygiene and Garbing
V	05-11	Hazardous Drug Orientation, Training and Competency
VI	06-11	Hazardous Drug Compounding
VII	10-20	Hazardous Drug (HD) Inventory Management

Applicable Forms:

I	02-04A	Cleaning Solution Preparation Log
II	02-04B	Sterile Daily/Weekly/Monthly Cleaning and Maintenance Log for Preparation Area(s) and Ante Area(s)
III	02-04C	Sterile Three Time Cleaning of Controlled Environments
IV	05-01A	Competency Assessment: Hand Hygiene and Garbing
V	05-01D	Competency Assessment: Cleaning and Disinfecting Sterile Area(s)
VI	05-11A	Competency Assessment: Hazardous Drug Hand Hygiene and Garbing
VII	05-11B	Competency Assessment: Hazardous Drug Aseptic Technique
VIII	05-11C	Competency Assessment: Hazardous Drug Cleaning, Deactivation, Decontamination and Disinfecting
IX	05-11D	Hazardous Drug Risk Acknowledgement Form

X 10-20A Hazardous Drug (HD) Inventory Management

Materials and Equipment

I Plastic/stainless steel buckets with rounded edges into which mops fit or appropriate size sprayer bottle/s (if a bucket less system is used)
II Plastic/stainless steel mop handles suitable for mop heads used
III Low particulate shedding cellulose mops (reusable) or disposable micro-fiber mop heads
IV Low particle shed wipes
V Appropriate disinfectant agent
VI Sterile 70% IPA
VII HD Deactivation Agent
VIII HD Decontamination Agent

Procedures:

I The Personal Protective Gowning and Gloving procedures will be followed which stipulates safety glasses must be worn.
  A Gloves must be worn while cleaning walls and ceilings.
  B Prior to beginning cleaning
    1 Staff will gather supplies needed.
    2 Adequate amounts of the designated disinfectant are prepared by carefully mixing the cleaning solutions.
    3 Most disinfecting agents must be diluted. Follow manufacturer's recommendations regarding appropriate dilutions.
    4 Fill the bucket or sprayer with the appropriate amount of water then add the correct amount of disinfectant to the water to reduce the likelihood of splashing.
    5 Document the preparation of the cleaning solution on the Cleaning Solution Preparation Log immediately after preparing the solution.
  C If using traditional buckets to perform cleaning, allow the mops to soak in their respective buckets in solution for approximately five (5) minutes prior to the start of cleaning.
  D Cleaning must occur from the cleanest to the dirtiest areas. The lowest class room or environment (i.e., ISO Class 5) must be cleaned before the ISO Class 7 buffer area/clean room followed by the ISO Class 7/8 ante-area then general preparation area.
  E General consideration when cleaning floors
    1 Clean floors after the ISO Class 5 areas, counters and other easily cleanable work surfaces have been cleaned and disinfected.
    2 Begin at the location farthest from the buffer area/clean room entrance working toward the exit to avoid walking over cleaned areas.
    3 Move any rollable carts, shelving and chairs as cleaning is accomplished.
    4 Perform necessary restocking or other in room activities prior to cleaning and floor washing so that buffer area/clean room may be exited and allowed to dry and remain at rest until the next shift.
  F No high particle shedding materials may enter the buffer area/clean room. This includes corrugated cardboard. Paper documents (i.e., compounding worksheets and order forms) are allowed, but should be kept to a minimum.
  G No worksheets or order forms may enter the PEC environment at any time.
  H Document the cleaning procedure with initials and date on the appropriate log immediately upon completion of the task to insure proper documentation.
II Cleaning, Deactivation, Decontamination and Disinfecting of the HD PEC will be performed prior

to General Cleaning and Maintenance. The steps are described in 06-11 Hazardous Drug Compounding.

III Daily Cleaning and Maintenance of the Controlled Environments:

A Perform Cleaning and Maintenance in the following order:

1 Clean/Sanitize the inside surfaces of ISO Class 5 PECs per applicable policy.

2 Discard all trash.

3 Clean/Sanitize the Waste Receptacle(s)

4 Clean/Sanitize Counters and easily cleanable work surfaces in the clean room/buffer area (stool tops, metro cart shelves, etc. (including underside, legs and feet/wheels)).

5 Wipe down equipment

6 Mop floors in the buffer area/clean room from farthest point away from the door progressing toward the door to the ante-area while moving carts and shelving.

7 Counters sink and easily cleanable work surfaces in the ante-area as long as those areas are on the "clean side" of the line of demarcation.

8 Counters and easily cleanable work surfaces in the ante-area/room beyond the line of demarcation ("dirty side").

9 Mop floors in the ante-area/room from the clean room/buffer area entrance to the exit door.

10 Perform any required daily activities related to cleaning the general preparation area as required.

IV Weekly Cleaning and Maintenance of the Controlled Environments:

A Perform Cleaning and Maintenance in the following order:

1 Discard all trash.

2 Clean/Sanitize the Waste Receptacle(s)

3 Clean/Sanitize the ceiling

4 Clean/Sanitize the walls

5 Clean/Sanitize the Storage Units

a All storage bins must have contents removed; bins cleaned inside and out, allowed to dry and contents replaced.

b All surfaces in room including doors, door handles, pass throughs, permanent shelving, etc.

6 Clean/Sanitize the inside surfaces of ISO Class 5 PECs

7 Clean/Sanitize Counters and easily cleanable work surfaces in the clean room/buffer area (stool tops, metro cart shelves, etc. (including underside, legs and feet/wheels)).

8 All surfaces of moveable carts, storage shelving and stools;

9 Wipe down equipment

10 Clean/Sanitize floors in the buffer area/clean room from farthest point away from the door progressing toward the door to the ante-area while moving carts and shelving.

11 Counters, sink and easily cleanable work surfaces in the ante-area as long as those areas are on the "clean side" of the line of demarcation.

12 Counters and easily cleanable work surfaces in the ante-area/room beyond the line of demarcation ("dirty side").

13 Clean/Sanitize floors in the ante-area/room from the clean room/buffer area entrance to the exit door.

14 Perform any required daily activities related to cleaning the general preparation area as required.

15 Mop Floors

V Monthly Cleaning and Maintenance of Controlled Environments:

A Monthly cleaning includes all of the elements of the week y and monthly cleaning plus additional activities in the following order:
1 Discard all trash.
2 Clean/Sanitize the Waste Receptacle(s)
3 Clean/Sanitize the ceiling
4 Clean/Sanitize the walls
5 Clean/Sanitize Compounding Equipment
6 Clean/Sanitize the Storage Units
a All storage bins must have contents removed; bins cleaned inside and out, allowed to dry and contents replaced.
b All surfaces in room including doors, door handles, pass throughs, permanent shelving, etc.
7 Clean/Sanitize the inside surfaces of ISO Class 5 PECs
8 Clean/Sanitize Counters and easily cleanable work surfaces in the clean room/buffer area (stool tops, metro cart shelves, etc. (including underside, legs and feet/wheels)).
9 Clean/Sanitize the Storage Units
10 Clean/Sanitize Drug Product Refrigerator
11 Clean/Sanitize Drug Product Freezer
12 Clean/Sanitize floors in the buffer area/clean room from farthest point away from the door progressing toward the door to the ante-area while moving carts and shelving.
13 Counters, sink and easily cleanable work surfaces in the ante-area as long as those areas are on the "clean side" of the line of demarcation.
14 Counters and easily cleanable work surfaces in the ante-area/room beyond the line of demarcation ("dirty side").
15 Clean/Sanitize floors in the ante-area/room from the clean room/buffer area entrance to the exit door.
16 Perform any required daily activities related to cleaning the general preparation area as required.

VI Routine Cleaning of the General Preparation Area:
A Though not part of the controlled environments, cleanliness and order is required in the General Preparation Area.
B The PIC or designee will stipulate how and when the general area is to be cleaned.
C Document cleaning on the Cleaning Log for General Preparation Area

VII Three-time Cleaning of Controlled Environments:
A Three-time cleaning may be performed when the following conditions occur:
1 After action levels are exceeded during environmental monitoring air or surface sampling procedures.
2 After any maintenance work performed in the clean room that would compromise environmental integrity.
B Three-time cleaning will include ~~a~~ using sporicidal agent Peridox RTU with a 3 minute dwell time ~~used according to its manufacturer's instructions allowing this agent to have sufficient contact time. (i.e., bleach / sporacide / bleach)~~

VIII Floor Refinishing:
A No Wax Floors:
1 These floors are never to be waxed in any circumstance.
B Wax Floors:

1 The floors of the buffer area/clean room and ante-area shall be stripped of their existing finish (depending on floor type) and refinished by qualified personnel on an as needed basis.
2 The PIC or designee determines when this should occur.
3 Generally, stripping anc refinishing is required more often on older floors. Newer floor materials may not need this treatment.
4 The materials utilized will be of such composition as to not compromise the integrity of the controlled environment and should be manufactured for the expressed purpose of maintenance of the type of flooring which has been installed.

partell PHARMACY	Partell Specialty Pharmacy 5835 S Eastern Ave Ste 101 Las Vegas, NV 89119-3031

02-04C.01 07/23 Three Time Cleaning of Controlled Environments Log

Cleaning MUST include all items on the Daily/Weekly/ Monthly Cleaning Log

Month:	Year

Sterile Water	Bleach	Volume of solution required should be mixed using the table of proportions.
1 L	20 mL	
2 L	40 mL	
5 L	100 mL	

Cleaning Details	# of Buckets	Signature of person preparing cleaning solutions	Signature if person(s) performing cleaning
1st Cleaning ~~Preempt Plus~~~~Sterile Water~~ ____ ~~L and~~ ~~Bleach ___ mL~~ Date: _____			
2nd Cleaning ~~Sterile Water ____ L and~~ ~~SporaKlenz® RTU ___~~ ~~mL~~Peridox RTU Date: _____			
3rd Cleaning ~~Sterile Water ____ L and~~ ~~Bleach ___ mL~~70% Sterile IPA Date: _____			

PIC or Designee Review: _____ Date: _____

08-10.01 mm/yy Cold Chain Timely Delivery Standards

Revision History:
I Initiated: mm/yy
II Revised:
A

Scope:
I This Policy and Procedure applies to all facility operations.

Purpose:
I The pharmacy shall supply or deliver drug products to patients in a safe manner that ensures the integrity of the products.
II This policy outlines the responsibilities of the facility to properly package and ship timely all medications in compliance with prevailing statues, rules, and regulations.
III This policy ensures mail order delivery time standards are met for medications which are not picked up directly from the facility.

Responsibility:
I The Pharmacist-in-Charge or designee is responsible for ensuring compliance with this policy and procedure.

Policy:
I The Pharmacist-in-Charge shall establish standards for packaging materials, packing processes, and methods use for the safe transportation of these medications.
II After the medication is compounded, labeled, and checked by a pharmacist, it shall be stored in proper conditions, i.e., refrigerated, if needed until ready for packing. This will allow the temperature of the product to reach the optimal storage temperature for maximum dating.
III The Pharmacist-in-Charge shall establish a clear training process for all employees who pack and ship medications from the facility to assure that these medications are properly handled while under the control of the facility.
A This training will include the handling of refrigerated and frozen pharmaceuticals.
IV The Dispensing Pharmacist shall assure that:
A The medication prepared for shipment from the facility is suitable for such transport.
B The medication is properly labeled and has the requisite labelling for safe use.
1 This labelling must include instructions for inspection by the patient or caregiver upon recipient, for the following actions:
a To be taken in the event that the medication does not arrive at their destination on time.
b When there is evidence that the integrity of the medication was compromised during shipment or delivery.
c What to do in case of any suspected or apparent damage to the medication.

General Information:
I

Definitions:
I For purposes of this policy, a "temperature excursion" means any deviation from the manufacturer's specifications or, in the absence of manufacturer specifications, applicable USP standards.

Applicable Document(s):
I USP <1079> Good Storage and Distribution Practices for Drug Products
II USP <659> Packaging and Storage Requirements

Applicable Form(s):
I 08-10A Shipping Log

Materials and Equipment:
I Appropriate packaging supplies (e.g., cushioned envelope, small boxes, packaging paper, bubble wrap)

II Computer system to include printer
III Courier company's contact information
IV Designated bin/area set up appropriately for prescriptions to be shipped
V Ice packs (for possible storage and/or shipping)
VI Patient's information (address, phone number)
VII Shipping labels

Procedure:

I The Dispensing Pharmacist shall perform all requisite checks and assure that the medication is released for final dispensing to the patient.
II The Dispensing Pharmacist will include in the package all requisite patient information leaflets, and clear instructions to the recipient how to easily detect improper storage or temperature variation, and instructions how to report the storage or temperature excursion to the facility.
III The facility staff will pack the medication using prescribed shipping materials according to established policy:
  A Prepackaging:
    1 Confirm prescription(s) and all correspondence are together. Correspondence can include bit are not limited to the following:
      a Pamphlet(s)
      b Patient information leaflet(s)
      c Offer to Counsel statement sheet
  B Insurance-
    1 If package contents exceed $100 verify with pharmacist-in-charge whether or not to insure the package.
  C Shipping Label-
    1 Create the shipping label.
    2 Confirm the following on the label:
      a Return Address has the pharmacy address. This may be excluded for security reasons.
      b The name on the prescription label matches the shipping label.
      c The address on the shipping label matches the patient's profile.
      d The package is being sent according to the shipping policy.
  D Packaging:
    1 Room temperature (Non-refrigerated) medications-
      a Ensure the prescription is tightly closed and spill proof. All liquid items should be sealed.
      b Ensure all requisite labelling, and patient leaflets will be contained within a clean plastic zip-bag.
      c The medication will then be packaged in a suitable sized cushioned mailing envelope, cardboard box, or other approved mailing container.
      d Affix the shipping label to the package.
    2 Refrigerated medications-
      a Ensure the prescription is tightly closed and spill proof. All liquid items should be sealed.
      b Ensure all requisite labelling, and patient leaflets will be contained within a clean plastic zip-bag.
      c A proper amount of frozen chemical ice blocks will be added to the medication package.
      d The medication will then be packaged in a suitable sized cushioned mailing envelope, cardboard box, or other approved mailing container.
      e Affix the shipping label to the package.

Note: When using courier, refrigerated items need to be sent at least for delivery within 2 days. When possible, overnight shipping is recommended.

Temperature-sensitive items are not shipped over the weekend unless authorized by the pharmacist and the patient knows to expect the shipment over the weekend.

E Document the completion of the shipping process.

F Place items to be shipped in a designated area after packaging is completed.

G Shipping Confirmation:

1 If required by the patient

a Notify the patient when they may expect their prescription.

b Request that the patient notify the pharmacy if the prescription is not received at the expected time.

Documentation:

I Common carrier label & tracking document(s) [paper or electronic]

II Variance reporting if an OOS occurs on a delivery.

08-10A.01 mm/yy Shipping Log

Shipping Date	Shipping Time	Rx Number	Patient Name	Shipping Address	Courier	Initials	Delivery Problem Information

September 22, 2023

FDA 483 responses for Partell Pharmacy 5835 South Eastern Ave., Suite 101 Las Vegas NV 89119 for FDA form 483 issued 03/08/2018.

Mark Sedar, Chief Operating Officer Nevada State Board of Pharmacy, 985 Damonte Ranch Pkwy, Suite 206, Reno, NV 89521 Office: 775-850-1440 Email: msedar@pharmacy.nv.gov

RE: Partell Pharmacy Herein referred to as "Partell" or Partell Specialty Pharmacy Las Vegas, NV

Chief Operating Officer Mark Sedar:

Pursuant to instructions by Lucila B. Nwatu, Investigator/CSO and Juanita P. Versace, Microbiologist, we respectfully submit our responses to FDA form 483 which was issued as a result of a recent FDA inspection of our premises. During the inspection of Partell Specialty Pharmacy Las Vegas, NV, Partell engaged cooperatively and constructively with FDA. We would like to assure FDA that Partell is committed to providing patients with the highest quality compounded medications prepared in compliance with all applicable standards and that, as demonstrated herein, we take our professional responsibilities very seriously.

To that end, patient safety and wellbeing are our primary concerns, and we strive to and do provide the highest quality preparations and services. Our quality assurance and standard operating procedures ("SOPs") follow demonstrated pharmacy best practices and are designed to produce high-quality compounded sterile preparations. We do this to ensure that we continue to meet recognized State pharmacy requirements and other standards applicable to compounding pharmacies, so that our patients can continue to access high-quality compounded medications to meet their individual medical needs.

Notwithstanding these and the other numerous actions described herein, Partell would like to take this opportunity to briefly discuss FDA's inspection of and application of Form 483 to Partell. Specifically, Partell is a Nevada state licensed pharmacy that compounds and dispenses human medications that, where appropriate, comply with Section 503A of the Federal Food, Drug, and Cosmetic Act ("Section 503A"). Accordingly, Partell engages in pharmacy-based compounding pursuant to the guidelines set forth by the Nevada State Board of Pharmacy and the United States Pharmacopeia ("USP"), which are the recognized standards for Nevada -based compounding pharmacies. Moreover, Partell has an impeccable safety record

concerning the compounded medications that it prepares according to the applicable standards.

Considering the above, without waiving its right to contest FDA's application of CGMPs, Partell provides the following responses to the Observations set forth in the 483.

OBSERVATION 1

The filter intended to render final product sterile is not adequate to accomplish sterilization and/or is not pharmaceutical grade.

Specifically,

a. Your firm uses the Vacuum Filter, Stericup (Millipore) sterile filter, when compounding large volume batches of sterile finished product. The Stericup does not appear to be pharmaceutical grade and the labeling for the Stericup states "Do not use these systems in direct patient care applications." There is no integrity testing method for the Vacuum Filter, Stericup (Millipore) sterile filter. The firm releases finished drug product without determining the suitability of the filter. Examples of products where the Stericup has been used as the sterilizing filter are Coenzyme Ql0, Ascorbic acid, and Vitamin B Complex.

Response:

We acknowledge your observation. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs to review the sterile filter selection including volume capacity and filter integrity testing.

b. There is no assurance that the bubble point testing of filters used to render drug products sterile is adequate to ensure the integrity of such filters. Your firm was unable to confirm what required minimum pressure is used when performing integrity testing on sterilizing filters. There is a discrepancy between the required minimum pressure written in the bubble point test log and the manufacturers requirement. For example, the log states '38psi' required for the PES-50 filter, yet the manufacturer requires 50 psi. Your firm does not document the actual value in the Formula Worksheet and simply enters "PASS or FAIL".

Response:

See previous response.

OBSERVATION 2

The cycle parameter (temperature, pressure, and time) used for heat sterilization of products intended to be sterile are not verified to be lethal to heat-resistant microorganisms.

Specifically,

a. Your firm performs all compounding and filling operations for terminally sterilized pellet products in an unclassified Biosafety Cabinet, located in an unclassified room. Pellet products include: • Estradiol, 10mg, 12.5mg, 15mg, 20mg, 25mg, 35mg, 40mg, 50mg, 55mg Pellets • Naltrexone, 200mg Pellets • Pregnenolone, 50mg, 100mg Pellets • Progesterone, 50mg Pellets • Testosterone/Anastrozole 120/8mg; 180/12mg; 200/20mg; 60/1mg; 60/4mg Pellets • Testosterone/Estradiol 60/6 mg Pellets • Testosterone 100 mg, 200 mg, 25 mg, 37.5 mg, 40 mg, 50 mg, 55 mg, 80 mg Pellets • Testosterone/ Finasteride 60/5 mg, 80/8mg Pellets • Testosterone/ Finasteride/Anastrozole 120/10/4 mg Pellets

Response:

We acknowledge your observation. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs to ensure a Biological Indicator is used with each sterilization cycle. The preparations worksheet will include the results of this test.

b. Your firm uses the Hirayama HV-25 Autoclaves for both terminal sterilization and sterilization of container closures, such as stoppers and final product vials. Effectiveness of Steam Sterilization is verified using Sporview Self-Contained Biological Indicators. The manufacturer recommends incubation conditions of 55°C to 60° C for a minimum of 24 hours. Biological Indicator dry block incubator is not calibrated to ensure the temperature can maintain 55-60°C for 24 hours. The dry block does not contain a visual thermometer to monitor the temperature during BI incubation.

Response:

We acknowledge your observation. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs to follow the manufacturer's recommendations including utilization of the dry block.

c. Your firm conducts terminal sterilization on sealed vials containing pellet products, using an autoclave cycle of 121 °C for 20 minutes. There is no adequate scientific justification for the autoclave cycle used to terminally sterilize implantable pellets, including consideration of heat penetration into the container closure and the pellets themselves. There is no assurance that 121 °C for 20 minutes is adequate for pellets in sealed containers.

Response:

We acknowledge your observation. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs for the pellet sterilization process, which will be reviewed to determine the appropriate temperature and cycle time for compounded pellets.

OBSERVATION 3

The final containers/closures used for drug products intended to be sterile have not been sterilized or depyrogenated.

Specifically,

a. Your firm does not depyrogenate the non-sterile stoppers and vials before conducting filling operation for all aseptically filled drug products.

Response:

We acknowledge your observation. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs to ensure the purchase of presterilized vials and stoppers.

b. Your firm does not depyrogenate the non-sterile stoppers and vials before conducting filling operation for all terminally sterilized pellet drug products.

Response:

See previous response.

OBSERVATION 4

Disinfecting agents and cleaning pads or wipes used in the ISO 5 area are not sterile.

Specifically,

To clean and disinfect the ISO-5 Laminar Air Flow Hood (LAFI·I), the firm uses non-sterile PolySat Wipers, nonsterile Alpha Wipe Dry Wipes, non-sterile Opti-cide 3, non-sterile Spor-Klenz, and sterile 70% Isopropyl Alcohol spray.

Response:

We acknowledge your observation. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs to improve our compounding process. Partell Pharmacy will change its standard process to include the use of sterile, non-shedding (low-lint) wipes, and this practice will now exceed USP General Chapter <797> guidance.

OBSERVATION 5

The use of sporicidal agents in the cleanrooms and/or ISO 5 areas is inadequate.

Specifically,

Your firm has not established sufficient contact time for all disinfectants to be used in the cleanroom. Your firm failed to follow manufacturer's recommended contact times for the disinfectants used in the controlled environments. For example, for non-sterile sporicidal agent Spor-Klenz, the manufacturer recommends a contact surface time of 30 minutes. Your daily cleaning/disinfecting log for controlled environments and procedure, does not indicate contact times. The pharmacy Lab Manager and Technicians confirmed that after spraying Spor-Klenz on the surface, the solution is immediately removed. Demonstration of the effectiveness of the cleaning operations was not assessed due to lack of established contact times.

Response:

We acknowledge your observations. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs Policy to specify the type of Sporicide and subsequent contact time required to achieve sporicidal effect.

OBSERVATION 6

You produced hazardous drugs without providing adequate cleaning of utensils to prevent cross-contamination.

Specifically,

Your firm uses non-dedicated glassware and utensils to weigh and mix non-sterile hazardous and non-hazardous ingredients, in preparation for aseptic filling operations. Examples of hazardous ingredients used in your facility include Testosterone Cypionate and Alprostadil.

Response:

We acknowledge your observations. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs to prevent cross-contamination or mix-ups.

OBSERVATION 7

Non-sterilized or non-depyrogenated tools or temporary containers are used in sterile production.

Specifically,

Your firm uses glassware and utensils to weigh and mix non-sterile ingredients, in preparation for aseptic filling operations. Your firm does not adequately clean the glassware and utensils to prevent cross-contamination. Glassware, spatulas, and mixing bars are washed in a dishwasher using Reverse Osmosis water. Your firm has not conducted any testing (microbialand analytical) of the water generated through your reverse osmosis (RO) system. The glassware is placed in an oven for approximately 20 minutes at 90°C. There is no assurance that these conditions sterilization or depyrogenation these materials prior to use in compounding sterile drug products.

Response:

We acknowledge your observations. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs. The policy and procedure will be updated to adequately address the cleaning of glassware and utensils to prevent cross contamination of utensils in preparation of aseptic filling operations.

OBSERVATION 8

Environmental monitoring in your aseptic processing areas is not adequate.

Specifically,

a. Review of the last biannual Environmental Monitoring report, dated 11/30/17, revealed that Micrococus species and Aspergillus were detected when viable air sampling was conducted in the IS0-5 Laminar Air Flow Hood. As a corrective action, your firm performed cleaning three times in the controlled environment, and air sampling was repeated. An investigation was not conducted and a root cause was not determined.

Response:

We acknowledge your observation. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs. The policy and procedure will require an investigation as to the cause of the issue. Staff will be re-educated, and our employees will document they are following the Policy and Procedure.

b. Monthly surface sampling is part of the firm's Environmental Monitoring program. Surface samples are taken with EnviroTest Media Paddles, immediately after spraying sterile 70% Isopropyl Alcohol on the surface.

Response:

We acknowledge your observation. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs, which will be designed to re-educate our employees on obtaining monthly surface sampling. Spraying sterile 70%IPA is to occur immediately after obtaining the sample not before.

OBSERVATION 9

Inadequate pressure differentials between higher quality air rooms and lower quality air rooms were observed.

Specifically,

a. Sterile drug filling is conducted inside the ISO 5 core of Laminar Air Flow Hood (LAFH). The evaluation of unidirectional airflow (e.g., smoke studies) for microbiological contamination was not performed under dynamic conditions in the ISO 5 LAFH, which is located in an ISO 7 environment.

Response:

We acknowledge your observation. All cleanroom certification tests are obtained under dynamic conditions.

b. During filling operations, we observed that the doors from the ISO 8 compounding room to the ISO 7 Ante room, and the door from the ISO 7 Ante-Room to the ISO 7 aseptic filling room, did not stay consistently closed. We heard multiple alarms during the aseptic

filling due to loss in pressure. The firm cannot assure continuous positive pressure during filling operations.

Response:

We acknowledge your observation. We have replaced the offending doors with sliding doors that do not open due to the air pressure.

OBSERVATION 10

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically,

Biannual media fill testing is performed but is not designed to simulate firm's routine aseptic operation.

a. Your firm conducts Media Fill in liquid filled bags versus vials. A commercially purchased kit containing 100 ml flexible container ofTSB (Tiyptic Soy Broth), 20 ml vial ofTSB, and a 3 ml ampule of red TSB, are used to conduct media fills. The content of the ampule is injected into the 20 ml vial of TSB. 1 ml of this solution is injected into the 100 ml TSB bag. This procedure is repeated 19 times. This does not simulate their filling process. The bag is not representative of the container/closures used during routine production.

Response:

We acknowledge your observation. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs a procedure will be updated to reflect the compounding process.

b. When filling large batch-size sterile products, the firm uses a fluid dispensing pump. For example, the fluid dispensing pump is used during filling of Methylcobalamin, 12.Smg/ml injection, whose batch size is 3000ml into 50 ml vials or 500ml into 5 ml vials. This pump is not included during the media fill simulation.

Response:

We acknowledge your observation. The Pharmacist in Charge and/or the Compliance Officer will develop policies and procedures, which will be incorporated into revised SOPs to perform a media fill simulation for the pump.

10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-State	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Closed door, long term care	☐ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☒ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Med-Plus Pharmacy, Inc.

Physical Address: 760 Arrow Grand Circle

City: Covina State: CA Zip: 91722

Mailing Address (if different from physical address): 2900 NW 60th Street

City: Fort Lauderdale State: FL Zip: 33309

Telephone: 866-463-3757 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 877-363-3757 Contact Email: ghunt@polarisrx.com

Website: www,medplusltc.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Albert Won

Supervising/Managing Pharmacist NV Pharmacist Registration #: 19452

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Madonna E. Anwer	NV Pharmacist Registration #: 22196
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Polaris Pharmacy Services of California LLC

Corporation/Organization Name: Med Plus Pharmacy

Mailing Address: 760 Arrow Grand Circle

City: Covina State: CA Zip: 91722

Telephone: 888-222-8405 Email: ccruz@polarisrx.com

Contact Person Name: Carlos M. Cruz

* Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Med Plus Pharmacy. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

David Rombico

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/12/22

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, DAVID ROMERO hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO (title) for MED PLUS PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 12 day of Oct, 20 22

Notary Public

IVOR STEWART
MY COMMISSION # GG 318665
EXPIRES: April 2, 2023
Bonded Thru Notary Public Underwriters

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DAVID ROMBRO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

10/12/22

Date

Board Use Only	Date Received: 11-2-22	Amount: 500.00 CK-137121

MedPlus Pharmacy
760 Arrow Grand Circle
Covina, CA 91722

Phone:	(866) 463-3757
FEIN:	06-1643725
State Rx Lic:	PHY58706
Owned by:	Polaris Pharmacy Services of Los Angeles, LLC (100%)
Parent:	Polaris Pharmacy Services of California, LLC (100%)
Manager:	David W. Rombro
Officers:	David W. Rombro (CEO), Robert Meyer (CFO), Steven Baker (COO)

Polaris Pharmacy Services of California, LLC

Owned by:	Polaris Pharmacy Services, LLC (100%)
Manager:	David W. Rombro
Officers:	Jason Liu (President), David W. Rombro (CEO), Robert Meyer (CFO)

Licensed Name: **MedPlus Pharmacy**

760 Arrow Grand Circle
Covina, CA 91722

Phone: (866) 463-3757
FEIN: 06-1643725
State Rx Lic: PHY58706

- Owned by: Med-Plus Pharmacy, Inc.
    - *which is owned by*: Polaris Pharmacy Services of Los Angeles, LLC (100%)
        - *which is owned by*: Polaris Pharmacy Services of California, LLC (100%)
            - *which is Owned by*: Polaris Pharmacy Services, LLC (100%)

Director (of Med-Plus Pharmacy, Inc.): David W. Rombro

Officers (of Med-Plus Pharmacy, Inc.): David W. Rombro (CEO), Robert Meyer (CFO), Steven Baker (COO)

Polaris Pharmacy Services, LLC

FEIN: 47-4098540

Owned by: Da Pharmacy Guys, LLC (22.03%), Enhanced Medical Services (24.30), EJJ Pharma, LLC (24.30%), and PPGRX North Carolina, LLC (29.37%).

Managers: David W. Rombro, Daniel Galbut, Harold Sussman

Officers: David W. Rombro (CEO), Robert Meyer (CFO), Steven Baker (COO)

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: California

Parent Company if any: Med-Plus Pharmacy, Inc.

Mailing Address: 760 Arrow Grand Circle

City: Covina State: FL Zip: 91722

Telephone: 8664633757 Fax: 8773633757

Contact Person: Carlos M. Cruz. Ccruz@polarisrx.com

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) (Please see attached)
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 105,263.16

3) What was the price paid per share? $578.00 per share

4) What date did the corporation actually receive the cash assets? 8/31/2022

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday X am _____ pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours X

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

California Secretary of State
Electronic Filing

FILED
Secretary of State
State of California

Corporation - Statement of Information

Entity Name: MED-PLUS PHARMACY, INC.

Entity (File) Number: C2480380
File Date: 05/28/2021
Entity Type: Corporation
Jurisdiction: CALIFORNIA
Document ID: GT63990

Detailed Filing Information

1. Entity Name: MED-PLUS PHARMACY, INC.

2. Business Addresses:
   a. Street Address of Principal Office in California: 760 Arrow Grand Circle
   Covina, California 91722
   United States of America

   b. Mailing Address: 760 Arrow Grand Circle
   Covina, California 91722
   United States of America

   c. Street Address of Principal Executive Office: 760 Arrow Grand Circle
   Covina, California 91722
   United States of America

3. Officers:
   a. Chief Executive Officer: Jason Y Liu
   760 Arrow Grand Circle
   Covina, California 91722
   United States of America

   b. Secretary: Jason Y Liu
   760 Arrow Grand Circle
   Covina, California 91722
   United States of America

Document ID: GT63990

California Secretary of State
Electronic Filing

Officers (cont'd):

c. Chief Financial Officer:

Jason Y Liu
760 Arrow Grand Circle
Covina, California 91722
United States of America

4. Director:

Jason Y Liu
760 Arrow Grand Circle
Covina, California 91722
United States of America

Number of Vacancies on the Board of Directors: 0

5. Agent for Service of Process:

Jeffery Petersen
12526 High Bluff Drive #300
San Diego, California 92130
United States of America

6. Type of Business: Long Term Care Pharmacy

By signing this document, I certify that the information is true and correct and that I am authorized by California law to sign.

Electronic Signature: Jason Liu

Use bizfile.sos.ca.gov for online filings, searches, business records, and resources.

Document ID: GT63990

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	MED-PLUS PHARMACY, INC.
Entity No.:	2480380
Registration Date:	08/09/2002
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of July 18, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 130660622

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 58706

NAME: MED-PLUS PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

760 ARROW GRAND CIR
COVINA CA 91722
LOS ANGELES COUNTY

ISSUANCE DATE

AUGUST 31, 2022

EXPIRATION DATE

AUGUST 1, 2024

CURRENT DATE / TIME

JULY 10, 2023
9:14:26 AM

LICENSE RELATIONSHIPS

NAME: MED-PLUS PHARMACY

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY

LICENSE NUMBER: 101776 **PRIMARY STATUS:** CLEAR

ADDRESS :
760 ARROW GRAND CIR
COVINA CA 91772
LOS ANGELES COUNTY

NAME: LEW, FLYNN HAY

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 37120 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

BOARD OF PHARMACY

LICENSING DETAILS FOR: LSC 101776

NAME: MED-PLUS PHARMACY

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR

ADDRESS

760 ARROW GRAND CIR
COVINA CA 91772
LOS ANGELES COUNTY

ISSUANCE DATE

AUGUST 31, 2022

EXPIRATION DATE

AUGUST 1, 2024

CURRENT DATE / TIME

JULY 10, 2023
9:15:11 AM

LICENSE RELATIONSHIPS

NAME: MED-PLUS PHARMACY

LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)

LICENSE NUMBER: 58706 **PRIMARY STATUS:** CLEAR

ADDRESS :
760 ARROW GRAND CIR
COVINA CA 91722
LOS ANGELES COUNTY

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

LICENSE NO. PHY 58706
RECEIPT NO. 31810432

VALID UNTIL AUGUST 01, 2024

MED-PLUS PHARMACY
760 ARROW GRAND CIR
COVINA CA 91722

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

)7/05/23
)7/05/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PHY

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 2/24/2022 Inspector: Marc Gasca

Firm: MED-PLUS PHARMACY INC Phone: (866) 463-3757

Address: 760 ARROW GRAND CIR City: COVINA Zip: 91722

Ownership: CORPORATION

Permit #: LSC101617 PHY57929 Permit Exp: 4/1/2022 DEA#: FM2431928 DEA Exp: 1/31/2023

Date of Self Assessment Form: 4/15/2021 Other Permit #: N/A Date of DEA Inventory: ___

Hours M-F: 24Hr Hours Saturday 24Hr Hours Sunday: 24Hr

PIC FLYNN H LEW RPH37120 Administrator ___

RPH Consultant ___

Staff	RPH Name:	License #:	Staff Name:	License #:
	AUDREY T SHING (IV PHAR	RPH52382	GEMMA B LAGASCA (IV SUP	TCH14700
	TIFFANY L NGUYEN (CMPD)	RPH58015	HERIBERTO M MEJIA (CMP	TCH54638
			KEVIN CONTRERAS (CMPD)	TCH93207
			MARTIN J CHOW (CMPD)	TCH89903
			MATTHEW L MENA (CMPD)	TCH145888
			NATHAN L RAMIREZ (CMPD)	TCH140701

Inspector Remarks:

Hybrid sterile compounding license renewal inspection

- ***Request for several documents for renewal of LSC 101617 was sent to PIC Flynn Lew on 1/24/2022 and***
- ***Documents were received on 2/4/2022, reviewed remotely***
- ***Inspection conducted in person at the facility on 2/24/2022, assisted remotely and onsite by PIC Flynn Lew (contact email: flynn.lew@medplusltc.com; contact phone number: 866-463-3757)***

General Information

Retail, closed-door pharmacy exclusively servicing skilled nursing facility patients.

- Compounding Self-Assessment: completed by PIC Lew on 6/8/2021
- Community Pharmacy/Hospital Outpatient Self-Assessment: completed by PIC Lew on 4/15/2021
- Original pharmacy and sterile compounding licenses/renewals posted: Verified
- Pharmacy Law Waivers: None used at this time, per PIC Lew
- FDA, DEA, and/or accreditation inspections w/ applicable reports issued within past 12 months: None to report per PIC Lew
- Adverse drug reactions in the past 12 months: None to report, per PIC Lew
- Previous CA Board of Pharmacy Inspection Report
  - Reviewed previous inspection report for previous corrections or written notice of noncompliance, previous noncompliance issues: Correction issued on 3/11/2021 pharmacy inspection report (PHY 58159), facility in compliance.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Sterile Compounding Area

No changes to the physical layout of the sterile compounding area, nor any changes to compounding equipment in the past 12 months per PIC Lew

Observed the following during the in-person inspection on 2/24/2022:

ISO 8 Ante Room (+ pressure) => ISO 7 Non-HD Cleanroom (+ pressure)

- **Positive pressure ISO 8 Ante Room**
  - Line of demarcation (LOD) at entry point of ante room, separating dirty and clean side
  - Sink with H/C water (hand hygiene station) on the clean side of LOD
  - Storage rack x 3
  - Non-shed wipes and designated cleaning supplies
- **Positive Pressure ISO 7 Non-HD Clean Room**
  - ISO 5 laminar flow hood
  - Storage cart x 2
  - Pass-through, leading to general pharmacy area

- **Types of Compounding/Risk Levels:**
  - No changes in types of CSPs compounded at the facility in past 12 months, per PIC Lew
  - Sterile to sterile
  - Non-hazardous CSPs only
  - Risk Level: Low-Medium

Certification/Testing of Primary and Secondary Engineering Controls

Certification performed by CleanRoom Services on 8/3/2021:

- **ISO 8 Ante Room (+ Pressure)**
  - Non-viable particle count testing performed under dynamic conditions, passing based on ISO14644-1:2015 Class 8/CAG-003-2006 testing standards
  - Room Air Exchange Rate (ACPH) = 48 ACPH (Minimum = 20 ACPH)
  - Positive pressure differential = 0.076 inches w.c. (Minimum = 0.02 inches w.c.)
  - Viable air sampling: Sample showed no growth, in compliance with USP <797> standards
  - Viable surface sampling: Sample showed no growth, in compliance with USP <797> standards
- **ISO 7 Non-HD Clean Room (+ Pressure)**
  - Non-viable particle count testing performed under dynamic conditions, passing based on ISO14644-1:2015 Class 7/CAG-003-2006 testing standards
  - Room Air Exchange Rate (ACPH) = 102 ACPH (Minimum = 30 ACPH)
  - Positive pressure differential = 0.0393 inches w.c. (Minimum = 0.02 inches w.c.)
  - Viable air sampling: Sample showed acceptable level of growth, in compliance with USP <797> standards
  - Viable surface sampling: Sample showed no growth, in compliance with USP <797> standards
- **Unidirectional Flow Hood (ISO 5) in Non-HD Clean Room**
  - Make: Nuaire/Model: NU-240-630/Serial Number: 201026091720
  - Airborne particle count testing performed under dynamic conditions, passing based on CAG-003-2006/ISO14644-1 Class 5 testing standards
  - Smoke study: Reviewed
  - Viable air sampling: Sample showed no growth, in compliance with USP <797> standards
  - Viable surface sampling: Sample showed no growth, in compliance with USP <797> standards

- **Most Recent Certification performed by CleanRoom Services on 2/2/2022 (reviewed onsite)**
  - Dynamic testing, non-viable air sampling, HEPA filter leak testing, air changes, smoke study (viewed), viable air/surface sampling: Reviewed

Policies and Procedures

- Annual review of policies and procedures, documented on 7/1/2021
- No new and/or updated sterile compounding policies and procedures within the past 12 months, per PIC Lew
- Policies and procedures: Reviewed
  - Cleaning and maintenance of ISO-classified areas
  - Hand hygiene and garbing
  - Refrigerated Drug Storage
  - Actions to be taken when action levels for colony-forming units (CFUs) are exceeded

Recordkeeping

- Master formula/compounding record
  - Reviewed for CSP name/strength, manufacturer/lot number/expiration date of each ingredient, equipment, necessary quality review, instructions for storage and handling of CSP, BUD
- Refrigerator/incubator/room temperature logs: reviewed for December 2021, January 2022
- Pressure differential logs: reviewed for December 2021 and January 2022
- Cleaning logs reviewed for December 2021, January 2022 for all ISO classified areas
  - Cleaning agents used: PeridoxRTU, PREempt RTU, sIPA
- Discussed monthly supervisor review of sterile compounding logs

Labeling Requirements

- *"Compounded by pharmacy"* on label: Verified
- Beyond use date: Verified
- Telephone number of pharmacy: Verified
- Name and strength of each active ingredient: Verified
- Instructions for storage, handling, and administration: Verified

Sterile Compounding Attire

- Low shedding coverall/gown, head cover, face mask, shoe covers: Available
- Sterile gloves and persistently active, alcohol-based hand cleanser: Available

Training/Competency

- Pharmaceutical calculations, gloved fingertip sampling, media fill testing, observational skills assessments (hand hygiene/garbing, cleaning/disinfection, aseptic technique): Reviewed for RPH Shing and TCH Mejia

Quality Assurance

- End-product potency and sterility testing performed by ARL
  - Reviewed potency and sterility results for Magnesium Sulfate 3gm/L injection (Lot #60323615), final results on 11/4/2021 and 11/16/2021 (respectively)

To complete this inspection, please provide a response to Order of Correction to Inspector Marc Gasca via email (marc.gasca@dca.ca.gov) **no later than 3/4/2022.**

Licensee Remarks:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) Flynn

Pharmacist (print) Flynn Lew

Inspector (sign) M. L.

Inspector (print) Marc Gasca

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 2/24/2022 Permit #: LSC101617

Time of Day: 10:31 AM

Name as shown on permit: **MED-PLUS PHARMACY INC**

Address: 760 ARROW GRAND CIR City: COVINA

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. CCR 1735.3(a)(2)(	Recordkeeping for Compounded Drug Preparations . For each compounded drug preparation, the pharmacy records shall include: A compounding log consisting of a single document containing all of the following: A pharmacy-assigned unique reference or lot number for the compounded drug preparation. Specifically, the pharmacy's compounding log did not contain a pharmacy-assigned unique reference or lot number.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) M.L.L. Signed Flynn

Inspector (print) Marc Garcia Print Name Flynn Lew

Date 2/24/22 Title PIC

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

Compound Worksheet

[redacted] MURRIETA-THE SPRINGS(11) ROOM # S301B PAGE: 1

@ 1155am

RX NUMBER : 07825582 RX DATE : 02/25/22
DRUG DISP : C-DAPTOMYCIN 400MG/50ML N QTY DISPENSED: 1
PHARMACIST: HA, CELESTE HEIGHT :
DOCTOR : S. GOUNDER WEIGHT : .00 lbs
ALLERGIES : AMOXICILLIN,MORPHINE,DEMEROL,PENICILLINS,GLUTEN
Prepared : 02/04/22 By:RPh:AS Tech:MJC Compound Lot#: 07825582 022522

Compound Name.. C-DAPTOMYCIN 400MG/50ML N

	Drug NDC	Description	Amount/Conc	M/U	Lot Number	Filler Init	Checker Init
1)	63398-0413-11	DAPTOMYCIN 500 MG VIAL	.80	VIA	AMY110		
	Manufacturer: DR.REDDY/S LAB						
	Expiration Date: 2/27						
2)	00338-0049-11	SOD CHLORIDE 0.9% INJ	50	ML	PU1809U6		
	Manufacturer: BAXTER HEALTHCA						
	Expiration Date: 2/27						
3)	00338-0049-04	SOD CHLORIDE INJ 0.9%(EXC)	10	ML			
	Manufacturer: BAXTER HEALTHCA						
	Expiration Date:						

nformation

ype: Compound
roup:

Total Amount: 60.80
Label Quantity:
Label Unit: BAG
Expiration Days: 2
Use By: 02/27/22

Category 1: IV
Category 2: IVG
Category 3:
Category 4:
Category 5:
Category 6:

otes:
OSE: 8ML=400MG

QUIPMENT:ISO 7 IV CLEAN ROOM,ISO 5 IV HOOD

UPPLIES:10 ML SYRINGE,NEEDLE, ALCOHOL SWAB

LEAN ROOM GEAR: BOUFFANT CAP, MASK, GOWN,
TERILE GLOVES, SHOE COVERS

ROCEDURES:

OMPLETE IV COMPOUNDING RECORD SHEET. PHARMACIST
O VERIFY DOSE AND CALCULATIONS. INSPECT VIALS

Piggyback Worksheet

[redacted] GORDON LANE CARE CENTER (ROOM # 2019A PAGE: 1

RX NUMBER : 07848399 RX DATE : 02/25/22
DRUG DISP : C-CEFTAZIDIME 500MG/50ML QTY DISPENSED: ok 3
PHARMACIST: HA, CELESTE HEIGHT :
DOCTOR : B. JANSARI WEIGHT : .00 lbs
ALLERGIES : DILAUDID,LIPITOR
Prepared : 02/23/22 By:RPh:MSY Tech:MJC Compound Lot#: 07848399022522

@ 1650 Am

Piggyback Name.. C-CEFTAZIDIME 500MG/50ML

Drug NDC	Description	Dose	D/U	X Factor =	Volume	V/U	Lot Number	Filler Init	Checker Init
63323-0127-20	CEFTAZIDIME 1 GM VIAL	2		1.0000 2		VIA	109982		P
Manufacturer: SAGENT PHARMACE									
Expiration Date: 9/23									
00338-0049-11	SOD CHLORIDE 0.9% INJ	200		1.0000 200		ML	P413040		P
Manufacturer: BAXTER HEALTHCA									
Expiration Date: 7/24									
00409-7118-07	STERILE WATER FOR INJECTION	40		1.0000 40		ML	P377553		P
Manufacturer: HOSPIRA/ICU MED									
Expiration Date: 10/24									

Δ 2/28/22

nformation

ype: Piggyback
roup:

Total Volume: 242
Label Volume:
Label Unit: BAG
Expiration Days: 3
Use By: 02/28/22

Category 1: IVG
Category 2: IV
Category 3:
Category 4:
Category 5:
Category 6:

otes:
ECONSTITUTE 1GM OF FORTAZ WITH 10ML SW, SHAKE
IAL GENTLY TO FORM SOLUTION. WITHDRAW AND INJECT
ML INTO NS 50ML BAG. SUPPLIES: 5ML SRYINGE, 18G
EEDLE EQUIPMENT: ISO 7 CLEAN ROOM AND ISO 5 IV
OOD STORAGE: KEEP UNDER REFRIGERATION AND DIS

dministration information

chedule:
low Rate:

Route: 404817000
Access:
Dosage: 11

Date/Time Tracking: N
Last Date: 00/00/00
Last Time:

Authorized:
Dispensed:

P413096
Lot
0.9%
Sodium Chloride
MED-PLUS PHARMACY LTC
760 ARROW GRAND CIRCLE
COVINA, CA 91722
866-463-3757
SAGENT PHARMACE
4.0000 REFILL
E CARE CENTER (
ANSARI
2019A
GLC
0716
RF: 03
GLC
REORDER
RX # 7848399
500MG/50ML
After: 02/28/22
C-CEFTAZIDIME 500MG/50ML
NDC# 25021-0127-20
Mfg: SAGENT PHARMACE
LOT#:

2798

MED-PLUS PHARMACY INC
760 ARROW GRAND CIR
COVINA, CA 91722-2147

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM0338740	01-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	06-01-2021

MED-PLUS PHARMACY INC
760 ARROW GRAND CIR
COVINA, CA 91722-2147

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM0338740	01-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	06-01-2021

MED-PLUS PHARMACY INC
760 ARROW GRAND CIR
COVINA, CA 91722-2147

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Med-Plus Pharmacy

Pharmacy/Wholesaler License # (if applicable): PHY 58706

Physical Address: 760 Arrow Grand Circle

City: Covina State: CA Zip: 91722

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 866-463-3757 Website: www.polarisrx.com

Licensing Company Email: ghurd@polarisrx.com

Section 2: Personal Information

First: Flynn Middle: Last: Lew

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☒ F ☐ X

Mailing Address: 760 Arrow Grand Circle

City: Covina State: CA Zip: 91722

Telephone: 866-463-3757 x1999 Email: flynn.lew@medplusllc.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
USC SCHOOL OF PHARMACY		9/1978-6/1982	
Address	**City**	**State**	**Zip**
1985 Zonal Ave.	Los Angeles	Ca	90089
Diploma/Degree obtained, if any			
Pharm.D.			

School Name		From - To (MM/YY – MM/YY)	
USC		9/1976-6/1978	
Address	**City**	**State**	**Zip**
925 W. 34th St.	Los Angeles	Ca	90089
Diploma/Degree obtained, if any			
none			

School Name		From - To (MM/YY – MM/YY)	
Van Nuys High School		9/1972-6/1976	
Address	**City**	**State**	**Zip**
6535 Cedros Ave.	Van Nuys	Ca	91411
Diploma/Degree obtained, if any			
High School diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1982 TO PRESENT	[redacted]ELKWOOD ST.	WEST HILLS	CA	91304
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Med-Plus Pharmacy			From - To (MM/YY – MM/YY): 7/2019- present
Business Address: 760 Arrow Grand Circle	City: Covina	State: Ca	Zip: 91722
Phone: (866) 463-3757	Title: Pharmacist-In-Charge		Number of Employed Hours: 40hr/week
Description of Duties: Pharmacist-In-Charge			

Business Name: Skilled Nursing Pharmacy			From - To (MM/YY – MM/YY): 1/2014-7/2019
Business Address: 900 Western Ave.	City: Glendale	State: Ca	Zip: 91201
Phone: (818) 553-8273	Title: Pharmacist-In-Charge		Number of Employed Hours: 40hr/week
Description of Duties: Pharmacist-In-Charge			

Business Name: Skilled Nursing Pharmacy			From - To (MM/YY – MM/YY): 10/2017-7/2019
Business Address: 16666 E. Johnson Dr.	City: City of Industry	State: Ca	Zip: 91745
Phone: (800) 519-4767	Title: Chief Compliance Officer		Number of Employed Hours: 40hr/week
Description of Duties: CCO activites for the corporate entity.			

Business Name: Omnicare Canoga Park			From - To (MM/YY – MM/YY): 2006-1/2014
Business Address: 8220 Remmet Ave.	City: Canoga Park	State: Ca	Zip: 91304
Phone: (818) 746-9800	Title: Pharmacist-In-Charge		Number of Employed Hours: 40hr/week
Description of Duties: Pharmacist-In-Charge			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Flynn Lew, **certify that as the designated representative for**

MedPlus Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. FL I am at least 21 years of age;
3. FL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. FL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. FL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. FL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. FL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Flynn Lew

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/20/2023

Date

I, Flynn Lew, **certify that as the designated representative for**

MedPlus Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. FL I am at least 21 years of age;
3. FL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. FL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. FL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. FL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. FL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Flynn Lew

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/20/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Flynn Lew

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/20/2023

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Flynn Lew, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/20/23

Date

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfullness, accuracy, or validity of that document.

Subscribed and Sworn to before me this 20th day of July - 2023.

Notary Public Signature

STATE OF CALIFORNIA COUNTY OF Los Angeles

Subscribed and sworn to (or affirmed) before me on this 20 day of July, 2023 by Flynn Lew proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

(Signature of Notary)

ADY SIMION
Notary Public - California
Los Angeles County
Commission # 2325475
My Comm. Expires Apr 24, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler MedPlus Pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable) PHY58706

Physical Address 760 Arrow Grand Circle

City Covina State CA Zip 91722

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 866-463-3757 Website www.MedplusLTC.com

Licensing Company Email ccruz@polarisrx.com

Section 2: Personal Information

First Steven Middle Randall Last Baker

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]N Ocean Blvd, Unit [redacted]

City Pompano Beach State FL Zip 33062

Telephone (800) 589-9747 Email SBaker@polarisrx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Medical College of Virginia		08/89-06/92	
Address	City	State	Zip
410 N 12th St.	Richmond	VA	23298
Diploma/Degree obtained, if any			
B.S. Pharmacy			
School Name		From - To (MM/YY – MM/YY)	
Southwest Virginia Community College		08/87-06/89	
Address	City	State	Zip
635 Community College Rd	Cedar Bluff	VA	24609
Diploma/Degree obtained, if any			
Associates Degree			
School Name		From - To (MM/YY – MM/YY)	
Richlands High School		08/84-06/87	
Address	City	State	Zip
8100 Richlands Highway	Richlands	VA	28574
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22-02/23	[redacted]N Ocean Blvd., Apt [redacted]	Pompano Beach	FL	33062
12/21-02/22	[redacted]SE 2nd Ave., Apt [redacted]	Delray Beach	FL	33443
03/20-12/21	[redacted]NE 5th Ave., Apt [redacted]	Delray Beach	FL	33483
02/19-03/20	[redacted]W Camino Real	Boca Raton	FL	33486
11/17-02/19	[redacted] Port Royale Dr. S	Fort Lauderdale	FL	33308
08/15-11/17	[redacted]SE 5th Ave.	Fort Lauderdale	FL	33301
06/10--6/16	[redacted] Match Point Pl	Lithia	FL	33547
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Polaris Pharmacy Services, LLC			08/15-Current	
Business Address		**City**	**State**	**Zip**
2900 NW 60th Street		Fort Lauderdale	FL	33309
Phone	**Title**			
954-919-1818	Chief Operating Officer			
Description of Duties				
Oversee Pharmacy Operations, Sales, Consulting, Nurses				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4,5,6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
3/19/2019	12/8/2021	MN	St Louis Park	Hennepin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
5500000183739893		MN Board of Pharmacy		
Reason/Charge				
Please see attached				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Polaris Pharmacy Services of Minnesota LLC				

Provide explanation below:

Please see attached

Original Signature (electronic, copies or stamps not accepted)

12/19/2022
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Steven Baker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/19/2022

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, Steve Baker, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/19/2022

Date

Subscribed and Sworn to before me this 19 day of Dec 2022.

Notary Public Signature

IVOR STEWART
MY COMMISSION # GG 318665
EXPIRES: April 2, 2023
Bonded Thru Notary Public Underwriters

(Seal)

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY,** and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: MedPlus Pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable): PHY58706

Physical Address: 760 Arrow Grand Circle

City: Covina State: CA Zip: 91722

Mailing Address (if different from physical address): 2900 NW 60th Street

City: Ft Lauderdale State: FL Zip: 33309

Telephone: 866-463-3757 Website: www.MedplusLTC.com

Licensing Company Email: ccruz@polarisrx.com

Section 2: Personal Information

First: Daniel Middle: Last: Galbut

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] N 49th Avenue

City: Hollywood State: FL Zip: 33021

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nova SouthEastern University		10/10 - 10/14	
Address	City	State	Zip
3301 College Ave	~~Davie~~ Ft. Lauderdale	FL	33314
Diploma/Degree obtained, if any			
Masters in Business			

School Name		From - To (MM/YY – MM/YY)	
Sy Syms School of Business/ Yeshiva University		01/99 - 01/03	
Address	City	State	Zip
500 W. 185th St.	NY	NY	10033
Diploma/Degree obtained, if any			
Bachelors			

School Name		From - To (MM/YY – MM/YY)	
Hebrew Academy		Birth - 06/98	
Address	City	State	Zip
2400 Pine Tree Drive	Miami Beach	FL	33140
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/2020-current	[redacted] Woodland Lane	Ft. Lauderdale	FL	33312
2004-2020	[redacted] N. 49th Ave	Hollywood	FL	33021
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Onyx Healthcare Consulting LLC				
Business Address	**City**	**State**	**Zip**	
1000 Gates Ave, 5th Floor	Brooklyn	NY	11221	
Phone	**Title**			
718-852-7000	Director of special projects / Gov't affairs.			

Description of Duties

Director of Special Projects - Govt affairs

Business Name			From - To (MM/YY – MM/YY)	
Hebrew Homes Management Services			10/08 - 09/21	
Business Address	**City**	**State**	**Zip**	
1800 NE 168th street suite 200	NMB	FL	3316	
Phone	**Title**			
	Director of Operations /			

Description of Duties

Healthcare Administrative duties, Oversaw general ops on a Macro level

Business Name			From - To (MM/YY – MM/YY)	
Enhanced Medical Services			06/15 - current	
Business Address	**City**	**State**	**Zip**	
4770 Biscayne Blvd suite 1400	Miami	FL	33137	
Phone	**Title**			
305-674-4848	Manager			

Description of Duties

Healthcare ventures / Management.

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

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Phone	Title		
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Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4,5,6 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
3/19/2019	12/8/2021	MN	St Louis Park	Hennepin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
5500000183739893		MN Board of Pharmacy		
Reason/Charge				
Please See Attached				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Polaris Pharmacy Services of Minnesota LLC				

Provide explanation below:

Please see Attached

Original Signature (electronic, copies or stamps not accepted)

12/15/22
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel Galbut

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/15/22

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, Daniel Galbut, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/16/22

Date

Subscribed and Sworn to before me this 16th day of December 2022.

Laran D Williams

Notary Public Signature

LARAN DETRELL WILLIAMS
Notary Public, State of Florida
Commission# GG 355566
My comm. expires July 16, 2023
(Seal)

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

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c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

4

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler MedPlus Pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 760 Arrow Grand Circle

City Covina State CA Zip 91722

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 866-463-3757 Website www.MedplusLTC.com

Licensing Company Email ccruz@polarisrx.com

Section 2: Personal Information

First Abraham Middle _____ Last Galbut

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Pinetree Drive

City Miami Beach State FL Zip 33140

Telephone [redacted] Email Agalbut@hudcap.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Miami Law School		09/73-01/76	
Address	City	State	Zip
1320 S. Dixie Hwy.,	Coral Gables	FL	33146
Diploma/Degree obtained, if any			
J.D.			
School Name		From - To (MM/YY – MM/YY)	
New York University		09/69-06/73	
Address	City	State	Zip
	New York	NY	10012
Diploma/Degree obtained, if any			
B.A>			
School Name		From - To (MM/YY – MM/YY)	
Mesivta of Greater Miami		09/66-06/69	
Address	City	State	Zip
4000 ALton Road	Miami,i Beach	Fl	33140
Diploma/Degree obtained, if any			
High School Deploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/01 To Present	[redacted] Pinetree Drive	Miami Beach	Fl	33140
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Galbut Walters & Associates LLP			6-76 to present
Business Address	**City**	**State**	**Zip**
4770 Biscayne Blvd. Suite 1400	Miami	Fl	33137
Phone	**Title**		
786-245-2302	Senior partner and principal		
Description of Duties			
Attorney			

Business Name			From - To (MM/YY – MM/YY)
NKW Properties LTD a Florida limited partnership			01/12 to present
Business Address	**City**	**State**	**Zip**
4770 Biscayne Blvd. Suite 540	Miami	FL	33137
Phone	**Title**		
786 245 2302	Principal and President of General partner		
Description of Duties			
Real estate and business Holding company for many different business and real estate holding companies,			

Business Name			From - To (MM/YY – MM/YY)
Enhanced Medical Services LLC.			2015 to present
Business Address	**City**	**State**	**Zip**
4770 Biscayne Blvd. Suite 1400	Miami	FL	33137
Phone	**Title**		
786 245 2302	Manager and president		
Description of Duties			
Investment and Holding company with interest in pharmacy company.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4& 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

from 2008 through 2011 i was sued by lenders and banks arising out of my ownership and interest in Hudson Capital, LLC, a real estate development company. All cases were either dismissed, resolved or settled with no personal judgments being entered against me.

2022 . My Law Firm and I are currently defendants in a malpractice lawsuit wherein a former client claiming that my firm failed to properly warn him of potential wire fraud. The former client received false wire instructions and wired funds to unknown parties. This matter is currently pending and being defended by my insurance company.

Original Signature (electronic, copies or stamps not accepted)

12/6/22
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Abraham Galbut

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/06/22

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami Dade

I, Abraham A Galbut, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/06/22

Date

Subscribed and Sworn to before me this 06 day of December 2022

Danielle Martin

Notary Public Signature

DANIELLE MARTIN
Notary Public - State of Florida
Commission # HH 217598
My Comm. Expires Jan 18, 2026
Bonded through National Notary Assn.

(Seal)

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Med-Plus Pharmacy

Pharmacy/Wholesaler License # (if applicable): PHY 58706

Physical Address: 760 Arrow Grand Circle

City: Covina State: CA Zip: 91722

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 866-463-3757 Website: www.polarisrx.com

Licensing Company Email: ghunt@polarisrx.com

Section 2: Personal Information

First: Flynn Middle: Last: Lew

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☑ F ☐ X

Mailing Address: 760 Arrow Grand Circle

City: Covina State: CA Zip: 91722

Telephone: 866-463-3757 x1999 Email: flynn.lew@medplusltc.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
USC SCHOOL OF PHARMACY		9/1978-6/1982	
Address	**City**	**State**	**Zip**
1985 Zonal Ave.	Los Angeles	Ca	90089
Diploma/Degree obtained, if any			
Pharm.D.			

School Name		From - To (MM/YY – MM/YY)	
USC		9/1976-6/1978	
Address	**City**	**State**	**Zip**
925 W. 34th St.	Los Angeles	Ca	90089
Diploma/Degree obtained, if any			
none			

School Name		From - To (MM/YY – MM/YY)	
Van Nuys High School		9/1972-6/1976	
Address	**City**	**State**	**Zip**
6535 Cedros Ave.	Van Nuys	Ca	91411
Diploma/Degree obtained, if any			
High School diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1982 TO PRESENT	[redacted]ELKWOOD ST.	WEST HILLS	CA	91304
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Med-Plus Pharmacy				From - To (MM/YY – MM/YY): 7/2019- present
Business Address: 760 Arrow Grand Circle		City: Covina	State: Ca	Zip: 91722
Phone: (866) 463-3757	Title: Pharmacist-In-Charge			Number of Employed Hours: 40hr/week
Description of Duties: Pharmacist-In-Charge				

Business Name: Skilled Nursing Pharmacy				From - To (MM/YY – MM/YY): 1/2014-7/2019
Business Address: 900 Western Ave.		City: Glendale	State: Ca	Zip: 91201
Phone: (833) 353-8273	Title: Pharmacist-In-Charge			Number of Employed Hours: 40hr/week
Description of Duties: Pharmacist-In-Charge				

Business Name: Skilled Nursing Pharmacy				From - To (MM/YY – MM/YY): 10/2017-7/2019
Business Address: 16666 E. Johnson Dr.		City: City of Industry	State: Ca	Zip: 91745
Phone: (800) 519-4767	Title: Chief Compliance Officer			Number of Employed Hours: 40hr/week
Description of Duties: CCO activites for the corporate entity.				

Business Name: Omnicare Canoga Park				From - To (MM/YY – MM/YY): 2006-1/2014
Business Address: 8220 Remmet Ave.		City: Canoga Park	State: Ca	Zip: 91304
Phone: (818) 746-9800	Title: Pharmacist-In-Charge			Number of Employed Hours: 40hr/week
Description of Duties: Pharmacist-In-Charge				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			Number of Employed Hours:
Description of Duties:				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Flynn Lew, **certify that as the designated representative for**

MedPlus Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. FL I am at least 21 years of age;
3. FL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. FL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. FL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. FL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. FL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Flynn Lew

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/20/2023

Date

I, Flynn Lew, **certify that as the designated representative for**

MedPlus Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. FL I am at least 21 years of age;
3. FL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. FL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. FL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. FL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. FL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Flynn Lew

Print Name (First, Last)

FL

Original Signature (electronic, copies or stamps not accepted)

07/20/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Flynn Lew

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/20/2023

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Flynn Lew, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/20/23

Date

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfullness, accuracy, or validity of that document.

Subscribed and Sworn to before me this 20th day of July - 2023

Notary Public Signature

STATE OF CALIFORNIA COUNTY OF Los Angeles
Subscribed and sworn to (or affirmed) before me on this 20 day of July, 2023 by Flynn Lew
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

(Signature of Notary)

ADY SIMION
Notary Public - California
Los Angeles County
Commission # 2325475
My Comm. Expires Apr 24, 2024

(Seal)

10B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-State	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Non-sterile Compounding
	☐ Location Change *	☐ Internet	☐ Sterile Compounding
	☐ Name Change*	☐ Nuclear	☒ Mail-Order Service
		☐ Other:	☐ Off-site Cognitive Services
	* If making a change, provide license #:		☐ Long Term Care
			☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Seven Hills Pharmacy, LLC

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 513-771-0367 Toll Free # (NAC 639.708, NRS 639.23286): 844-643-0169

Fax: 513-771-0369 Contact Email: compliance@truepill.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Spitzer ✓

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21780 ✓

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Christopher Spitzer	NV Pharmacist Registration #: 21780
Name: Christopher Gibson	NV Pharmacist Registration #: 22645
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Postmeds, Inc.

Corporation/Organization Name: Seven Hills Pharmacy LLC

Mailing Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Telephone: 650-353-5495 Email: compliance@truepill.com

Contact Person Name: Loan Nguyen

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager (title) for Seven Hills Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Daniel Simkin

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/9/22

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Daniel Simkin hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager (title) for Seven Hills Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 9th day of December, 20 22

Notary Public

KEITH McGRUDER
COMM# 2293123
Notary Public - California
Los Angeles County
My comm. Expires July 12, 2023

Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)	✓	✓		
• List the top four stockholders and their percent ownership. NRS 639.231(3)	✓	✓		
• List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)		✓		
• For General Partnerships, list the name of each partner. NAC 639.214(2) • For Limited Partnerships, list the names of (NAC 639.214(3)): o All General Partners; o All Limited Partners who hold 10% or more of the interest.			✓	
• Certificate of Corporate Status or Certificate of Good Standing from the Secretary of State's Office where the business is domiciled, dated within the last 6 months.	✓	✓	✓	✓
• Designated Representative Form http://bop.nv.gov/Services/newapps/Business/ must be completed by the Designated Representative. NAC 639.5005. The requirement does not apply to: a. An applicant or a licensee that is a publicly traded corporation; b. An applicant or licensee whose pharmacy is determined by the Board to be located within a large retail store, including, without limitation, a grocery store, variety store or department store under common ownership; or c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• Personal History Record Application http://bop.nv.gov/Services/newapps/Business/ must be completed by: a. For Non-publicly traded - The top 4 shareholder/stockholders. b. For Partnerships - All general partners; all limited partners who hold 10% or more of the interest. c. For Sole Owner - The owner.		✓	✓	✓
• Sterile Compounding Questionnaire must be completed if the pharmacy will provide sterile compounded drugs. Access form at http://bop.nv.gov/Services/newapps/Business/.	✓	✓	✓	✓
• Submit a copy of your most recent pharmacy inspection from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. (REQUIRED FOR NON-NEVADA PHARMACIES ONLY) NRS 639.2328(2)(f)	✓	✓	✓	✓
• Submit a copy of your license, certification, permit or registration issued to your pharmacy from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. (REQUIRED FOR NON-NEVADA PHARMACIES ONLY) NRS 639.2328(2)(a)	✓	✓	✓	✓
• License Verification by the regulatory board or licensing authority of the state or territory in which the pharmacy is located. You may use the License Verification form here: http://bop.nv.gov/Services/newapps/Business/. (REQUIRED FOR NON-NEVADA PHARMACIES ONLY) NRS 639.2238(2)(g)	✓	✓	✓	✓
• Copy of DEA Registration if handling controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)	✓	✓	✓	✓
• Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)	✓	✓	✓	✓
• Transmit Controlled Substance Prescription Data- Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel Simkin

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/9/22
Date

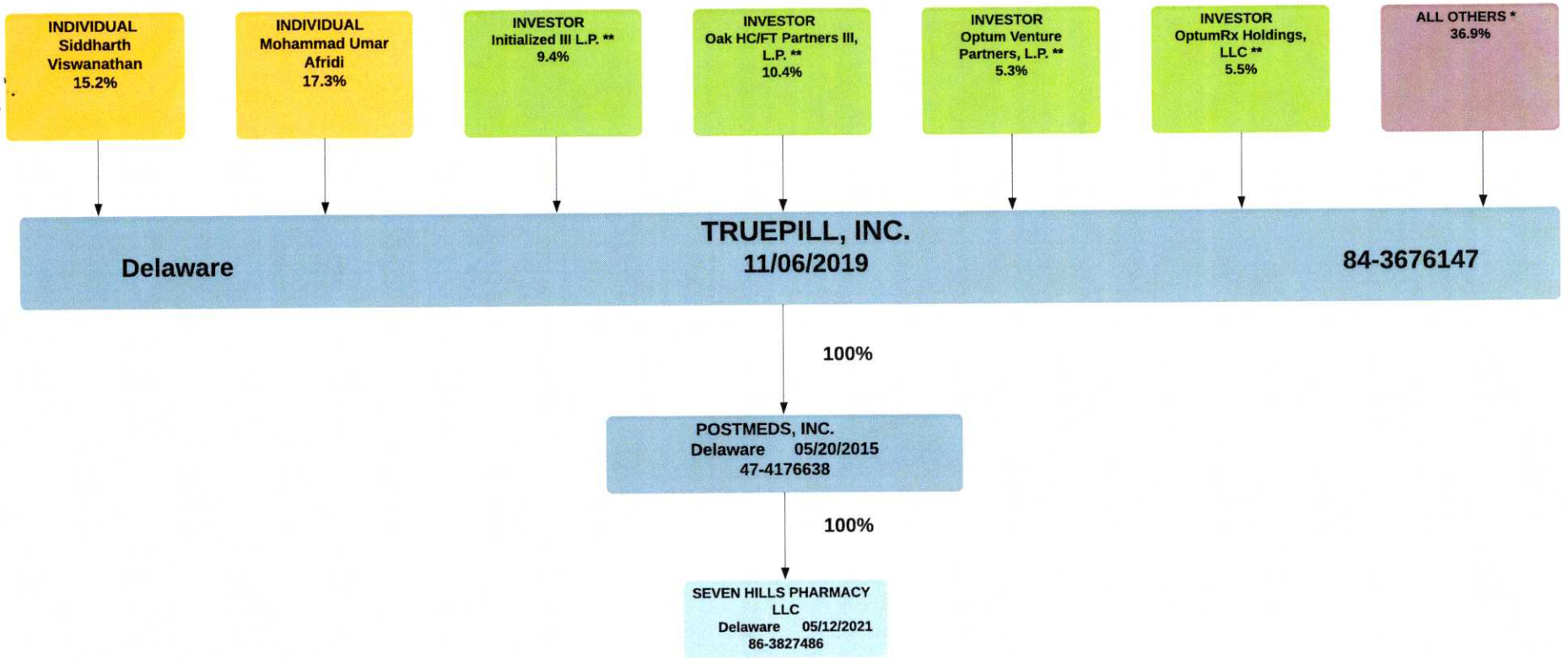
Board Use Only	Date Received: 1·4·23	Amount: 500 cc

1/25/23

Nov 3, 2021 10:06 AM

Seven Hills Pharmacy - Board of Pharmacy ONLY

CONFIDENTIAL! DO NOT DISTRIBUTE TO THIRD PARTIES



*No individual/entity in this group owns > = 3% of Truepill, Inc., and therefore no individul/entity in this group owns > = 5% of the Provider

**No individual owns >= 5% of Truepill, Inc., and therefore no individual/entity in this group owns > = 5% of the Provider

Corporation | Limited Liability Company | Investor | Individual | Other

This organizational chart was prepared by the Legal Team & contains entity name, state of domicile, date of formation & EIN.
For additional details, please contact entities@truepill.com

List of Managers

Name	Title	Business Address	Home Address	Business Phone	Home Phone	SSN	DOB
Daniel Simkin	Manager	3121 Diablo Ave, Hayward, CA 94545	[redacted] Hyperion Ave, Los Angeles, CA 90029	650-353-5495	[redacted]	[redacted]	[redacted]
Siddharth Viswanathan	Manager	3121 Diablo Ave, Hayward, CA 94545	[redacted] Long Bridge Street, Apt 514, San Francisco, CA 94158	650-353-5495			
Mathew Davis-Ratner	Manager	3121 Diablo Ave, Hayward, CA 94545	[redacted]51st Ave S, Seattle, WA 98118	650-353-5495			

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show SEVEN HILLS PHARMACY LLC, a Delaware Limited Liability Company, Registration Number 4684707, was registered in the State of Ohio on May 24, 2021, is currently authorized to transact business in this state.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 11th day of October, A.D. 2022.

Ohio Secretary of State

Validation Number: 202228404922

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 0232000312

Seven Hills Pharmacy Llc

2722 E Kemper Rd
Sharonville, OH 45241-1818
Hamilton County

Terminal - Pharmacy - Category 3

Outpatient Pharmacy Inspection

November 7, 2022

License 0232000312 - Seven Hills Pharmacy Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Sharon Shields
Start 11/7/2022 9:06 AM
End 11/7/2022 11:48 AM

Organization

Name
Seven Hills Pharmacy Llc

License Type
Terminal - Pharmacy - Category 3

Category

License Number
0232000312

Business Type
II - Independent Community Retail (1 Outlet)

DEA Number

Responsible Person
Christopher Spitzer, R.Ph.

Hours of Operation
M-F 9a-5p; Sat/Sun closed

Contact

Address
2722 E Kemper Rd
Sharonville, OH 45241-1818
Hamilton County

Primary Number
(727) 421-8504

Fax Number
(513) 771-0369

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Christpoher Gibson, R.Ph.		Pharmacist	03236967		
Lisa Beth Klein		Certified Pharmacy Technician	09305487	(414) 336-9652	lklein15@gmail.com
Christopher Spitzer, R.Ph.		Responsible Person	03236754		

1) Initial Inspection Information

3) What is the name and current version of the dispensing software being used by the pharmacy?

Observation
Pharmacy uses both Pioneer and TruePill operating system. Operating systems are client specific in their use. Pharmacy is phasing out use of Pioneer.

5) Facility description

Observation
Facility is a retail pharmacy servicing the patients of various online prescriber entities. Pharmacy has the ability to serve the community (walk-in patient). Pharmacy does not accept insurance. Pharmacy has limited drug stock. Pharmacy processes approximately 150 prescriptions per day. Pharmacy employs two pharmacists and one certified pharmacy technician. Pharmacy ships prescriptions to patients in Ohio and in other states using USPS, UPS, and FedEx.

2) * Licensing, Responsible Person and DEA Registration

1) Have there been any changes in the facility's ownership, business name or trade name, category, or address without submitting a new application to the Board?

No

2) Does the responsible person match what is indicated in eLicense?

Yes

3) Does the pharmacy have a valid registration issued by the Drug Enforcement Administration?

Yes

Observation
FS1293884 expires 2/28/2025

3) * Minimum Standards

1) Does the pharmacy have internet access to current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio?

Yes

2) Does the pharmacy have access to the telephone number of a poison control center?

Yes

3) Are the pharmacy's hours publicly posted?

Yes

4) Are all pharmacy staff wearing name tags/badges that include the employee's job title?

Yes

7) Are the library and equipment housed in a suitable, well-lit and well-ventilated room or department and maintained in a clean, sanitary and orderly condition?

Yes

8) Are areas where drugs and devices are stored and prepared dry, well-lit, well-ventilated, and maintained in a clean, sanitary and orderly condition?

Yes

9) Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?

Yes

4) Personnel

1) Are staff working at the pharmacy properly licensed/registered with the Board?

Yes

5) Are certified pharmacy technicians working within their applicable scope of practice?

Yes

8) Are pharmacy support personnel working within their permitted scope?

Not Applicable - No support personnel working or employed during inspection.

Observation
List of support personnel responsibilities: www.pharmacy.ohio.gov/supportres

OAC 4729:3-1-01 (Z)
(1) An individual employed or performing contracted services at a location licensed as a terminal distributor of dangerous drugs, trained to perform clerical duties associated with the practice of pharmacy, including pricing, cashiering, drug purchasing, delivering, scheduling deliveries, answering non-professional telephone inquiries, transportation of dispensed medications within a hospital, documenting and processing third-party billing information for reimbursement, or any other activity as determined by the board.

(2) An individual contracted by a terminal distributor of dangerous drugs to perform drug inventories.

(3) Except for those responsible for the delivery of dangerous drugs, support personnel shall not have unsupervised access to dangerous drugs.

(4) Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee.

(5) Support personnel may have access to or retrieve information from patient records, including a database or patient profile to perform clerical duties associated with the practice of pharmacy. Support personnel shall not enter prescription information into a patient profile.

(6) Support personnel may perform the following:

(a) Transporting dangerous drugs from a loading dock, warehouse or other area that receives shipments from a licensed wholesaler or other person licensed in accordance with section 4729.52 of the Revised Code; and

(b) Stocking and retrieving from inventory non-controlled dangerous drugs that are not dispensed by the pharmacy.

(7) The terminal distributor of dangerous drugs shall be responsible for ensuring all support personnel comply with state and federal requirements to ensure the confidentiality of patient health records.

(8) Stocking of automated drug dispensing units and floor stock with intravenous fluids that are non-controlled dangerous drugs and are not dispensed by an institutional pharmacy.*

(9) Overwrapping/placing in plastic dangerous drugs that have been compounded or dispensed (i.e. appropriately labeled) by a terminal distributor of dangerous drugs.*

(10) Entering demographic and insurance information into a patient's profile.*

10) Drug Purchases

1) Does the licensee maintain complete and accurate records of drugs purchased?

Yes

Observation
Wholesalers:

- McKesson
- TopRx
- Keysource
- Anda

2) Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?

Yes

11) * Security, Control, and Storage of Dangerous Drugs

1) Is a pharmacist providing supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, and all records relating to the distribution of dangerous drugs in the pharmacy?

Yes

3) Are all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control?

Yes

4) Are there any unauthorized persons present in the pharmacy?

No

7) Can the pharmacy be secured by a physical barrier or alarm system?

Yes

Observation
The only change to the barricade since March 2022 inspection was the replacement of the garage-style door. Door was replaced with a metal roll down bay-style door. Door is secured by the alarm system. No other changes to the barricade have been made since inspection in March 2022. Barricade is adequate.

8) Is a licensed pharmacist the only person with access to keys or other methods for accessing the pharmacy?

Yes

10) Does the pharmacy have a secure area only accessible by pharmacists for customers to deposit new or refill prescription orders when the pharmacy is closed?

No - Not applicable

11) Does the pharmacy maintain dangerous drugs or hypodermics outside of the confines of the pharmacy?

No

12) Does the pharmacy provide services by means of a secured drive-through facility?

No

12) Temperature Controls

1) Are refrigerators and/or freezers used for the storage of drugs maintained at the proper temperature?

Yes

Observation
Pharmacy has one refrigerator for vaccine storage. Pharmacy uses TempAlert to monitor the temperature of the refrigerator. Observed refrigerator to be at appropriate temperature. Pharmacy does not have vaccine stock or any refrigerator/freezer drug stock on site at the time of inspection.

2) Does the pharmacy have a policy to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs?

Yes

3) Are refrigerators and freezers use for the storage of drugs free of food or beverage products?

No

13) *Theft or Significant Loss of Drugs and Drug Documents

1) Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?

No

3) REMINDER: Theft or significant loss of dangerous drugs and drug documents.

Observation
REMINDER

A licensee is required to report to the the Board and law enforcement authorities of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to a prescriber, terminal distributor, or drug distributor.

A licensee is required to report, immediately upon discovery, to the Board and law enforcement authorities any theft or loss of uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms (Form 222), written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed.

For more information on reporting, visit: www.pharmacy.ohio.gov/theft

14) * Controlled Substance Inventory

1) Does the licensee conduct an annual inventory of controlled substances?

Yes

Observation
Pharmacy does not have any controlled substance drug stock on site at the time of inspection.
OAC 4729:5-3-07
All Category III licensees must complete an annual inventory even if drugs are not on-site (zero balance). Records of inventories must be maintained for at least three years. Inventories must follow the process for conducting a DEA controlled substance inventory.

16) Drug Collection Receptacles

1) Does the pharmacy operate a drug take back program (i.e. collection receptacle)?

No

17) Drug Samples

1) Does the pharmacy have sample drugs as part its inventory?

No

23) Return to Stock

4) Does the pharmacy use delivery agents?

Yes - Compliant

Observation
Pharmacy uses USPS, UPS, and FedEx. Pharmacy does not return any delivered drugs back to stock for redispensing. All drug stock returned from delivery agents are sent to Inmar for destruction.

8) REMINDER: The contents of a prescription vial or container shall not be returned to the manufacturer's stock bottle.

Observation
REMINDER: The contents of a prescription vial or container shall not be returned to the manufacturer's stock bottle.
OAC 4729:5-5-22 (B)(4)

25) Customized Medication Packaging (Adherence Packaging)

1) Does the pharmacy dispense customized patient medication packages (sometimes referred to as adherence packaging)?

No

27) Charitable Pharmacies

1) Is this pharmacy a charitable pharmacy?

No

31) *Expired/Adulterated Drugs

2) Are there expired/adulterated drugs present in the licensee's active drug stock?

No

33) Prescription Pick-Up Station

1) Does the pharmacy accept prescriptions from pick-up stations or other intermediaries?

No

39) Drug Repository Program

1) Does this pharmacy operate a drug repository program?

No

40) Temporary Removal of Drugs

1) Does the licensee engage in the temporary off-site storage of dangerous drugs?

No

46) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation

The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient.
These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Boar of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (the resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health srevices.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

50) Inspection Affirmation

1) Inspection Affirmation

Observation

As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Christopher Spitzer, R.Ph. _____

(signature)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS1293884	02-28-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-23-2022

SEVEN HILLS PHARMACY LLC
2722 E. KEMPER RD
SHARONVILLE, OH 45241

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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Form DEA-223 (9/2016)

Truepill
CA old license PHY 56100
ME old license MO40002429
NC old license 13413
LA license PHY.007761-NR

Louisiana Board of Pharmacy

The Louisiana Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated May 11, 2022. The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated March 8, 2022. The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

Maine Board of Pharmacy

The Maine Board of Pharmacy notified the pharmacy on March 30, 2022 that its non-resident license was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license on November 2, 2022.

California Board of Pharmacy

The California Board of Pharmacy issued the pharmacy a letter of admonishment CI 2019 84877 dated January 23, 2020, concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy a modified citation and fine CI 2019 78633 dated June 16, 2020, with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy a citation and fine order of abatement CI 2020 89223 dated August 25, 2021, with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2017 78633	TRUEPILL (FORMERLY POSTMEDS INC.), PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059 subd. (a)/Bus. & Prof. Code § 4067 subd. (a)	Furnishing dangerous drugs without a prescription/Internet; Dispensing Dangerous Drugs or Devices without Prescription; No person shall dispense or furnish, or cause to be furnished dangerous drugs...on the internet...without a prescription issued pursuant to a good faith examination	Citation without a fine
Bus. & Prof. Code § 4174	Dispensing on order of nurse practitioner or person of similar status.	Citation without a fine

CONDUCT:

Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Business and Professions Code 4059 (a) states in pertinent part a person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. In conjunction with Business and Professions Code 4067 (a) which states no person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations and (f) for the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242. In conjunction with Business and Professions Code 2290.5 (a) For purposes of this division, the following definitions shall apply: (3) "Health care provider" means either of the following: (A) a person who is licensed under this division. Between 4/1/2018 to 10/31/2018, Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by prescribers who were not licensed in California. Specifically, 2 prescriptions were issued by Nurse Practitioner Jenny Ingle; 9 prescriptions were issued by Dr. Brook Randal; 6 prescriptions were issued by Dr. Jessica Rubino and 4 prescriptions were issued by Dr. Sudhi Trye. These prescribers were not licensed in California at the time the prescriptions were initiated and shipped to a California resident. Postmeds pharmacy dispensed the prescriptions issued by unlicensed prescribers to

California residents in violation of Business and Professions Code 4059 (a) and Business and Professions Code 4067 (a).

Dispensing by Pharmacist Upon Order of Nurse Practitioner: Business and Professions Code 4174 states in pertinent part notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6. Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds without an established protocol in place: Physician's Assistant Leanne Mays issued 8 prescriptions and Physician's Assistant Susan Owen issued 6 prescriptions. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds entering into a protocol after the prescriptions were issued: Nurse Practitioner Joni Gunzburger issued 4,782 prescriptions; Nurse Practitioner Cristin Hackel issued 10,819 prescriptions and Nurse Practitioner Jessica Horwitz issued 4,711 prescriptions. Postmeds Pharmacy dispensed the prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into standardized procedures or protocols as required by Business and Professions Code 4174.

CITATION ISSUED ON: June 16, 2020	**TOTAL AMOUNT OF FINE(S): $0.00**

PAYMENT OF FINE(S) DUE BY: July 16, 2020

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

January 23, 2020

VIA CERTIFIED MAIL

LETTER OF ADMONISHMENT

TRUEPILL
ATTN: MOHAMMAD UMAR AFRIDI, CEO
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2019 84877
TRUEPILL
PHY 56100

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

JURISDICTION: Bus. & Prof. Code § 4315; 1764/56.10(a) - Unauthorized disclosure of prescription and medical information

Unauthorized disclosure of prescriptions: California Code of Regulations section 1764 states in pertinent part that no pharmacist shall exhibit, discuss, or reveal the contents of any prescription or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative and Civil Code section 56.10 subdivision (a) states, in pertinent part, no provider of health care shall disclose medical information regarding a patient of the provider of health care without first obtaining an authorization. Truepill Pharmacy was not in compliance with these regulations. Specifically, on 4/17/2019, Truepill Pharmacy (PHY56100) located at 3121 Diablo Avenue in Hayward, CA shipped prescription RX#1186395 to the wrong person. The prescription was intended for AR but was shipped to the address of MS in error. Also, Truepill Pharmacy shipped prescriptions to patients with a shipping label showing the return address of NuRx located at 6838 Ellicott Drive in East Syracuse, NY and from Apostrophe located at 330 2nd Street in Oakland, CA. NuRx and Apostrophe are not licensed pharmacies and prescription packages returned as undeliverable to these locations would cause the disclosure of medical information without authorization.

Shipping prescriptions to an unauthorized person violates California Code of Regulations section 1764 and Civil Code 56.10.

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely February 22, 2020, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Barbera Schleicher, Public Inquiry Analyst at (916) 518-3081.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 25, 2021

TRUEPILL
ATTN: FRANCESCO CONSOLE, PIC
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2020 89223
TRUEPILL
PHY 56100

The attached Citation CI 2020 89223, has been issued to TRUEPILL, PHY 56100. A copy has been sent to the pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to insure the pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Sincerely

Joshua Monforte
Citation and Fine Analyst

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

COPY

Citation Number	Name, License No
CI 2020 89223	TRUEPILL, PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	$5,000.00
Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295	Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	Citation without a fine

CONDUCT:

California Code of Regulations 1714, section b states, (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, Truepill Pharmacy, PHY56100, located at 3121 Diablo Ave, Hayward, CA 94545 was in violation when they failed to keep dangerous drugs stored according to policy and procedure 2001.4, Oversight of Pharmacy Safety, which states: "The Pharmacy will make all attempts at maintaining a room temperature below 85F and ideally between 68-77F". Between 7/1/2020 and 9/14/2020, on numerous occasions, dangerous drug storage temperatures, summarized in Table 2, exceeded the recommended storage temperatures. The most egregious of these temperature spikes were:

a)On 8/13/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 161 hours over 77 F and 47 hours over 85F.
b)On 9/6/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 59 hours over 77 F and 17 hours above 85F.
c)On 8/13/2020, in the Parata Automated dispensing machine located in the warehouse, dangerous drugs were stored for approximately 163 hours above 77 F and 44 hours above 85 F.

Business and Professions Code 4169 section (a), subdivision (2) states, A person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code as it relates to Health and Safety Code 111295 which states, It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated. Specifically, Truepill Pharmacy, PHY56100, located at3121 Diablo Ave, Hayward, CA 94545 was in violation when they used the MKT calculation alone instead of in conjunction with manufactures stability data as stated in USP <1079>, which provides guidance for assessing possible adulteration to dangerous drugs stored at the pharmacy due to excessive heat. In particular, USP<1079> states, "Knowing the MKT for an excursion is useful for evaluating the potential impact on product quality. However, it is also essential to know the upper and lower temperature limits of any excursion. If these extreme temperatures are outside available stability data, it may not be possible to predict the quality impact of the excursion with any confidence regardless of the MKT. At higher temperatures the kinetics of degradation may change or new degradation reactions may occur. Truepill Pharmacy did not consider the manufacture's stability data for at least 72 dangerous drugs stored in the cage area of the warehouse which were held and offered for sale when determining if a dangerous drug was adulterated by the extreme heat, summarized in Table 3. For each one of the 72 dangerous drugs, the maximum temperature for storage was listed by the manufacturer as 77F or storage information was not listed. As there was no stability temperature for at least the 72 drugs in question and per USP<1079>, the MKT cannot be without the stability data, these drugs which were held and offered for sale were adulterated.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

- Either (1) full payment of the assessed fine(s) in the amount of $5,000.00; or payment in the amount of $1,000.00 and (2) provide proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within ninety (90) days.

COPY

If you choose option (2), within 90 days of this citation, you shall submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If you timely submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, this citation shall be reduced to $1,000.00 and proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations shall be considered satisfactory abatement of the citation.

If you fail to submit proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, the stay shall be lifted and the fine(s) in the amount of $5,000.00 shall be due and owing from you within thirty (30) days of any such failure.

CITATION ISSUED ON: August 25, 2021	TOTAL AMOUNT OF FINE(S): $5,000.00

PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: September 24, 2021

COPY

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[*Remainder of page intentionally left blank; signature page to follow.*]

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
Hearing Officer for the Board

svb

Silicon Valley Bank

3003 Tasman
Santa Clara, California 95054
408-654-7400

90-4039
1211

CASHIER'S CHECK No. 208457

Remitter: **Postmeds, Inc.**
Permit No. 7761

Date	Check No.	Amount
Apr 13,2022	208457	$10,574.80

PAY EXACTLY
*** **Ten Thousand Five Hundred Seventy-Four and 80/100** **Dollars**

TWO SIGNATURES REQUIRED OVER $50,000.00

Pay to the order of: **Louisiana Board of Pharmacy**

⑈208457⑈ ⑆121140399⑆ 7899900470⑈

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS**:

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date: _____

_____
Notary Public

_____

My commission expires: _____

Truepill
CA old license PHY 56100
ME old license MO40002429
NC old license 13413
LA license PHY.007761-NR
KS license 22-117859
DEA license FP6189725

DEA Order to Show Cause
Although the matter remains pending and no discipline has issued, for transparency with the Board and out of an abundance of caution, the Pharmacy wishes to disclose that on December 15, 2022, the federal Drug Enforcement Agency ("DEA") issued the Pharmacy an administrative Order to Show Cause ("OSC") regarding revocation of its DEA registration FP6189725. On January 13, 2023, the Pharmacy answered the OSC.

Kansas Board of Pharmacy
The Kansas Board of Pharmacy issued the pharmacy an amended Summary Order effective February 8, 2023. The pharmacy did not report the change of ownership in a timely manner, and paid a fine. The Kansas Board of Pharmacy approved the change of ownership application, and issued license 22-117859 on May 20, 2022.

Louisiana Board of Pharmacy
The Louisiana Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated May 11, 2022. The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated March 8, 2022. The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

Maine Board of Pharmacy

The Maine Board of Pharmacy notified the pharmacy on March 30, 2022 that its non-resident license was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license on November 2, 2022.

California Board of Pharmacy

The California Board of Pharmacy issued the pharmacy a letter of admonishment CI 2019 84877 dated January 23, 2020, concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy a modified citation and fine CI 2019 78633 dated June 16, 2020, with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy

by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy a citation and fine order of abatement CI 2020 89223 dated August 25, 2021, with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

U.S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Springfield, Virginia 22152

IN THE MATTER OF

Truepill
3121 Diablo Ave
Hayward, CA 94545

DEA Certificate of Registration FP6189725

ORDER TO SHOW CAUSE

Telemedicine is an important tool for providing increased access to medical treatment that has been relied upon by hundreds of millions of Americans since the onset of the COVID-19 pandemic in 2020. Unfortunately, this access is being exploited by a subset of medical practitioners and businesses seeking opportunities to profit by wrongfully providing controlled substances without a legitimate medical purpose.

DEA has an obligation to protect the public by ensuring that pharmacists only fill prescriptions for controlled substances which are prescribed for legitimate medical purposes by practitioners acting in the usual course of professional practice. It is critical that entities engaged in the practice of online pharmacy are appropriately registered and subject to reporting, disclosure, and other requirements imposed under law. These requirements allow entities engaged in the legitimate practice of telemedicine to continue safely providing critical services and protect the safety and health of the American public.

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) and its implementing regulations prohibit actors from operating as an "online pharmacy" without the appropriate DEA registration. Truepill does not have the requisite registration to act as an online pharmacy. But since September 2020, it has acted as an online pharmacy, and in a two-year period filled 72,000 controlled substance prescriptions, of which 60% were for stimulants, such as amphetamines used in the treatment of Attention Deficit/Hyperactivity Disorder (ADHD).

Truepill was the pharmacy for telehealth companies, including Cerebral, that marketed ADHD treatments, including Adderall ® and its generic forms, directly to consumers using Internet advertisements and social media. Cerebral arranged for patients to receive prescriptions for ADHD treatments through a telehealth visit, and for Truepill to fill those prescriptions. In numerous instances, Truepill dispensed controlled substances pursuant to prescriptions that were not issued for a legitimate medical purpose in the usual course of professional practice. Many of these prescriptions were written by providers that lacked the requisite state certifications to prescribe and who issued multiple prescriptions for a patient to receive more than a 90-day supply of a

Schedule II controlled substance, including prescriptions for the treatment of ADHD, in violation of federal regulations.

Accordingly,

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Truepill an opportunity to Show Cause before the Drug Enforcement Administration (DEA), at the DEA Hearing Facility, 700 Army Navy Drive, 2nd Floor, Arlington, Virginia 22202, or a location designated by the Administrative Law Judge, on March 21, 2023, or on such a subsequent date designated by the Administrative Law Judge (if Truepill requests such a hearing), as to why DEA should not revoke Truepill's DEA Certificate of Registration (COR or registration), Number FP6189725, pursuant to 21 U.S.C. § 824(a)(4), and deny any applications for any other DEA registrations, because Truepill's registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f).

As detailed below, this Order states DEA's basis to revoke the above-referenced DEA registration, including a ***non-exhaustive summary*** of the matters of fact and law at issue, as well as citations to laws and regulations that Truepill has violated (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which DEA construes *in pari materia*). In order to preserve Truepill's rights in this proceeding, Truepill may appear in these revocation proceedings by filing a notice of appearance or request for hearing in the manner prescribed by regulations within 30 days from the receipt of this Order. On or before the date of Truepill's appearance, Truepill may submit a corrective action plan that will be considered by DEA in accordance with 21 U.S.C. § 824(c).

LEGAL REQUIREMENTS

Entities That Must Register as Online Pharmacies

Federal law proscribes any person from distributing or dispensing a controlled substance except as authorized by the Controlled Substances Act (CSA). *See* 21 U.S.C. §§ 841(a)(1); 842(a)(1). Federal law further explicitly provides that it is unlawful for "any person" to "deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized" by the CSA. 21 U.S.C. § 841(h)(1).

An "online pharmacy" is "a person, entity, or Internet site . . . that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet." 21 U.S.C. § 802(52)(A); *see also* 21 C.F.R. § 1300.04(h) (same). Further, the term "'deliver, distribute, or dispense by means of the Internet' refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet." 21 U.S.C. § 802(51). To act as an online pharmacy, a pharmacy must "request that the Administrator modify its registration to authorize the pharmacy to dispense controlled substances by means of the Internet as an online pharmacy." 21 C.F.R. § 1301.19(a); *see* 21 C.F.R. § 1301.11(b).

The CSA instructs that "it is unlawful for any person who falls within the [CSA's] definition of 'online pharmacy' . . . to deliver, distribute, or dispense a controlled substance by means of the

Internet" unless that person is "validly registered with a modification of such registration authorizing such activity." 21 C.F.R. § 1301.11(b). "Accordingly, any pharmacy registered" with DEA "that falls within the definition of an online pharmacy and proposes to dispense controlled substances by means of the Internet must obtain a modification of its registration authorizing such activity." *Id.*; *see also* 21 C.F.R. § 1301.19(f) ("No person . . . required to obtain a modification of a registration . . . authorizing it to operate as an online pharmacy may engage in any activity for which such modification of registration is required until the application for such modified registration is granted and an active Certificate of Registration indicating the modification of the registration has been issued by the Administrator to such person."). The CSA explicitly provides that "delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity" is a violation of section 841(h)(1). 21 U.S.C. § 841(h)(2)(A).

Requirements Applicable to Online Pharmacies

An online pharmacy is subject to a number of requirements under the CSA. Among other things, an online pharmacy must:

- "[D]isplay in a visible and clear manner on its homepage a statement that it complies with the requirements of this section with respect to the delivery or sale or offer for sale of controlled substances." 21 U.S.C. § 831(a); 21 C.F.R. § 1304.45(a); *see also* 21 U.S.C. § 802(53) ("The term 'homepage' means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.").

- Post "in a visible and clear manner" on its homepage or a page clearly linked from its homepage, the following information:

    - "The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted."

    - "A list of the States in which the pharmacy is licensed to dispense controlled substances."

    - "A certification that the pharmacy is registered under" the CSA "to deliver, distribute, or dispense" controlled substances "by means of the Internet."

    - The following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via telemedicine in

accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54))."

See 21 U.S.C. § 831(c); 21 C.F.R. § 1304.45.

- Notify the DEA Administrator, thirty days before offering a controlled substance for sale, delivery, distribution, or dispensing, of, among other things: the information the online pharmacy is required to post on its Internet site under 21 U.S.C. § 831(c), and 21 C.F.R. § 1304.45; each Internet site address used by the online pharmacy; the DEA registration numbers of every pharmacy that delivers, distributes or dispenses controlled substances pursuant to orders made through each of those identified websites; and a certification that the information provided on its Internet site under 21 U.S.C. § 831(c), and 21 C.F.R. § 1304.45 is true and accurate. *See* 21 U.S.C. § 831(d); 21 C.F.R. § 1304.40(b).

- Display on its homepage a declaration that it has made an appropriate notification to the DEA Administrator. *See* 21 U.S.C. § 831(e); 21 C.F.R. § 1304.40(d).

- Monthly report to the DEA Administrator of the total quantity of controlled substances the online pharmacy has dispensed for each calendar month in which it dispenses either 100 or more controlled substance prescriptions, or 5,000 or more dosage units of controlled substances. If the pharmacy's dispensing does not meet either threshold in a given month, it must report a negative response for that month. *See* 21 C.F.R. § 1304.55.

Requirements Applicable to All Pharmacies

A "prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. A pharmacist is only permitted to fill prescriptions "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Although "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.*

"DEA has consistently interpreted this provision as prohibiting a pharmacist from filling a prescription for a controlled substance when [s]he either knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Wheatland Pharmacy*, 78 Fed. Reg. 69,441, 69,445 (2013) (internal quotation marks and citation omitted, alternation in original). Section 1306.04(a) "expressly requires pharmacists to identify and resolve suspicions that a prescription is illegitimate." *Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7331 (2018).

A violation of these regulations is a violation of federal law. *See* 21 U.S.C. § 842(a)(1) (making it unlawful to dispense controlled substances in violation of 21 U.S.C. § 829, whose scope is defined in part by 21 C.F.R. §§ 1306.04, 1306.06). Any attempt to violate these regulations is also a violation of federal law. *See* 21 U.S.C. § 846.

Additionally, DEA may find that a registrant's DEA COR is inconsistent with the public interest if the registrant acted carelessly or negligently in handling controlled substances, even if the registrant did not intend to violate the Controlled Substances Act. *See, e.g., Med. Shoppe*, 79 Fed. Reg. 59,504, 59,506 (2014) ("Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify revocation or denial." (quoting *Paul J. Caragine, Jr.*, 63 Fed. Reg. 51,592, 51,601 (1998))).

Pharmacies are also required to keep appropriate records as set forth in the CSA. "Recordkeeping is one of the CSA's principal tools for preventing the diversion of controlled substances." *Wayne Pharmacy*, 85 Fed. Reg. 63,579, 63,582 (2020). Such recordkeeping is one of the central features of the CSA's regulatory regime because "a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances." *Superior Pharmacy I & Superior Pharmacy II*, 81 Fed. Reg. 31,310, 31,337 (2016). Thus, a finding that a registrant "failed to maintain complete and accurate records . . . supports the conclusion that [the registrant] has committed such acts as to render its continued registration 'inconsistent with the public interest.'" *Id.* at 31,338 (quoting 21 U.S.C. § 824(a)(4)).

Pharmacies are also required to, among other things, "maintain, on a current basis, a complete and accurate record of each [controlled] substance . . . received, sold, delivered, or otherwise disposed of." 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.21(a); *see also* 21 C.F.R. § 1304.22(c) (specific recordkeeping requirements for dispensers).

An individual practitioner is not authorized, on a single occasion, to issue multiple prescriptions for a patient to receive more than a 90-day supply of a Schedule II controlled substance. *See* 21 C.F.R. § 1306.12(b).

State of California Authority to Dispense Controlled Substances

As noted above, a pharmacy may only fill valid prescriptions. *See* 21 U.S.C. § 829; 21 C.F.R. § 1306.06.

California law provides that to practice as a nurse practitioner in California, a nurse practitioner must hold, among other things, a valid and active registered nursing license issued by the Board of Registered Nursing (Nursing Board). Cal. Bus. & Prof. Code § 2835.5. Additionally, for a nurse practitioner licensed in California to prescribe a controlled substance, the Nursing Board must certify that the nurse practitioner satisfactorily completed a course in pharmacology covering the controlled substances to be prescribed and must issue a Furnishing Number to the nurse practitioner. *See id.* §§ 2836.1(g)(1), 2836.2, 2836.3.

To practice as a doctor of naturopathic medicine in California, one must hold a valid and active naturopathic medicine license issued by the California Naturopathic Medicine Committee. *See* Cal. Bus. & Prof. Code §§ 3630, 3633, 3644(d)(2). Schedule III through V controlled substances may only be dispensed by a naturopathic doctor under supervision by a physician or surgeon and pursuant to standardized procedures or protocols established between them. *See* Cal. Bus. & Prof. Code § 3640.5(f).

To practice as a physician assistant in California, one must hold a valid physician assistant license issued by the California Physician Assistant Board. *See* Cal. Bus. & Prof. Code § 3519;

see also Cal. Bus. & Prof. Code §§ 3501, 3503, 3516. Schedule II through V controlled substances may only be prescribed by a physician assistant under supervision by a physician or surgeon and pursuant to a practice agreement. *See* Cal. Bus. & Prof. Code §§ 3502.1 and 3516.

Additionally, practitioners licensed outside California may only be authorized to practice within California by the California Director of Emergency Medical Services Authority during a gubernatorially declared state of emergency. *See* Cal. Bus. and Prof. Code § 900.

BACKGROUND

1. Truepill is registered as a retail pharmacy under DEA COR Number FP6189725 in Schedules II through V with a registered address of 3121 Diablo Avenue, Hayward, California 94545. Truepill's registration expires by its own terms on November 30, 2025.

2. Truepill is not registered as an online pharmacy with DEA.

3. Truepill is licensed by the State of California as a community pharmacy with license number PHY58585. Truepill's pharmacy license expires by its own terms on March 1, 2023.

4. Between on or about September 14, 2020, and September 13, 2022, of the more than 72,000 controlled substances Truepill filled, nearly 46,000 were stimulants, accounting for more than 60% of the controlled substances Truepill dispensed.

5. Truepill's DEA COR should be revoked, and any applications for registration should be denied, because Truepill has committed such acts as would render its registration inconsistent with the public interest. *See* 21 U.S.C. §§ 823(f), 824(a)(4). Specifically, Truepill has acted as an online pharmacy without obtaining an appropriate DEA registration and without meeting a number of legal requirements applicable to online pharmacies. Truepill has, on numerous occasions, unlawfully filled controlled stimulant prescriptions issued by prescribers with no state authority to issue such prescriptions. Truepill has also repeatedly filled controlled stimulant prescriptions there were for more than a 90-day supply, in violation of 21 C.F.R. § 1306.12(b).

6. Dextroamphetamine-amphetamine, which is often sold under the brand names Adderall® and Adderall XR®, is a Schedule II stimulant.

7. Methylphenidate, which is often sold under the brand name Ritalin®, is a Schedule II stimulant.

OPERATING AS AN ONLINE PHARMACY WITHOUT DEA REGISTRATION

8. Truepill provides both pharmacy and technical services to corporate customers, including telehealth companies such as Cerebral. Moreover, Truepill employs a number of customer service representatives to assist its corporate customers.

9. On its Internet site, Truepill describes itself as a "virtual pharmacy," providing "[a]n end-to-end virtual pharmacy experience." Furthermore, Truepill claims that "Truepill's virtual pharmacy enables you to create the convenient experience your customers want."

10. Truepill provides its corporate customers with a software platform containing, among other things, patient information, prescriber information, and prescription information to facilitate the delivery of prescriptions by means of the Internet.

11. Truepill's Internet site also extensively describes how its software programs assist its corporate customers in providing patients with prescriptions. Among other things, the Truepill's Internet site includes the following statements:

    a. Truepill states that it can help companies "[d]eliver medications to your patients using powerful programmatic APIs [Application Programing Interfaces] that give you full control." It further states that these companies can "[p]air our pharmacy fulfillment services with our telehealth solutions to make your programs more accessible to patients who may find it difficult to commute to a doctor's office."

    b. Truepill informs that it provides other software that uses the Internet to facilitate the filling of prescriptions, including, among others, telehealth APIs to help practitioners create and update patient records, and to provide the practitioners' patients with patient health questionnaires, all in "the Truepill ecosystem." Truepill makes clear that its telehealth API customers are "third-party provider networks and physician groups that that can diagnose, treat and prescribe for your patient population. These providers are all part of licensed professional medical corporations who are independently owned and operated."

    c. Truepill explains that it uses a "fulfillment API" to assist providers to "efficiently get medications to your patient's door across all 50 states." Truepill goes on to explain how its software platform uses the Internet to electronically create patient records, obtain prescriptions, and allow practitioners to create fill requests that they submit to Truepill electronically.

    d. Truepill states that it offers a "team of marketers, merchandisers, and fulfillment experts" to help telehealth companies "maximize the value of your e-commerce program."

12. Through these services, Truepill "deliver[ed], distribute[ed], or dispense[ed]" "a controlled substance by means of the Internet," despite not being registered as an online pharmacy, in violation of 21 U.S.C. § 841(h)(1) and 21 C.F.R. §§ 1301.11(b) & 1301.19(f).

FAILURE TO MAKE AND DISPLAY REQUIRED REPORTS AND NOTIFICATIONS

13. Despite operating as an online pharmacy, Truepill failed to put on its Internet site information required by the CSA, including:

a. A statement on its homepage that Truepill complies with the requirements of 21 U.S.C. § 831 with respect to the delivery or sale or offer for sale of controlled substances, in violation of 21 U.S.C. § 831(a) and 21 C.F.R. § 1304.45(a).

b. A visible and clear statement on its homepage, or a page clearly linked from its homepage including:

   i. the name, professional degree, and states of licensure of its pharmacist-in-charge;

   ii. a telephone number at which its pharmacist-in-charge can be contacted;

   iii. a list of states in which Truepill is licensed to dispense controlled substances;

   iv. a certification that Truepill is licensed under the CSA to deliver, distribute, or dispense controlled substances by means of the Internet; and

   v. the following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54)).";

all in violation of 21 U.S.C. § 831(c) and 21 C.F.R. § 1304.45.

14. Truepill failed to notify the DEA Administrator of the information listed in 13.b., *supra*, through the submission of an application for a modified registration thirty days before offering a controlled substance for sale, delivery, distribution, or dispensing together with a certification that such information is true and accurate, in violation of 21 U.S.C. § 831(d) and 21 C.F.R § 1304.40(a)(1). Truepill also did not notify the DEA Administrator of each Internet site address it used, nor of the DEA registration numbers of every pharmacy that delivers, distributes or dispenses controlled substances pursuant to orders made through each of those identified websites, in violation of 21 U.S.C. § 831(d) and 21 C.F.R. § 1304.40(b)(3) and (4).

15. Truepill failed to display on the homepage of its Internet site that it had made an appropriate notification to the DEA Administrator under 21 U.S.C. § 831(d) and 21 C.F.R. § 1304.40(b), in violation of 21 U.S.C. § 831(e) and 21 C.F.R. § 1304.40(d).

16. Truepill failed to the provide the DEA Administrator with any of the monthly reports required by 21 C.F.R. § 1304.55.

UNLAWFUL DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES PURSUANT TO PRESCRIPTIONS FOR GREATER THAN 90-DAY SUPPLY

17. Between on or about September 13, 2020, and September 13, 2022, in dozens of instances, Truepill dispensed Schedule II controlled substances for prescriptions written on a single date by an individual practitioner to an individual patient for a greater than 90-day supply. A non-exhaustive set of examples is provided below.

18. On August 24, 2020, a practitioner issued **Patient N.S.** five prescriptions amounting to a 150-day supply of dextroamphetamine-amphetamine extended release (ER) 10 mg capsules, which are often sold under the brand name Adderall XR®, a total of 300 capsules, which Truepill dispensed.

19. On January 12, 2021, a practitioner issued **Patient L.H.** four prescriptions amounting to a 120-day supply of methylphenidate 20 mg tablets, which are often sold under the brand name Ritalin®, a total of 120 tablets, which Truepill dispensed.

20. On January 12, 2021, a practitioner issued **Patient L.H.** four prescriptions amounting to a 120-day supply of methylphenidate ER 54 mg tablets, which are often sold under the brand name Ritalin®, a total of 120 tablets, which Truepill dispensed.

21. On February 11, 2021, a practitioner issued **Patient D.K.** two prescriptions amounting to a 120-day supply of dextroamphetamine-amphetamine 20 mg tablets, which are often sold under the brand name Adderall®, a total of 120 tablets, which Truepill dispensed.

22. On February 11, 2021, a practitioner issued **Patient D.K.** two prescriptions amounting to a 180-day supply of dextroamphetamine-amphetamine ER 30 mg capsules, which are often sold under the brand name Adderall XR®, a total of 180 capsules, which Truepill dispensed.

23. On March 9, 2021, a practitioner issued **Patient H.M.** three prescriptions amounting to a 210-day supply of dextroamphetamine-amphetamine 10 mg tablets, which are often sold under the brand name Adderall®, a total of 315 tablets, which Truepill dispensed.

24. On November 8, 2021, a practitioner issued **Patient N.B.** four prescriptions amounting to a 120-day supply of dextroamphetamine-amphetamine ER 15 mg capsules, which are often sold under the brand name Adderall XR®, a total of 120 capsules, which Truepill dispensed.

25. On November 8, 2021, a practitioner issued **Patient N.B.** four prescriptions amounting to a 120-day supply of dextroamphetamine-amphetamine 5 mg tablets, which are often sold under the brand name Adderall®, a total of 120 tablets, which Truepill dispensed.

UNLAWFUL DISPENSING OF CONTROLLED SUBSTANCES PURSUANT TO PRESCRIPTIONS ISSUED BY PRACTITIONERS WITHOUT STATE AUTHORITY

26. Between on or about September 13, 2020, and September 13, 2022, Truepill dispensed controlled substances to patients located in California pursuant to prescriptions written by numerous practitioners who were neither sufficiently licensed in California to do so nor holders of an Authorization for Out-of-State Health Care Practitioner issued by the California Emergency Medical Services Authority (Temporary Emergency Authorization). These practitioners included nurse practitioners, physician assistants, and doctors of naturopathic medicine.

27. A non-exhaustive set of insufficiently licensed practitioners who also did not hold a Temporary Emergency Authorization include: **Nurse Practitioner N.B.**; **Nurse Practitioner T.C.**; **Nurse Practitioner D.S.**; **Nurse Practitioner H.M.**; **Nurse Practitioner J.M.**; **Nurse Practitioner A.N.**; **Nurse Practitioner S.O.**; **Nurse Practitioner A.S.**; and **Nurse Practitioner N.S.**

RECORDKEEPING AND AUDIT FINDINGS

28. In September and October of 2022, DEA investigators conducted an audit of Truepill's controlled substance records by conducting an inventory of certain controlled substances present at Truepill's registered location and comparing that inventory to the records maintained and provided by Truepill. DEA's audit identified 1,674 missing dosage units of dextroamphetamine-amphetamine ER 20 mg, often sold under the brand name Adderall XR®, for which Truepill was unable to account, in violation of 21 C.F.R. §§ 1304.21(a) and 1304.22(c). *See Bill Lloyd Drug*, 64 Fed. Reg. 1,823, 1,824 (1999) ("The shortages and overages revealed by the accountability audit show that Respondent does not keep complete and accurate records of its controlled substance handling as required by 21 U.S.C. 827 and 21 CFR 1304.21.").

29. This shortage of 1,674 units constituted over two percent of the dextroamphetamine-amphetamine ER 20 mg, often sold under the brand name Adderall XR®, for which Truepill was accountable during the audit period. Truepill's failure to account for a significant number of dosage units of controlled substances not only violated its obligation to maintain accurate records, but also constituted a failure to comply with its obligation to maintain effective controls against the diversion of controlled substances into illicit channels. *See, e.g.*, *Superior Pharmacy*, 81 Fed. Reg. at 31,337.

THE following procedures are available to Truepill in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Truepill may file with DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Truepill fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause, Truepill may file with DEA a waiver of hearing together with a written statement regarding its position on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should Truepill decline to file a request for a hearing, or should Truepill request a hearing and then fail to appear at the designated hearing, Truepill shall be deemed to

have waived the right to a hearing, and DEA may cancel such hearing and may enter a final order in this matter without a hearing based upon the evidence presented. *See* 21 C.F.R. §§ 1301.43(d), 1301.43(e).

Requests for hearing should be filed by email with the Office of Administrative Law Judges at the following address: ECF-DEA@dea.gov, with a copy simultaneously provided to the Government at the following address: DEA.Registration.Litigation@dea.gov. Except as provided below with respect to a corrective action plan, correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. A copy of the same shall also be served on Government counsel, Edward O. Siclari, and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45.

OPPORTUNITY TO SUBMIT CORRECTIVE ACTION PLAN

In addition to the procedural options set forth in paragraphs 1 and 2 above, in accordance with 21 U.S.C. § 824(c)(2)(C), Truepill has the opportunity to submit a corrective action plan, which must be received by the Acting Assistant Administrator, Diversion Control Division, on or before the date of its appearance. Truepill is not required to submit a corrective action plan, nor will any adverse inference be drawn if Truepill chooses not to do so. If Truepill wishes to submit a corrective action plan, it must be submitted directly to the Acting Assistant Administrator, Diversion Control Division, who will decide whether, in view of the plan and the allegations set forth in this Order to Show Cause, the proceedings to revoke Truepill's registration should be discontinued, or deferred for the purposes of modification, amendment, or clarification of such plan. Any corrective action plan should be clearly labeled "Corrective Action Plan" and submitted by email to Thomas W. Prevoznik, Acting Assistant Administrator, Diversion Control Division, at the following address: CAPresponse@usdoj.gov.

A copy of the corrective action plan shall also be served on Government counsel, Edward O. Siclari, and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152.

In the event Truepill submits a corrective action plan and the Acting Assistant Administrator decides not to discontinue or postpone the proceedings, please note that such a decision is not a final determination by the agency regarding Truepill's corrective action plan or registration. In such circumstances, the Administrator may nonetheless consider the corrective action plan in issuing the final order at the conclusion of the proceedings.

Finally, please be advised that the submission of a corrective action plan shall not constitute a request for a hearing under paragraph 1 above or a written statement regarding Truepill's position on the matters of fact and law involved under paragraph 2 above. As indicated, if Truepill chooses to submit a corrective action plan and also wishes to proceed under paragraph 1 or 2 above, it must separately submit its request for a hearing (paragraph 1) or written statement (paragraph 2) in accordance with the instructions above.

THOMAS PREVOZNIK Digitally signed by THOMAS PREVOZNIK Date: 2022.12.15 17:15:08 -05'00'

Thomas W. Prevoznik
Acting Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Edward O. Siclari, Counsel for the Government

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

/s/ Brenda L. Head
Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): N/A

Physical Address: 2722 E Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: Website:

Licensing Company Email:

Section 2: Personal Information

First: Mohammad Middle: Umar Last: Afridi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: 5[redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Lavaca St PMB [redacted]

City: Austin State: TX Zip: 78701

Telephone: Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Manchester UK		06/2005	
Address	**City**	**State**	**Zip**
Oxford Rd	Manchester	UK	
Diploma/Degree obtained, if any			
Masters in Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/22-Current	Sorrento, Hawley Lane	Hale Barns, WA15 ODR	UK	
12/21-7/22	[redacted]La Canada Way	Bee Cave	TX	78738
5/19-12/21	[redacted]Elisha Lane	San Ramon	CA	94583
1/18-5/19	[redacted] True Wind Way Unit 607	Redwood	CA	94063
1/16-1/18	[redacted] Willow Rd #202	Pleasanton	CA	94588
1/14-1/16	[redacted] W San Carlos St 383	San Jose	CA	95126
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Truepill			6/2016 - 8/2022
Business Address	**City**	**State**	**Zip**
1700 S Amphlett Blvd	San Mateo	CA	94402
Phone	**Title**		
650-353-5495	CEO		

Description of Duties

Managed and directs the company toward goals and objectives, oversee executive business decisions

Business Name			From - To (MM/YY – MM/YY)
CVS			12/2012 - 1/2016
Business Address	**City**	**State**	**Zip**
Various Bay area locations	San Jose	CA	
Phone	**Title**		
	Pharmacist		

Description of Duties

Verified prescriptions for accuracy, patient consultations, supervise pharmacy technicians and clerks

Business Name			From - To (MM/YY – MM/YY)
Rite Aid			9/2010-7/2012
Business Address	**City**	**State**	**Zip**
	Seattle	WA	
Phone	**Title**		
	Pharmacist		

Description of Duties

Verified prescriptions for accuracy, patient consultations, supervise pharmacy technicians and clerks

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1/24/2019		CA		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CI 2017 80030		California Board of Pharmacy		
Reason/Charge				
Failure to provide documentation substantiating completion of continuing education. Unprofessional conduct				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

CI 2017 80030 issued on January 24, 2019
Mr. Afridi received a citation and fine following an audit of the Continuing Education ("CE") requirements imposed on pharmacists by the State of California. California Board of Pharmacy alleges Mr. Afridi had not completed all CE requirements to maintain his California Registered Pharmacist license.

Mr. Afridi has paid the fine imposed by the California Board of Pharmacy. Upon receipt of the fine, the California Board of Pharmacy considered the matter closed and took no further action. Mr. Afridi's California Registered Pharmacist License remains active in good standing.

Mr. Afridi has since registered for the NABP CE Monitor tracking service, enabling him to remain compliant now and in the future.

M. U. Afridi
Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/16/2019		CA		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CI 2019 86472	California Board of Pharmacy

Reason/Charge
furnished dangerous drugs on order of nurse practitioners who had not yet entered into an established protocol in place

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

CI 2019 86472 issued on December 16, 2019
Mr. Afridi received a citation while pharmacist-in-charge of Truepill PHY 56100. The California Board of Pharmacy alleges Truepill furnished dangerous drugs on order of nurse practitioners and physician assistants who had not yet entered into an established protocol in place.

M. U. Afridi
Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/25/2021		AL		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21-L-0080		Alabama Board of Pharmacy		
Reason/Charge				
Failure to timely notify the Alabama Board of Pharmacy of the California Board of Pharmacy Citation and Fine				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

21-L-0080 issued on October 25, 2021
Alabama Board of Pharmacy issued a Final Order to Mr. Mohammad Afridi, Alabama Registered Pharmacist #20384, regarding the California Board of Pharmacy Citation and Fine described below. Alabama Board of Pharmacy scheduled a reciprocal discipline hearing on the matter. The hearing was to discuss the California Board of Pharmacy Citation and Fine and to issue reciprocal discipline. Alabama Board of Pharmacy fined Mr. Afridi for failure to timely notify the Alabama Board of Pharmacy of the California Board of Pharmacy Citation and Fine. Mr. Afridi paid the fine to the Alabama Board of Pharmacy. Upon receipt of the fine, the Alabama Board of Pharmacy considered the matter closed and took no further action. Mr. Afridi's Alabama Registered Pharmacist License remains active in good standing.

M. U. Afridi
Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/07/2022		MI		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
53-22-000152		Michigan Board of Pharmacy		
Reason/Charge				
Failure to timely notify the Michigan Board of Pharmacy of the California Board of Pharmacy Citation and Fine				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

53-22-000152 issued on 03/07/2022
Michigan Board of Pharmacy issued a consent Order to Mr. Mohammad Afridi, Michigan Registered Pharmacist #53-02-046254, regarding the California Board of Pharmacy Citation and Fine described below. Michigan Board of Pharmacy requested explanation of the California citation. Michigan Board of Pharmacy fined Mr. Afridi for failure to timely notify the Michigan Board of Pharmacy of the California Board of Pharmacy Citation and Fine. Mr. Afridi paid the fine to the Michigan Board of Pharmacy. Upon receipt of the fine, the Michigan Board of Pharmacy considered the matter closed and took no further action. Mr. Afridi's Michigan Registered Pharmacist License remains active in good standing.

Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Mohammed Afridi does not have a direct ownership interest in any licensed pharmacy. Mr. Afridi does have an ownership interest in the grandparent level holding company of licensed pharmacies. In the interests of transparency the Postmeds, Inc (direct owner of Seven Hills Pharmacy, LLC) has been involved in discipline cases. Which are described in Postmeds Discipline summary (provided along with the original NV application).

MA

Original Signature (electronic, copies or stamps not accepted)

6/12/23

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Mohammed Afridi does not have a direct ownership interest in any licensed pharmacy. Mr. Afridi does have an ownership interest in the grandparent level holding company of licensed pharmacies. In the interests of transparency the following pharmacies (also owned by Postmeds Inc) were voluntarily closed:

Lake Forest Pharmacy, LLC - closed on 6/23/22
Belle Isle Pharmacy, LLC - closed on 6/23/22
Wind City pharmacy, LLC - closed on 6/14/22
Queen City Pharmacy, LLC - closed on 8/17/2022

The following pharmacies have also closed since the initial submission of this application:
Overlake Pharmacy, LLC - closed on 03/15/23
LA Pharmacy, LLC - closed on 03/15/23
Marymoor Pharmacy, LLC - closed on 04/21/23
River City Pharmacy, LLC - closed on 04/14/23

M.U.A

Original Signature (electronic, copies or stamps not accepted)

6/12/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mohammad Afridi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/12/23

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: N/A

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Siddharth Middle: Last: Viswanathan

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]Long Bridge Street, Apt [redacted]

City: San Francisco State: CA Zip: 94158

Telephone: [redacted] Email: compliance@truepill.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Carnegie Mellon University		09/2002-05/2006	
Address	**City**	**State**	**Zip**
5000 Forbes Avenue	Pittsburgh	PA	15213
Diploma/Degree obtained, if any			
Bachelor of Science Mechanical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Watkins Mill High School		09/1998-05/2002	
Address	**City**	**State**	**Zip**
10301 Apple Ridge Road	Gaithersburg	MD	20879
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2021 - Present	[redacted] Long Bridge Street, Apt [redacted]	San Francisco	CA	94158
02/2017 - 12/2020	[redacted] Long bridge Street, Apt [redacted]	San Francisco	CA	94158
09/2015 - 01/2017	[redacted] King Street, Apt [redacted]	San Francisco	CA	94107
11/2009 - 08/2015	[redacted] Farrel Court	Mountain View	CA	94043
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Truepill			01/2016 - present
Business Address	**City**	**State**	**Zip**
3100 Diablo Avenue	Hayward	CA	94545
Phone	**Title**		
855-910-8606	CEO and Co-Founder		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
LinkedIn			01/2011 - 08/2014
Business Address	**City**	**State**	**Zip**
700 E. Middlefield Road	Mountain View	CA	94043
Phone	**Title**		
650-687-3600	Product Manager		

Description of Duties

Worked on CardMunch and other relationship management products for the world's largest professional network. Led the integration, relaunch, and growth of LinkedIn CardMunch, which was the most downloaded iPhone application for busines

Business Name			From - To (MM/YY – MM/YY)
Cardmunch, Inc. (acquired by LinkedIn)			11/2009 - 12/2010
Business Address	**City**	**State**	**Zip**
57 W El Camino Rea	Mountain View	CA	94040
Phone	**Title**		
	Co-Founder		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Johnson & Johnson			07/2006 - 12/2008
Business Address	**City**	**State**	**Zip**
One Johnson & Johnson Plaza	New Brusnwick	NJ	08933
Phone	**Title**		
732-524-0400	Global Operations Leadership Development		

Description of Duties

Part of a 2-year rotational program and held positions in the medical device (orthopedic implants, diabetic monitors) and pharmaceutical sectors. Key project involved the ramp-up a new$70M distribution facility for the pharmaceutical business

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Siddharth Viswanathan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/10/2022

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Francisco

I, Siddharth Viswanathan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/13/2022

Date

Subscribed and Sworn to before me this 13th day of October, 2022

Notary Public Signature

JUDY ANN PARDINI
Notary Public - California
San Mateo County
Commission # 2329943
My Comm. Expires Jul 23, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: N/A

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Mathew Middle: Sloan Last: Davis-Ratner

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] 51st Ave S

City: Seattle State: WA Zip: 98118

Telephone: [redacted] Email: compliance@truepill.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Columbia Law School			2007-2010	
Address		City	State	Zip
435 W 116th St		New York	NY	10027
Diploma/Degree obtained, if any				
J.D				
School Name			From - To (MM/YY – MM/YY)	
Stanford University			2002-2007	
Address		City	State	Zip
450 Serra Mall		Stanford	CA	94305
Diploma/Degree obtained, if any				
M.A. and B.A.				
School Name			From - To (MM/YY – MM/YY)	
Troy High School			1998-2002	
Address		City	State	Zip
2200 Dorothy Ln		Fullerton	CA	92831
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2021 - present	[redacted]51st Ave S	Seattle	WA	98118
3/2020 - 12/2021	[redacted]Dahlia Pl	Corona del Mar	CA	92625
12/2018 - 2/2020	[redacted]44th Ave.	San Francisco	CA	94122
1/2017 - 12/2018	[redacted]Dahlia Pl	Corona del Mar	CA	92625
8/2015 - 12/2017	[redacted]Comerford Ln SE	Turner	OR	97392
5/2011 - 8/2015	[redacted]Dahlia Pl	Corona del Mar	CA	92625
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Truepill, Inc			3/2020-present
Business Address	**City**	**State**	**Zip**
3121 Diablo Ave	Hayward	CA	94545
Phone	**Title**		
833-860-1057	General Counsel		
Description of Duties			
responsible for legal function of company			

Business Name			From - To (MM/YY – MM/YY)
Smith Health, Inc			4/2019-3/2020
Business Address	**City**	**State**	**Zip**
300 Brannan St	San Francisco	CA	94107
Phone	**Title**		
8444540123	Head of Legal and Corporate Operations		
Description of Duties			
responsible for legal, compliance, people and facilities functions of company			

Business Name			From - To (MM/YY – MM/YY)
Incipio, LLC			1/2017-8/2018
Business Address	**City**	**State**	**Zip**
3347 Michelson Dr STE 100	Irvine	CA	92612
Phone	**Title**		
8007330088	General Counsel & Secretary		
Description of Duties			
responsible for legal function of company			

Business Name			From - To (MM/YY – MM/YY)
Kundalini Farms, LLC			8/2015-12/2019
Business Address	**City**	**State**	**Zip**
14415 Comerford Ln SE	Turner	OR	97392
Phone	**Title**		
n/a	Co-Founder		
Description of Duties			
esponsible for operational functions of company			

Business Name			From - To (MM/YY – MM/YY)
Nextgen Healthcare, Inc			7/2013-9/2015
Business Address	**City**	**State**	**Zip**
18111 Von Karman Ave Suite 600	Irvine	CA	92612
Phone	**Title**		
9492552600	Vice President, Associate General Counsel and Assistant Secretary		
Description of Duties			
member of legal function of company			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Latham & Watkins LLP			11/2010-7/2013	
Business Address		**City**	**State**	**Zip**
650 Town Center Dr #20		Costa Mesa	CA	92626
Phone	**Title**			
7145401235	Associate			
Description of Duties				
associate in legal services organization				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mathew Davis-Ratner

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/28/22

Date

Please have this section completed in the presence of a Notary Public.

State of Washington, ss. County of King

I, Mathew Davis-Ratner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/28/22

Date

Subscribed and Sworn to before me this 28 day of October 2022.

Notary Public Signature

GENNELL CLAUDETTE HUNTER
Notary Public
State of Washington
Commission # 203817
My Comm. Expires Oct 11, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable): 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website:

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Christopher Middle: William Last: Spitzer

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Gardenside Lane

City: Loveland State: OH Zip: 45140

Telephone: Email: christopher.spitzer@truepill.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Massachusetts, Dartmouth		09/16 - 05/18	
Address	**City**	**State**	**Zip**
285 Old Westport Rd	North Dartmouth	MA	02747
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Massachusetts College of Pharmacy and Health Sciences		09/04 - 05/10	
Address	**City**	**State**	**Zip**
179 Longwood Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Gateway Regional High School		09/00 - 06/04	
Address	**City**	**State**	**Zip**
12 Littleville Rd	Huntington	MA	01050
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/18 - present	[redacted] Gardenside Ln	Loveland	OH	45140
10/17 - 03/18	[redacted] Sanctuary Ln	Maineville	OH	45039
09/13 - 09/17	[redacted] Winchester St	Brookline	MA	02446
09/10 - 08/13	[redacted] Island Hill Ave	Malden	MA	02148

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Seven Hills Pharmacy			09/21 - present	
Business Address		**City**	**State**	**Zip**
2722 E. Kemper Rd		Sharonville	OH	45241
Phone	**Title**		**Number of Employed Hours**	
(513) 771-0367	Pharmacist-in-Charge		2,200	
Description of Duties				
Managing all pharmacy operations, hiring pharmacy/warehouse personnel, filling/shipping prescriptions, inventory management				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			1/18 - 8/21	
Business Address		**City**	**State**	**Zip**
13 Mary St		Cincinnati	OH	45216
Phone	**Title**		**Number of Employed Hours**	
(800) 746-7287	District Leader, Pharmacy Supervisor, Pharmacy Manager		7,040	
Description of Duties				
Responsible for the overall retail store operations in assigned district (28 Stores), P&L management, operating COVID clinics, inventory management				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Christopher Spitzer Pharmacist Registration #: 03236754

Pharmacy Name: Seven Hills Pharmacy, LLC

Initial each statement below to indicate you have read and agree with the following:

CS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

CS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

CS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

CS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

CS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	✔	

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:
Written Reprimand and Penalty	Ohio	3/9/2022	A-2021-0336

Criminal Action:	State:	Date:	Case #:	County:	Court:
N/A					

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

12/7/22
Date

Christopher W. Spitzer
[redacted] Gardenside Ln
Loveland, OH 45140
[redacted]

September 9, 2022

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste. 206
Reno, NV 89521

To whom it may concern,

Attached please find the details concerning a recent settlement between myself and the Ohio Board of Pharmacy. The fine of $250 has already been paid and the additional CE hours (5) will be submitted by the end of the month.

If you need any more information from me feel free to reach out via phone/email at any time.

Sincerely,

Christopher W. Spitzer

RECEIVED
SEP 19 2022
NEVADA STATE BOARD
OF PHARMACY

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF: **CASE NO. A-2021-0336**

Christopher Spitzer, RPh **License No. 03-236754**
[redacted] Gardenside Lane
Loveland, Ohio 45140

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Christopher Spitzer, RPh, for the purpose of resolving all issues between the parties relating to the Board investigation of Christopher Spitzer and CVS Pharmacy #6123 for failing to report a pharmacist for arriving to work his scheduled shift at CVS Pharmacy while impaired and under the influence of alcohol. Together, the Board and Christopher Spitzer are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.16 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Sections 4729.07 and 4729.08 of the Ohio Revised Code to practice pharmacy in the state of Ohio.

2. Christopher Spitzer is a licensed pharmacist in the state of Ohio under license number 03-236754, who was listed as the District Manager at CVS Pharmacy #6123, located at 7500 Beechmont Avenue, Cincinnati, Ohio, at the time of the Allegations in the Notice of Opportunity for Hearing dated March 9, 2022.

FACTS

1. The Board initiated an investigation of Christopher Spitzer, pharmacist license number 03-236754, and CVS Pharmacy #6123 for failing to report a pharmacist for arriving to work his scheduled shift at CVS Pharmacy while impaired and under the influence of alcohol.

2. On or about March 9, 2022, the Board sent a Notice of Opportunity for Hearing to Christopher Spitzer, which outlined the allegations and provided notice of his right to a hearing, his rights in such hearing, and his right to submit contentions in writing.

3. On or about March 31, 2022, Christopher Spitzer, timely requested an administrative hearing, which was subsequently scheduled for April 6, 2022. Settlement of this matter was reached prior to hearing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Christopher Spitzer neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated March 9, 2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Christopher Spitzer agrees to pay to the Board a monetary penalty in the amount of $250.00. This fine will be attached to Christopher Spitzer' license record and must be paid no later than 180 days from the effective date of this Order. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.

4. Christopher Spitzer must obtain five hours of approved continuing pharmacy education (0.5 CEUs) which may not also be used for license renewal. The 0.5 CEUs must be completed within six months from the effective date of this agreement. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

5. The Board hereby imposes a written reprimand on Christopher Spitzer's pharmacist license, number 03-236754.

6. Christopher Spitzer agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Christopher Spitzer understands that he has the right to be represented by counsel for review and execution of this agreement.

8. Christopher Spitzer agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which he currently holds a professional license, including to the Board on renewal applications or applications for a new license.

9. Christopher Spitzer explicitly withdraws his request for a hearing, waives an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

14. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Christopher Spitzer, RPh, Respondent	7/20/22 Date of Signature
James J. Leo, Attorney for Respondent	7/20/22 Date of Signature
Shawn Wilt, RPh, President, State of Ohio Board of Pharmacy	08.11.2022 Date of Signature
N/A Henry Appel, Ohio Assistant Attorney General	N/A Date of Signature

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Christopher Spitzer, **certify that as the designated representative for**

Seven Hills Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. x I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Spitzer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/18/22

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Spitzer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/18/22

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Hamilton

I, Christopher Spitzer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/18/22

Date

Subscribed and Sworn to before me this 18th day of October 2022

Notary Public Signature

HAYLEY ABNEY - NOTARY PUBLIC
COMM EXP: AUG 4, 2025
STATE OF OHIO

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: N/A

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Daniel Middle: Yitzhak Last: Simkin

Alias(es, nicknames, name changes, etc.): Donny Simkin

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Hyperion Ave

City: Los Angeles State: CA Zip: 90029

Telephone: [redacted] Email: compliance@truepill.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Valley Torah High School		09/96 - 06/00	
Address	City	State	Zip
12517 Chandler Blvd	Valley Village	CA	901607
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Stanford University		09/03 - 06/07	
Address	City	State	Zip
450 Serra Mall	Stanford	CA	94305
Diploma/Degree obtained, if any			
BA English			

School Name		From - To (MM/YY – MM/YY)	
UCLA School of Law		08/13 - 05/16	
Address	City	State	Zip
385 Charles E Young Dr E	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
JD			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/19 - Present	[redacted] Hyperion Ave	Los Angeles	CA	90029
05/15 - 07/19	[redacted] Lucile Ave [redacted]	Los Angeles	CA	90027
02/15 - 05/15	[redacted] S Wooster St [redacted]	Los Angeles	CA	90035
04/14 - 02/15	[redacted] Weyburn Ter [redacted]	Los Angeles	CA	90024
10/12 - 04/14	[redacted] Castle Heights Ave	Los Angeles	CA	90034
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Truepill, Inc.			08/21 - Present
Business Address	**City**	**State**	**Zip**
3121 Diablo Ave	Hayward	CA	94545
Phone	**Title**		
(855) 910-8606	Associate General Counsel		
Description of Duties			
Attorney			

Business Name			From - To (MM/YY – MM/YY)
Barta Tate			04/18 - 03/20
Business Address	**City**	**State**	**Zip**
1801 Century Park E STE 1200	Los Angeles	CA 9006	
Phone	**Title**		
(310) 479 - 1454	Associate		
Description of Duties			
Attorney			

Business Name			From - To (MM/YY – MM/YY)
Strook & Stroock & Lavan LLP			09/16 - 12/17
Business Address	**City**	**State**	**Zip**
2029 Century Park E 18th Floor	Los Angeles	CA	90067
Phone	**Title**		
(310) 556 - 5800	Associate		
Description of Duties			
Attorney			

Business Name			From - To (MM/YY – MM/YY)
Sparks Consulting			08/12 - 09/13
Business Address	**City**	**State**	**Zip**
Virtual			
Phone	**Title**		
(214) 557 - 0111	Senior Associate		
Description of Duties			
Athletic and academic counseling			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✔	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
12/25/2012	N/A	CA	Los Angeles	Los Angeles

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
#3VY002301-01	Superior Court of California

Reason/Charge
Driving under the influence of an alcoholic beverage

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
DANIEL YITZHAK SIMKIN	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:

On January 29, 2013, Manager Daniel Simkin received a misdemeanor alcohol DUI conviction under California Vehicle Code section 23152(b). See Los Angeles Superior Court (2013), Case #3VY002301-01; see also Exhibit A, Misdemeanor Sentencing Memorandum – Vehicle Code. On March 22, 2016, this misdemeanor conviction was dismissed under California Penal Code section 1203.4. See Exhibit B, Order for Dismissal.
On January 11, 2018, Mr. Simkin was admitted to the State Bar of California and remains active and in good standing (State Bar Number: 319806).

Original Signature (electronic, copies or stamps not accepted)

10/28/22
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel Simkin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/28/22

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Daniel Simkin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/31/22

Date

Subscribed and Sworn to before me this 31st day of October 2022.

Notary Public Signature

KEITH McGRUDER
COMM# 2293123
Notary Public - California
Los Angeles County
My comm. Expires July 12, 2023

(Seal)

Exhibit A

SUPERIOR COURT OF CALIFORNIA
COUNTY OF LOS ANGELES

THE PEOPLE OF THE STATE OF CALIFORNIA,
OR 01/15/2013 Bkg no. 3409911
Plaintiff,

vs.

DANIEL YITZHAK SIMKIN [redacted] M

V23152a/no prior

V23152b

Defendant(s).

MISDEMEANOR COMPLAINT

Case number: 3VY00230

FILED
JOHN A. CLARKE
Executive Officer/Clerk

By_____
Deputy Clerk

Issued by
CARMEN A. TRUTANICH
City Attorney

By_____
KATHLEEN FORD (LT)
Deputy City Attorney

Comes now the undersigned and states that he is informed and believes, and upon such information and belief declares: That on or about 12/25/2012 at and in the City of Los Angeles, in the County of Los Angeles, State of California, a misdemeanor, to wit, violation of Subdivision (a) of Section 23152 of the California Vehicle Code was committed by the above-named defendant(s) (whose true name(s) to affiant is(are) unknown), who at the time and place last aforesaid, did willfully and unlawfully drive a vehicle while being under the influence of an alcoholic beverage and a drug and under the combined influence of an alcoholic beverage and a drug.

MCI 23152(A)/29

COUNT II

For a further, separate and second cause of action being a different offense, belonging to the same class of crimes and offenses set forth in Count I hereof, affiant further alleges that on or about 12/25/2012 at and in the City of Los Angeles, in the County of Los Angeles, State of California, a misdemeanor, to wit, violation of Subdivision (b) of Section 23152 of the California Vehicle Code was committed by the above-named defendant(s) (whose true name(s) to affiant is(are) unknown), who at the time and place last aforesaid, did willfully and unlawfully drive a vehicle with 0.08 percent or more, by weight, of alcohol in his or her blood.

The allegations of prior convictions listed in Count I of this complaint are hereby incorporated by reference as allegations of prior convictions for the purposes of this Count of the complaint.

MCI 23152(B)/29

All of which is contrary to the law and against the peace and dignity of the People of the State of California. Declarant and complainant therefore prays that a warrant may be issued for the arrest of said defendant(s) and that he may be dealt with according to law.

Attached hereto and incorporated by reference as though fully set forth are written statements and reports which constitute the basis upon which I make the within allegations.

A declaration in Support of the Issuance of Such Warrant is Submitted.

Executed at Los Angeles, California, on

I declare under penalty of perjury that the foregoing is true and correct.

A. Martinez
Declarant and Complainant

INFORMAL DISCOVERY NOTICE

TO THE ABOVE-NAMED DEFENDANT(S) AND/OR ATTORNEY(S) FOR DEFENDANT(S):

Plaintiff, the People of the State of California, hereby requests discovery/disclosure from the defendant(s) and his or her attorney(s) in this case pursuant to Penal Code Sections 1054.3 and 1054.5.

YOU ARE HEREBY NOTIFIED that if complete disclosure is not made within 15 days of this request, plaintiff will seek -- on or before the next court date, or as soon as practicable thereafter -- a court order enforcing the provisions of Penal Code Section 1054.1, subdivisions (b) and (c). This is an ongoing request for any of the listed items which become known to the defendant(s) and his or her attorney(s) after the date of compliance.

The written statements and reports attached hereto constitute discoverable materials designated in Penal Code Section 1054.1. Any additional material discoverable pursuant to Penal Code Section 1054.1 that becomes known to plaintiff will be provided to the defense.

If, prior to or during trial, as a result of this request plaintiff obtains additional evidence or material subject to disclosure under a previous defense request or court order pursuant to Penal Code Section 1054.1, plaintiff will disclose the existence of that evidence or material within a reasonable time.

DISCOVERY MATERIALS SHOULD BE DELIVERED TO A DEPUTY CITY ATTORNEY IN TRIAL COURT ON THE FIRST TRIAL DATE.

Line Reference Target LRT-BE4-V3

SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

MISDEMEANOR SENTENCING MEMORANDUM - VEHICLE CODE

Defendant: DANIEL Simlin			Case No: 3VY00150
Date:	Dep't/Div.: 103	Prosecutor:	Defense: SAMAN Manavi
Judge: OMANS	Clerk: HARPOOK	Reporter:	Interpreter/Language:

As to Count 1, a violation of Penal Code § [ ] 23152(a)/(b) [ ] 23103 per 23103.5 [ ] 14601 _ [ ] 12500(a) [ ] _____ with ___ admitted priors.

Arraignment For Judgment

[ ] Arraignment for judgment and time for sentencing waived. There is no legal cause why judgment should not now be pronounced.

Sentence

1. [ ] **Probation is denied.** Defendant is to serve ____ days/hours in the Los Angeles County Jail, forthwith, [ ] consecutive [ ] concurrent with _____. Defendant to receive total credit of _____ days/hours (credit ____ days/hours actual plus _____ days GT/WT).
2. [ ] Pay a fine of $ 390 plus all applicable penalty assessments and enhancements.
3. [ ] Pay all fines and assessments as set forth in Paragraph 20 below.
4. [ ] **Execution of the foregoing sentence is suspended, on the following terms and conditions.**

Conditional Sentence (PC §1203b/Order of Probation (PC §1203a)

[ ] **Imposition of sentence is suspended (ISS)** [ ] With supervision by county probation officer (formal probation)
For a period of 36 months upon the following terms and conditions:

1. [ ] **Serve _____ days/hours in the Los Angeles County jail,** [ ] consecutive [ ] concurrent with _____. Defendant to receive credit of _____ days/hours actual plus _____ days/hours GT/WT. [ ] Time may be served in any penal institution.
   [ ] Time may be served on consecutive weekends of two days each, beginning _____ **(772)**
   [ ] Time may be served in any city jail having actual confinement, at defendant's expense. **(021)**
   [ ] Defendant may not participate in Sheriff's home detention/EHM per PC 1203.016(e). **(771)** [ ] Work furlough / early release not allowed.
   [ ] Last _____ days of jail time to be served in: [ ] Antelope Valley Rehabilitation Center [ ] _____ Program. **(002)**
   Defendant to be released only to an authorized representative of that program and is to comply with all program terms and conditions. **(013)**
   If defendant leaves or is discharged from the program prior to completion, defendant is to report to court on the next court day. **(013)**
2. [ ] **Pay a fine of $ 390 plus penalty assessments or** in default thereof serve ____ additional days in County jail, consecutive **or** perform _____ days of Community Labor/ _____ or perform _____ days/hours of approved Community Service with credit for _____ days actual or $_____ toward fine for jail time already served. [ ] Fine may be paid in monthly installments of $_____. **(124)** [ ] Defendant to report to Financial Evaluator to work out a payment plan.
   [ ] Defendant elects jail in lieu of fine, forthwith, consecutive to all other time, credit _____ days actual plus _____ days GT/WT.
3. [ ] Perform _____ days of work for Community Labor/ _____ or perform _____ days/hours of approved Community Service, with credit for _____ days actual. Sign up for all work or Community Service only at a court-approved volunteer center or in the clerk's office. Failure to complete court-ordered work or Community Service without excuse may result in jail. **This work or Community Service is in addition to that done in lieu of fine.**
4. [ ] Make **restitution to victim** _____ per PC §1202.4(f). **(048)** [ ] in an amount to be determined at a hearing. **(067)** [ ] *Harvey* waiver taken.
   [ ] in the stipulated sum of $_____ **(048)** [ ] per any final civil judgment against you. **(100)** [ ] Liability is admitted but amount is disputed.
5. [ ] **Enroll within 21 days (or within 21 days from your release from custody) and successfully complete an approved:** Defendant's BAC: ____ %. [ ] **Refusal**
   [ ] 12 hour (SB 1176) [ ] 3 mo. (AB541)**(327)** [ ] 6 mo. (AB 768) [ ] 9 mo. (AB1353) [ ] 18 mo. (SB38)**(328)** [ ] 30 mo. alcohol education program.
   The DMV will not restore your driving privilege until you successfully complete a licensed alcohol education program. [ ] Obtain program details Clerk or Health Officer.
6. [ ] Attend 16 Alcoholics Anonymous/Narcotics Anonymous meetings at the rate of ___ times per week, IN ADDITION to those required as part of the alcohol education program. **(246)**
7. [ ] **Do not drive any vehicle with any measurable amount of alcohol or drugs in your blood,** or refuse to take and complete any blood alcohol/drug chemical test, any field sobriety test or any preliminary alcohol screening test when requested by any peace officer. **(711)**
8. [ ] Do not drive a motor vehicle without a valid driver's license in your possession, or without liability insurance in at least the minimum amounts required b law. **(374)**
9. [ ] Abstain from the use of all alcoholic beverages and stay out of all places where they are a chief item of sale. **(300)**
10. [ ] Enroll in and complete the [ ] Hospital and Morgue ("HAM") Program. **(471)** [ ] MADD Victim Impact Program **(472)** [ ] _____
11. [ ] The court finds that defendant presents a traffic safety or public safety risk and, per VC §13352.4(d), disallows issuance by DMV of a restricted license. **(249)**
12. [ ] **Your driver's license is hereby ordered [ ] suspended [ ] revoked** for a period of ____ months ____ years. [ ] **"M" service given in open court. (283)**
    You may not drive a motor vehicle unless and until your driving privilege is restored. [ ] Defendant under age 21 at time of offense.
13. [ ] You are hereby declared to be a Habitual Traffic Offender for a period of _____ years. **(263)**
14. [ ] Comply with the "Supplemental Terms of Probation – Ignition Interlock Device" regarding installation of an ignition interlock. **(248)**
15. [ ] Do not own, use possess, buy or sell any controlled substances, or associated paraphernalia, except with valid prescription, and stay away from places where users, buyers or sellers congregate. Do not associate with persons known by you to be controlled substance users or sellers, except in an authorized drug counseling program. **(926)**
16. [ ] Submit your person and property to search and seizure at any time of the day or night, by any Probation Officer or other peace officer, with or without a warrant, probable cause or reasonable suspicion. **(576)**
17. [ ] The vehicle with license plate _____ is, after notice and hearing, ordered impounded for _____ days per Vehicle Code § 23594(a). **(703)**
18. [ ] The vehicle with license plate _____ is, after notice and hearing, ordered confiscated and sold per Vehicle Code § 23596(a).
19. [ ] If you are deported from or otherwise leave the United States, notify the Court [and Probation] in writing of your address and telephone number outside the United States within 72 hours of deportation or departure. Continue to pay all of your financial obligations to the Court [and to Probation] while outside the United States. **(474)**
20. [ ] **Pay all of the following (check all that apply):**

[ ] **A restitution fine** of [ ] $100.00, [ ] $_____, per PC §1202.4(b) through (e). **(098)**	[ ] **An administrative screening fee** of $25 per PC 1463.07/GC §29550(f) (D released OR)
[ ] **A probation revocation restitution fine** in the same amount as the restitution fine, per PC §1202.44, payment is stayed until probation is revoked and sentence imposed.	[ ] **A citation processing fee** of $10.00 per PC §1463.07 and GC §29550(f) (if D cited and released in field or at jail facility.)
[ ] **A criminal conviction/facilities assessment** of $30.00 per Gov't Code §70373(a). (SA:CC)	[ ] An alcohol abuse education and prevention penalty assessment of $_____ ($50 max.) per VC §23645
[ ] **A criminal fine surcharge** of $_____ per Penal Code §1465.7 (20% of base fine). (SA:AB)	[ ] An alcohol and drug problem program assessment of $_____ ($100.00 max.) per VC §23649
[ ] **A court security fee** of $20.00 per PC §1465.8(a)(1). (per count) (SA:SF)	[ ] A drug program fee of $150.00 (per drug count except §11357(b)) per H&S §11372.7(a).
[ ] **A criminal justice administration fee** of $_____ payable to the local arresting agency, per Gov't Code §§ 29550(c), 29550.1 or 29550.2 (agency's actual cost)	[ ] A crime lab fee of $50.00 plus penalty assessment per H&S Code §11372.5. **(184)**
[ ] **Cost of probation services** per PC 1203.1b, [ ] as determined by the Probation Officer, subject to a hearing if requested, in the amount of $_____ per month.	

NOTIFY DMV OF ANY ADDRESS CHANGE WITHIN 10 DAYS

21. [ ] _____
22. [ ] **Obey all laws** and orders of the Court **(541)**, [ ] and rules and regulations of the Probation Department. **(542)**
    [ ] **Defendant acknowledges that he/she understands and accepts the terms and conditions of probation. (810)**
    [ ] Defendant ordered to pay attorney fees [ ] in the amount of $_____ [ ] in the amount determined by the Financial Evaluator.
    [ ] **Counts/allegations** _____ **are dismissed/stricken** on the People's motion pursuant to Penal Code Section 1385 as to this defendant.

Compliance Dates: Defendant is ordered to appear in person on each of the following compliance dates. (683)

Surrender for jail: [ ] *Cruz* waiver taken:		Restitution Hearing in Div/Dep't _____ at 8.30 a.m.	
Pay fine/fees in full by: [ ] installments allowed	1-29-14 c/s	POE/Proof of Completion of Alcohol Program:	6-28-13 c/s
Complete jail/work/c-s by:		Other:	

I understand, accept and will comply with the foregoing conditional sentence and compliance dates and will return to Court as ordered.

Defendant's Signature:	Attorney's Signature Joining:

Defendant's Address: _____
Defendant's Telephone: _____

_____
Judge/Commissioner of the Superior Court

CRIM 088 (Rev. 5/1/09) DISTRIBUTION: Pink - Court Copy White - Defendant Copy

Exhibit B

CR-181

ATTORNEY OR PARTY WITHOUT ATTORNEY: STATE BAR NO:	FOR COURT USE ONLY
NAME: Daniel Yitzhak Simkin FIRM NAME: STREET ADDRESS: [redacted] Lucile Avenue AP[redacted] CITY: Los Angeles STATE: CA ZIP CODE: 90026 TELEPHONE NO: [redacted] FAX NO: E-MAIL ADDRESS: [redacted] ATTORNEY FOR (name):	FILED LOS ANGELES SUPERIOR COURT MAR 23 2016 Sherri R. Carter, Executive Officer By Bonnie Leck Dep. Bonnie Leck
PEOPLE OF THE STATE OF CALIFORNIA v. DEFENDANT: Daniel Yitzhak Simkin DATE OF BIRTH: [redacted]	
ORDER FOR DISMISSAL **(Pen. Code, §§ 17(b), 17(d)(2), 1203.4, 1203.4a, 1203.41, 1203.49)**	CASE NUMBER: 3VY00230-01

The court finds from the records on file in this case, and from the foregoing petition, that the petitioner *(the defendant in the above-entitled criminal action)* is eligible for the following requested relief:

1. The court **GRANTS** the petition for reduction of a felony to a misdemeanor (maximum punishment of 364 days per Pen. Code, § 18.5) under Penal Code section 17(b) and/or for reduction of a misdemeanor to an infraction under Penal Code section 17(d)(2) and reduces the following convictions:
   - ☐ ALL FELONY CONVICTIONS in the above-entitled action;
   - ☐ ALL MISDEMEANOR CONVICTIONS in the above-entitled action; OR
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

2. The court **DENIES** the petition for reduction of a felony to a misdemeanor under Penal Code section 17(b) and/or for reduction of a misdemeanor to an infraction under Penal Code section 17(d)(2) for:
   - ☐ ALL FELONY CONVICTIONS in the above-entitled action;
   - ☐ ALL MISDEMEANOR CONVICTIONS in the above-entitled action; OR
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

3. The court **GRANTS** the petition for dismissal regarding the following convictions under Penal Code ☒ § 1203.4, or ☐ § 1203.4a, or ☐ § 1203.41, or ☐ § 1203.49, and it is ordered that the pleas, verdicts, or findings of guilt be set aside and vacated and a plea of not guilty be entered and that the complaint be, and is hereby, dismissed for:
   - ☒ ALL CONVICTIONS in the above-entitled action; or
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

4. The court **DENIES** the petition for dismissal regarding the following convictions under Penal Code ☐ § 1203.4, or ☐ § 1203.4a, or ☐ § 1203.41, or ☐ § 1203.49 for:
   - ☐ ALL CONVICTIONS in the above-entitled action; or
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

5. In granting this order under the provisions of Penal Code section 1203.49:
   a. The court finds that the petitioner was a victim of human trafficking when he or she committed the crime.
   b. ☐ The court orders the relief described in section 1203.4, or
      ☐ The court orders the relief described in section 1203.4, with the following exceptions *(specify)*:

Form Approved for Optional Use
Judicial Council of California
CR-181 [Rev. January 1, 2016]

CR-181

PEOPLE OF THE STATE OF CALIFORNIA v DEFENDANT:	CASE NUMBER:
DANIEL YITZHAK Simkin	BVY00230-01

6. If this order is granted under the provisions of Penal Code section 1203.4 or 1203.41:
   a. The petitioner is required to disclose the above conviction in response to any direct question contained in any questionnaire or application for public office, or for licensure by any state or local agency, or for contracting with the California State Lottery Commission.
   b. Dismissal of the conviction does not *automatically* relieve petitioner from the requirement to register as a sex offender. (See, e.g., Pen. Code, § 290.5.)

7. If the order is granted under the provisions of Penal Code section 1203.49, the Department of Justice is hereby notified that the petitioner was a victim of human trafficking when he or she committed the crime, and the relief ordered.

8. If the order is granted under the provisions of either Penal Code section 1203.4, 1203.4a, 1203.41, or 1203.49, the petitioner is released from all penalties and disabilities resulting from the offense except as provided in Penal Code sections 29800 and 29900 (formerly sections 12021 and 12021.1) and Vehicle Code section 13555. In any subsequent prosecution of the petitioner for any other offense, the prior conviction may be pleaded and proved and shall have the same effect as if probation had not been granted or the accusation or information dismissed. The dismissal does not permit a person to own, possess, or have in his or her control a firearm if prevented by Penal Code sections 29800 or 29900 (formerly sections 12021 and 12021.1). Dismissal of a conviction does not permit a person prohibited from holding public office as a result of that conviction to hold public office.

9. In addition, as required by Penal Code section 299(f), relief under Penal Code sections 17(b), 17(d)(2), 1203.4, 1203.4a, 1203.41, or 1203.49 does *not* release petitioner from the separate administrative duty to provide specimens, samples, or print impressions under the DNA and Forensic Identification Database and Data Bank Act (Pen. Code, § 295 et seq.) if petitioner was found guilty by a trier of fact, not guilty by reason of insanity, or pled no contest to a qualifying offense as defined in Penal Code section 296(a).

FOR COURT USE ONLY
SUPERIOR COURT OF LOS ANGELES COUNTY
CALIFORNIA

Date: 3/22/16

Rebecca Grant
(JUDICIAL OFFICER)

11

11A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☑ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☑ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: BPI Labs, LLC

Physical Address: 12393 Belcher Road

City: Largo State: FL Zip Code: 33773

Telephone: 727-471-0850 Fax: 727-544-3595

Toll Free Number: 1-833-423-5243 (Required per NAC 639.708)

E-mail: complaints@belcherpharma.com Website: www.bpi-labs.com

Supervising Pharmacist: Cletis Kontoulakis Nevada License #: 22391

SERVICES PROVIDED

Yes/No

☑ ☐ Parenteral
☑ ☐ Sterile Compounding
☐ ☑ Non Sterile Compounding
☑ ☐ Mail Service Sterile Compounding
☐ ☑ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: $500 check 3450

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3015156709

Please provide the name of the facility as registered with the FDA and the registration number:
BPI Labs, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
BPI Labs

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Cletis Koukoulakis Nevada License Number: 22391

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☐

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Cletus Koukoulakis

Print Name of Authorized Person

03/24/22

Date

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Belcher Pharmaceuticals, LLC

Business Name: Belcher Pharmaceuticals, LLC

Current Business Address: 6911 Bryan Dairy Road

City: Largo State: FL Zip Code: 33773

Telephone: 727-471-0850 Fax: 727-544-3595

List any physician shareholders and percentage of ownership.

Name: N/A %:

Name: N/A %:

Name: N/A %:

Name: N/A %:

Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 08/16/2022
Amount:
License #: 22391

Cletis M. Koukoulakis

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:08/16/2022
Expires:10/31/2023

Cletis M. Koukoulakis

License #
22391
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

NEVADA

STATE BOARD OF PHARMACY

Pharmacist

Expires: 10/31/2023
STATUS: Active

License Type: Pharmacist
License #: 22391
Effective Date:08/16/2022

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Cletis M. Koukoulakis

NONTRANSFERABLE

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

2995

Department of Health

BPI LABS LLC BPI Labs

License Number: PH32473

Data As Of 5/1/2023

Profession	Pharmacy
License	PH32473
License Status	CLEAR/
Qualifications	Special Sterile CompoundingOutsourcing Facility
License Expiration Date	2/28/2025
License Original Issue Date	12/10/2019
Address of Record	12393 BELCHER RD. Suite 450 and 420 LARGO, FL 33773
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

Company Management

bpi Labs

- **Jugal Taneja - Managing Member**

Responsible Corporate Officer of Belcher Pharmaceuticals.

BS in Mining & Petroleum, MSc in Mechanical Engineering, and MBA with over 30 years of experience managing healthcare and high-tech manufacturing companies, community banks, and petroleum energy industries.

Phone Number: (727) 471-0850 Extension 222, Email: jt@belcherpharma.com

- **Supriya Taneja - Vice President and General Counsel**

Juris Doctor, Law (Corporate Law concentration) with over 16 years in the healthcare industry. Licensed attorney specializing in health care regulatory and contract law for 12 years with a large firm. Her practice included both health law, including regulatory compliance, fraud and abuse, HIPAA, and licensure and certification, and corporate transactional matters for a range of healthcare providers, reviewing employment contracts and business sale agreements.

Phone Number: (727) 471-0850 Extension 241, Email: sst@belcherpharma.com

- **Fabio Lanzieri - President**

Leading marketing and sales. PhD in International Business and MBA with over 35 years of experience in pharmaceutical industry, with 20 years in executive roles.

Phone Number: (732) 339 3573, Email: fabiol@bpi-labs.com

- **Chandra Kasireddy - Director Technical Operations (Head of Operations Unit)**

Overseeing Sterile Drug Products Manufacturing and Technical Operations, Warehouse and Purchasing, Regulatory Affairs, Product Development, AR&D and Quality Control, Microbiology, and Maintenance.

Bachelor in Pharmacy with over 20 years of experience in production, validation / qualification, technology transfer, quality assurance, and operations in pharmaceutical products.

Phone Number: (727) 471-0850 Extension 289, Email: chandrak@belcherpharma.com

- **Mauricio Salazar - Chief Quality & Compliance Officer (Head of Quality Unit)**

Overseeing In-Process Quality Assurance, Product Release, Quality Systems, Training, Compliance, Complaints, Calibration, Validation, and EHS.

Industrial Engineer with over 20 years of experience in quality and compliance in pharmaceutical products, medical devices, and consumer goods.

Phone Number: (727) 471-0850 Extension 200, Email: mauricios@belcherpharma.com

- **Lana Radowick - Chief Financial Officer**

BS in Accounting and MBA (Strategic Management Concentration) with over 20 years of experience in public accounting, steel industry, and dental appliance manufacturing and distribution across 7 international entities in Europe, Asia, and Middle East.

Phone Number: (727) 471-0850 Extension 276, Email: lanar@belcherpharma.com

- **Cletis Koukoulakis, Pharm.D., C.Ph. - 503B Supervisory Pharmacist**

Over 20 years in Pharmacy Compounding Experience and Management, Pharmacy and Long Term Care Consulting.

Phone Number: (727) 471-0850 Extension 751, Email: cletisk@belcherpharma.com

BPI Labs' associates possess over 100 years of combined experience in pharmaceuticals development, manufacturing, and distribution. Currently, approximately 50 employees work for BPI Labs, LLC; refer to attached organizational structure.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: BPI Labs, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 12393 Belcher Road

City: Largo State: FL Zip: 33773

Mailing Address (if different from physical address): 12393 Belcher Road, Suite 450

City: Largo State: FL Zip: 33773

Telephone: 727-471-0850 Toll Free # (NAC 639.708, NRS 639.23286): 1-833-423-5243

Fax: 727-471-0858 Contact Email: cletisk@belcherpharma.com

Website: www.bpi-labs.com

Nevada Business License # (if applicable) N/a

Supervising/Managing Pharmacist Name (NRS 639.220): Cletis Koukoulakis

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22391

Name of Person with direct knowledge of compounding procedures: Cletis Koukoulakis

Email of Person with direct knowledge of compounding procedures: cletisk@belcherpharma.com

Telephone of Person with direct knowledge of compounding procedures: 727-471-0850 x 751

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ■ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Currently produced one batch of Testosterone Pellets (225mg), distributed one order each to two FL wellness clinics.

Future plans for vials and prefilled syringe products to hospitals and diagnostic clinics.

We are a full generic drug manufacturer with 12 sterile products on the commercial market.

4. Will you be utilizing beyond use dates in excess of USP-797? ■ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

We follow the same robust stability program executed with our commercial products. The SOP (IQC-002) is included for review.

6. What laboratory performs this additional testing?

Name: Medizap (for e beam terminal sterilization of pellets only) -- Everything else in-house (full R&D, QC, Micro Labs)

Address: 600 B St Suite 300, San Diego, CA 92101

City: San Diego State: CA Zip: 92101

Telephone: (775) 386-6677

7. What is your procedure for visual inspection of compounded sterile products?

I have included the SOP (IPD-007) for visual inspection.

8. How often do you perform glove fingertip and medial fill testing?
Media fill testing is completed every six months. We have fully contained robotic filling isolators. There is glove access to the sterile areas without breaching the isolators, the gloves fingertips are tested with touchplates after every batch. The gloves are also tested for punctures before each batch begins.

9. What is your policy if an employee fails a glove fingertip or media-fill test?
It would not be an employee, but if one of the glove sets fails, then a full investigation would be initiated.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initital and annual trainning SOP (ITD-001) is provided.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Cleaning of Processing and Non-Processing Rooms SOP (IGN-028) is provided.

12. Who performs the sterile compounding process at your facility?
Robotic fill machines, assisted by Engineers and production technicians.

13. Who is responsible and accountable for the sterile compounding process at your facility?
All personel involved in the manufacturing process, 503B products under the supervision of the licensed pharmacist, with Quality Assurance checks and final release of batch.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Specifications and standard test methods for all containers and closures are generated for primary and secondary packaging components (testing types include description, physical tests, sterility and endotoxin (if applicable), and C of A check).

Final product shipping studies are performed (drop/ship test) utilizing primary and secondary containers.

Stability and freeze thaw studies are performed to document product behavior during temperature excursions.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A - No sterile Hazardous Compounding		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
503B : Testosterone Pellets 225mg (10 count blister pack)

Current Commercial products include :
Hyoscyamine Sulfate Inj, USP 0.5mg/mL (NDC 54288-111-01),
Epinephrine Inj, USP 10mg/10mL (NDC 54288-120-01),
Epinephrine Chloride Nasal Solution 10mg/10mL (NDC 54288-123-01),
Tetracaine HCL Inj, USP 20mg/2mL (NDC 54288-127-01),
Phenobarbital Sodium Inj, USP 65mg/mL (NDC 54288-136-01) ,
Phenobarbital Sodium Inj, USP 130mg/mL (NDC 54288-137-01) ,
Papaverine HCl Inj, USP 60mg/2mL (NDC 54288-142-01),
Methylene Blue Inj, USP 100mg/10mL (NDC 54288-147-01),
Epinephrine Chloride Nasal Solution 30mg/30mL (NDC 54288-154-01)

2. What sterilization methods are utilized at your facility?
A 3 step 0.22 micron filtration process with one time use sterile bags and tubing. Autoclave for any glassware or components used during the mixing process.

3. Does your facility utilize biological indicators? ■ Yes ☐ No

4. If yes, describe how they are utilized:
In the robotic machines, a risk assessment is established. BIs are placed , VPHP cycles are run, results are assessed and guidelines are established after achievieving acceptable levels.

BIs are also utilized n the component prep and filter tubing process, those that undergo autoclaving.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cletis Koukoulakis, Pharm.D.
Name of Person who Completed the Form

Pharmacist and Manager of Medical Affairs
Title

Signature (copies or stamps not accepted)

04/27/23
Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
503b Outsourcing Inspection

File # 26555
Insp # 185806

NAME	PERMIT NUMBER	DATE OF INSPECTION
BPI LABS LLC	32473	04/03/2023
DOING BUSINESS AS		
BPI LABS		
STREET ADDRESS	**TELEPHONE #**	**EXT**
12393 BELCHER RD. Suite 450 and 420	727-471-0850	
CITY	**COUNTY**	**STATE/ZIP**
LARGO	PINELLAS	FL/33773

Additional Information

Business Operation Hours

Registered Pharmacist / Intern / Tech

ACS Manager

Optional Information

Basic License Data - PSD

License Relations

Pharmacy Affiliate

TANEJA, MANJU	License #
TANEJA, SUPRIYA	License #

RX DPT MGR/COR/POR

KOUKOULAKIS, CLETIS MICHAEL	License # 36693

503b - Outsourcing Inspection

Quality

Firm has an independent Quality Control Unit	Yes
The QC unit has the authority and responsibility to approve or reject all components, drug product containers or closures, end process materials, packaging materials, labeling and drug products.	Yes
QC unit reviews and approves/rejects: SOP's, Batch Records (completeness and accuracy, components, API's, materials, OOS results	Yes
Investigations are conducted within time limits specified per SOP *1 batch Testosterone 225mg pellets released since previous inspection, no complaints related to batch.*	N/A
All written quality procedures are current and approved	Yes
The QC unit follows their procedures	Yes
QC unit personnel are qualified through training and experience.	Yes
The production batch record and release test results are reviewed for accuracy and completeness prior release of finished product *Reviewed Batch Record for Testosterone 225mg pellets.*	Yes

Facilities and Equipment

The facility design is suitable for compounding sterile products	Yes
The layout and organization of the facility is designed to prevent contamination and mix ups.	Yes
The control of air pressure, dust, humidity and temperature is adequate for the manufacturing, processing, storage or testing of drug products	Yes
Pressure gauges that monitor pressure differentials are calibrated	Yes

503b Outsourcing Inspection

Insp # 185806 BPI LABS LLC File # 26555

The facility is maintained in a clean and sanitary condition	Yes
Certifications conducted under dynamic, worst case conditions with the maximum number of personnel allowed per SOP present	No
The facility has written procedures that describe in sufficient detail the cleaning schedule, methods, equipment and material	Yes
The facility has a procedure for rotating cleaning solutions	Yes
Sporicidal agents are used . How often *Monthly*	Yes
The facility has documentation of the effectiveness of the cleaning solutions	Yes
Primary and secondary engineering controls currently certified *No PEC's, particle count testing in rooms, ISO 8 rooms for compounding of pellets.*	Yes
Ceiling tiles are clean room grade and gasketed and sealed/clipped.	N/A
Air return vents are not blocked	Yes
HEPA filters are all leak tested *In house HEPA leak testing.*	Yes
Compounding of hazardous drugs is clearly separated from non hazardous drugs to prevent cross contamination. *Testosterone Pellets compounded in suite that is used for Testosterone only.*	Yes
All equipment has written procedures for use.	Yes
Facility has documentation of equipment calibration, maintenance, cleaning.	Yes
All equipment is validated for its intended use.	Yes
Refrigerators and freezers are monitored with a calibrated thermometer.	Yes
Documentation of training personnel on use of equipment.	Yes
Surfaces that contact materials or finished goods non-reactive, non-adsorptive and non- additive	Yes

Personnel Qualification

All Personnel involved in the preparation and handling of csp's are trained and qualified in their roles.	N/A
Facility has a written training program that describes the required training, frequency of training and process for evaluating the performance of individuals involved in sterile compounding.	N/A
Facility has documentation that compounding personnel have the required skills necessary to perform their assigned task	Yes
Compounding personnel receive ongoing periodic GMP training by GMP trainers.	Yes
Are GMP trainers qualified through experience and training.	Yes
Prior to beginning to prepare CSP's personnel have completed training and have demonstrated proficiency in the principles and hands on skills of aseptic manipulations. *Firm only produces pellets which are sterilized by E Beam after packaging*	N/A
Compounding personnel have ongoing training for specific tasks they are authorized to perform.	Yes
Personnel have been periodically trained in core competencies, visual observation is conducted to confirm personnel have necessary skills (i.e. Hand hygiene and garbing, aseptic manipulations, cleaning and disinfecting).	N/A
Personnel sampling including GFT is conducted after compounding and documented on each batch record.	N/A
Personnel have completed media fill simulations for all aseptic compounding under the most difficult and challenging processing conditions which include the most manipulations/units, most complex flow of material, longest time to compound and all breaks.	N/A
Personnel are retrained and requalified after failure of media fill, GFT or batch failures.	N/A

Environmental Monitoring

Facility has an environmental monitoring program.	Yes
Air quality is monitored regularly using volumetric air sampling to ensure the environment remains suitable for sterile compounding.	Yes
Settling plates are used during compounding to monitor the quality of air during compounding processes and documented in the batch records.	Yes
Surface sampling is conducted after each batch prior to cleaning and documented on batch records.	Yes
Surface sampling is routinely conducted in all classified spaces in those locations identified to be at highest risk of contamination	Yes
Media used in environmental and personnel monitoring has been shown to promote the growth of microorganisms and contains agents to neutralize cleaning solutions and disinfectants.	Yes
Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment.	Yes
Adverse changes in the environment are investigated and promptly remediated. *No growth has occurred in the rooms.*	N/A
Alert and action levels for CFU counts have been established in SOP's for the facility.	Yes
Air pressure differentials are continuously monitored and demonstrate that a cascading pressure differential is maintained throughout the compounding area during production of sterile compounding. *Manual documentation*	Yes

Materials

Facility has a quality agreement with API suppliers to ensure all API's are manufactured in registered FDA facilities.	Yes
Facility tests API's for identity, strength and purity to confirm the specifications in the Certificate of Analysis.	Yes
Facility maintains and follows SOP's for testing of incoming materials.	Yes

503b Outsourcing Inspection

Insp # 185805 | BPI LABS LLC | File # 26555

Facility has appropriate sterile PPE *Firm only produces pellets which are sterilized by E Beam after packaging*	N/A
Materials for cleaning the PEC's are sterile and the effectiveness is validated. *No PEC's.*	N/A
Filters used for sterilization have documentation that they are compatible with the product, are pharmaceutical grade, non-pyrogenic and capable of sterilizing the intended volume.	N/A
Integrity testing is conducted on all filters used to sterilize product.	N/A
All materials are quarantined until approved by the QC department.	Yes
Written procedures identify storage times beyond which materials must be reexamined before use.	N/A
Release of re tested material clearly identified for reuse.	N/A
Written procedures identify steps in the materials for production.	Yes
Written procedures include release by QC, documentation of correct weight or measure and proper identification of containers.	Yes

Production

Materials are sanitized prior to introduction into the clean room	Yes
All glassware is depyrogenated and cycles are validated and documented.	N/A
Autoclaved cycles are properly validated with BI's.	N/A
Sterilization methods are validated *Ebeam.*	Yes
All components are identified on batch records and traceable to the finished product.	Yes
SOP's identify hold times for depyrogenated glassware and the hold times have been validated.	N/A
Deviations and OOS's are adequately documented and thoroughly investigated.	N/A
Facility maintains complete batch records for all compounded sterile products	N/A
Facility maintains separate, complete, readily retrievable records of dispensing into the State of Florida	Yes
Written procedures indicate how and who verifies that correct containers and packages are used for the finished product.	Yes
All finished products are held in quarantine until QC has completed testing and releases the batch.	Yes
Personnel who conduct visual inspection of finished products have been qualified through training and yearly eye exams.	N/A
Firm has an SOP for adverse event reporting to FDA	Yes
Firm has record of adverse event reports submitted to FDA	N/A

Labeling

Written procedure specify who is authorized to issue labels.	Yes
Written procedure specify how labels are issued, used, reconciled with production, returned when unused, and the specific steps for evaluation of any discrepancies.	Yes
Written procedures call for the destruction of excess labeling on which lot and control #'s have been stamped or imprinted.	Yes
Written procedures require that representative samples of units be visually examined upon completion of packaging to verify correct labeling.	Yes
Drug labels include the statement "this is a compounded drug, the name, address and phone # of the facility	Yes
The label of the drugs contain the lot or batch #, the established name of the drug, dosage form and strength, quantity or volume, the date the drug was compounded, the expiration date, storage and handling instructions, NDC # (if available), the statement "not for resale" and a list of active and inactive ingredients identified by established name and the quantity or proportion of each ingredient and route of administration.	Yes
The label or container contains the following: www.fda.gov/medwatch and 1-800-FDA-1088	Yes
Written procedures detail how equipment is to be checked immediately prior to use for removal of any labels and labeling from prior print operations. *10 Pellets into blister, labeled and sealed.*	Yes

Laboratory

Contract labs are FDA registered	Yes
Facility has qualified their contract labs	Yes
All products have stability studies to justify the BUD *Testosterone 225mg BUD 1 year with studies.*	Yes
Stability studies, microbial effectiveness testing on the preservative, container closure studies and sterility testing have been conducted to ensure the CSP continues to meet all specifications over the intended shelf life of the product.	N/A
Sterility testing for all batches is conducted using a USP 71 test.	Yes
Method suitability has been conducted for all products	N/A
Endotoxin testing is conducted on all batches.	Yes
Potency is conducted on all batches.	Yes
Appropriate # of articles/volume is tested for sterility	N/A
Facility maintains and follows SOP for product release.	Yes
Facility has approved finished product specifications for all csp's.	N/A

Remarks:

Facility has compounded and distributed 1 lot of Testosterone 225mg pellets. Dedicated Testosterone Suite.
Inspection completed with Mauricio Salazar and Cletis Koukoulakis.

503b Outsourcing Inspection

Insp # 185806

BPI LABS LLC

File # 26555

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

STAIKOS, GILLIAN

Date:4/3/2023

Representative:

Cletus Koukoulakis

Date:4/3/2023

SOP No.	Title	Revision No.
ITD-001	TRAINING SYSTEM	04

Prepared By / Date	Reviewed By / Date	QA Approved By / Date	Effective Date
Sanja Mizic 07/12/22	Srdjan V 07/13/22	M. Salazar 07/18/22	JUL 2 7 2022
			Change Control No.
Title: QA Group Leader	Title: QA/C Supervisor	Title: CQCO	I-22417

1.0 PURPOSE

To outline the procedure for training personnel to perform their job functions in compliance with cGMP requirements and all federal and state regulations applicable to BPI Labs. This document will describe training requirements and procedures in terms of new employee orientation, continuing training program, cGMP training, new / revised documents, and other training, and qualification techniques.

2.0 SCOPE

This procedure applies to all personnel employed at the company as full time, part time, or temporary basis.

Training activities are coordinated by the Quality Assurance Department.

3.0 RESPONSIBILITY

3.1 All employees are responsible to attend the new employee orientation at the time of hiring, conduct training on a continuous basis as per approved curriculum and qualification technique, attend to cGMP training at least once a year, and perform training on new and revised documents, as required.

3.2 Quality Assurance Department is responsible for:

3.2.1 Determining the training requirements and qualification techniques (when applicable) for employees together with department managers.

3.2.2 Maintaining training curriculums and qualification techniques (when applicable) for job functions.

3.2.3 Coordinating and conducting new hire training with department managers.

3.2.4 Conducting cGMP training for all employees at least once a year.

3.2.5 Coordinating and/or conducting training of existing employees with department managers.

3.2.6 Maintaining training records for all employees.

3.2.7 Identifying and training trainers within the company.

3.2.8 Identifying and hiring external training resources when required.

3.2.9 Ensuring trainers possess the necessary qualifications to conduct training.

3.2.10 Assessing training effectiveness.

3.2.11 Providing training tracking and trending information for Management Reviews.

3.3 Department Managers are responsible to:

3.3.1 Ensure that all new employees attend to the new employee orientation at the time of hiring.

3.3.2 Assure that their employees are trained on the documents and job skills relevant to their area.

3.3.3 Ensuring their personnel do not perform job tasks or functions for which they are not appropriately trained.

3.3.4 Creating with the assistance of Quality Assurance training curriculums and qualification techniques for their employees.

3.3.5 Conducting on the job training of employees.

3.3.6 Identifying via performance evaluations training deficiencies of their reportees.

3.3.7 Coordinating and conducting training to promptly resolve training deficiencies of their reportees.

3.4 BPI Labs management is responsible for providing the necessary resources to implement a training system compliant with cGMPs and all federal and state regulations applicable to the company.

4.0 REFERENCES

4.1 21 CFR Part 211.25 Personnel qualifications

4.2 21 CFR Part 820.25 Personnel

4.3 SOP IQA-002 Document Control System

4.4 SOP IPD-017 Qualification and Validation of Inspection Processes

4.5 Form ITD-001-F1 Training Record Form

4.6 Form ITD-001-F2 Self Training Record Form

4.7 Training Curriculum TC-IGN-001 All Departments - (All Employees) New Employee Training

4.8 Training Curriculum TC-IGN-002 All Departments - (All Employees) Annual Employee Training

4.9 Training Curriculum TC-IGN-003 All Departments - (All Employees) Biennial Employee Training

4.10 Qualification Technique QT-ITD-001 Training and Development - cGMP Training

4.11 Qualification Technique QT-IEH-002 EH - General Industry Safety Training

5.0 ATTACHMENTS

Not Applicable.

6.0 PROCEDURE

6.1 General requirements:

6.1.1 Documentation and Filing of Training Records:

6.1.1.1 A training record (Forms ITD-001-F1 and ITD-001-F2) is documented accordingly for any type of training upon training completion. Form ITD-001-F1 is used to document all trainings other than self training. Form ITD-001-F2 is utilized to document self training only. Following sections shall be completed:

6.1.1.1.1 Topic or Document Name.

6.1.1.1.2 Document Number and its Document Revision, when applicable.

6.1.1.1.3 Type of Training (what kind of training).

6.1.1.1.4 Method of Training (how is the training conducted). This is not applicable on Form ITD-001-F2.

6.1.1.1.5 Trainer. This is not applicable on Form ITD-001-F2.

6.1.1.1.6 Date of Training.

6.1.1.1.7 Employee Name, Department, and Signature.

6.1.1.1.8 Acknowledgement of Training Understanding. This is not applicable on Form ITD-001-F1.

6.1.1.2 Upon training completion, employees, department head, or designee submit all original training records to Training and Development.

6.1.1.3 Training and Development verifies the training record for accuracy and completeness and files training records appropriately.

6.1.1.4 Training and Development keeps all employees training records and any other document pertaining to training.

NOTES:

a) Training curriculums and qualification techniques are also considered a training record since these documents are used by personnel to acknowledge the completion of self training.

b) The signature log included in the batch and packaging records is also considered a training record since the personnel involved during the manufacturing, packaging, and inspection activities of the product use this record to acknowledge their competence and understanding of the work to be done and the precautions required during the execution of each activity.

6.2 Type of Training:

6.2.1 New Employee Orientation:

6.2.1.1 At the time of hiring all new employees are required to attend the new employee orientation program following general and specific training.

6.2.1.2 New Employee Training (General and Specific Training):

6.2.1.2.1 General Training consist in an overview and completion of respective forms, overview of general safety, overview of cGMPs, overview of quality systems, and a general SOP self training session as per Training Curriculum TC-IGN-001. A combination of group training and self-training method is used as part of the training session and discussion.

6.2.1.2.2 Discussion and completion of respective forms (i.e., Employee Signature List, Employee Screening Questionnaire, Respiratory Medical Evaluation Questionnaire, Respiratory Fitness Test, Company Safety Policies) is coordinated by Training and Development and acknowledged on respective Training Curriculum TC-IGN-001.

6.2.1.2.3 An overview of federal regulations, current Good Manufacturing Practices based on 21 CFR Parts 210, 211, 820, and 4, WHO Guidelines – Hormones, FDA Guidance – 503B, DBPR, DOH, internal audits, warning letters, and annual trend of 483s, overview of general safety, and overview of quality systems is coordinated by Training and Development and documented on respective Training Curriculum TC-IGN-001.

6.2.1.2.4 General SOP Self Training (coordinated by Training and Development) identifies a list of SOPs / documents required to complete general SOP self-training session. New employees are required to read each SOP / document according to section 6.3.1; self training record is documented upon completion using the respective Training Curriculum TC-IGN-001. Training and Development coordinates questions and answers session upon self training session completion to ensure trainee has comprehended the material read.

6.2.1.2.5 Upon completion of General cGMP Training, General Department Core Training and Specific Training Curriculum are issued to employee on the respective employee's training folder for execution. Respective training is coordinated by each department supervisor or designee based on respective training curriculums and depending on functions to be performed.

6.2.1.2.6 An assessment is done by the department head or designee based on the person's education, job experience, and previous training to determine the extent of the training and its method of training (i.e., self-training, on the job training).

6.2.1.2.7 Conducted self-training is documented on respective General Department Core Training Curriculum, and Specific Training Curriculum assigned to employee's training folder. In addition, conducted on the Job / Hands on Training is documented using Form ITD-001-F1.

6.2.1.2.8 Upon completion of respective training curriculums, the department head or designee informs by any means (i.e., via e-mail) to Training and Development.

6.2.1.2.9 Training and Development ensures that all trainings were properly performed and documented, and acknowledgement of completion of

respective training curriculums is performed by employee, supervisor and training group accordingly by placing signatures and date on respective section at the end of Department and Specific Training Curriculums (refer to section 6.5 for details of training evaluation).

6.2.1.2.10 After acknowledgement of completion of training curriculum, final release is performed. Employee is required to sign on respective section of Training Curriculum TC-IGN-001 (i.e., Completion of Department General Training section). Lastly, employee and supervisor are required to perform respective acknowledgment of completion of new employee training by placing respective signatures and date on the Acknowledgement of Completion of New Employee Training section using Training Curriculum TC-IGN-001. Training Group releases the trainee for normal activities by informing the department head or designee by any means (i.e., via e-mail) if all training requirements were met using TC-IGN-001.

NOTE: As a general practice, new employees should complete the new employee orientation training ideally within 3 months from their hiring date.

6.2.2 Biennial Training (Continuing Training Program):

6.2.2.1 Training curriculums are used as a tool to assure that training is performed on a continuing basis. They include the list of documents and skills training that are required to perform assigned position adequately. Training curriculums need to be executed by employees at least once every two years.

6.2.2.2 Each department supervisor prepares training curriculums by position following SOP IQA-002, contacts at the beginning of the period his / her employees to plan for the execution of the training curriculum throughout the two-year period, identifies additional training needs, updates training curriculums as needed, and coordinates any extra training not included in the training curriculum.

6.2.2.3 After completion of respective training curriculum, acknowledgement of completion of training curriculum is performed as part of employee evaluation. Signature and date are placed by employee, supervisor, and training group on respective section as part of an overall evaluation of the training curriculum (refer to section 6.5 for details of training evaluation).

NOTES:

a) **Employee's training folder is prepared using the training plan. The training plan is established after discussing with the supervisor / manager to include all the applicable training curriculums based on the employee's job functions and responsibilities.**

b) **Training and Development group prepares a training folder using the training plan by employee including the applicable training curriculums to be executed during the respective training period (i.e., TC-IGN-002, TC-IGN-003, General Department Training Curriculum). Applicable training curriculums are distributed to respective employee's training folder based on each employee's applicable job functions and responsibilities.**

c) The Training and Development group keeps track of the progress of the employee's biennial training curriculum on a quarterly basis.

d) Training curriculum impact assessment is performed each time a training curriculum is revised via change control in order to assess that the respective document is not impacted by the change and to determine the need of distribution to respective training folders (i.e., if an additional SOP is added to the training curriculum, that training curriculum might not require to be distributed within the training period if respective training has been completed as part of change control).

e) Training plan is assessed for the employees who are transferred to other functions or departments. The training plan is updated accordingly for such employees and the progress about completion of the issued training curriculums as per the updated training plan is tracked by Training and Development group for completeness. As a general practice, this training should be completed ideally within 3 months from the transfer / new functions date.

6.2.3 Annual Training (Update of Forms, cGMP Training and General Safety Training):

6.2.3.1 Update of Forms (i.e., Employee Signature List, Employee Screening Questionnaire, Respiratory Medical Evaluation Questionnaire, Respiratory Fitness Test, Company Safety Policies) are discussed and coordinated by Training and Development at least once a year and acknowledged by employee on respective Training Curriculum TC-IGN-002.

6.2.3.2 cGMP training is conducted for all employees by Training and Development at least once a year as per Training Curriculum TC-IGN-002. Topics are selected from federal regulations (i.e., 21 CFR Parts 210, 211, 820, and 4, WHO Guidelines – Hormones, FDA Guidance – 503B, DBPR, DOH, internal audits, warning letters, and annual trend of 483s), documentation practices, data integrity, compliance programs, among others.

6.2.3.3 General Safety Training is conducted for all employees by Training and Development at least once a year as per Training Curriculum TC-IGN-002. Training consists of a refreshment of the company's safety program standard operating procedures.

6.2.3.4 Conducted cGMP and General Safety trainings are documented on respective group training form ITD-001-F1, and acknowledgement of completion of training is documented by employee on training curriculum TC-IGN-002 located on each employee respective training folder.

6.2.3.5 Completion of Training Curriculum TC-IGN-002 is acknowledged by employee, supervisor, and training group by placing respective signature and date on "Acknowledgement of Completion of Annual General Employee Training Section" at the end of respective training curriculum.

6.2.4 New / Revised Documents Training:

6.2.4.1 As a general practice, training on new / revised documents is applicable at least to SOPs, Forms, STMs, Master Batch Records, and Master Packaging Records before they become effective.

6.2.4.2 When a document is written or revised and that document is needed by users that are not the authors, reviewers, or approvers, training should be conducted.

6.2.4.3 During the change control approval process, area management and Quality Assurance evaluate the impact of changes against the established training curriculums in the quality system and training needs and decide the extent and the method of training (i.e., individual training, group training, practical training) as well as determine all the individuals affected with the change; this decision is documented on the change control form. Upon training notification from Quality Assurance, area management or designee coordinates the execution of the training ideally in not more than fifteen (15) business days from the training notification date.

6.2.4.4 Training sessions can be coordinated by the subject matter expert (i.e., author) depending on the topic of the activity (i.e., change control system). A training assessment quiz might be administered to the employees, as required by trainer, Quality Assurance, and / or area management.

6.2.4.5 Upon completion of the training the designee informs Training and Development / Document Control and submits all training records accordingly.

6.2.4.6 Each department destroys the training document copies (training copy) upon training completion. Under no circumstances the training copy can be used for reference, nor can it replace the official effective copy.

6.2.4.7 Once training requirements are met, Training and Development and Document Control confirm each other to ensure that the document can be made effective.

6.2.4.8 Only employees trained in the most recent version of the document can be released to perform the work described in the document.

6.2.4.9 Following the initial training period, the department supervisor conducts training of the missing employees (i.e., for those who are on short term disability or leave) and documents this activity in a separate training record.

6.2.4.10 Department head is responsible for assuring that all reporting personnel are trained on job-related documents.

NOTES:

a) Minor changes to documents such as but not limited to editorial updates to documents, creation or revision of documents used for reference only (i.e., official list), change in revision number and revision history without any change in the content of the document as a result of triennial review, and change due to typographical errors, might not require training. This decision is documented on the change control form.

b) Major changes to documents such as but not limited to addition of equipment in master batch records and master batch packaging records, update of processes and parameters in master batch records and master batch packaging records, revision of analytical procedure in test methods, update of practices in SOPs, and implementation of new Forms require training.

6.2.5 Other Training:

6.2.5.1 Department supervisor, Training and Development and / or Quality Assurance may determine that one or more employees need training or retraining. If that is the case, a trainer is designated, and a training session is conducted. Whenever retraining is conducted the training record should be identified as such.

6.2.5.2 Department supervisors identify outside training needs for their employees, as required, and coordinate the registration for the courses. Employees submit copy of the training certificate to Training and Development department upon completion.

6.3 Method of Training:

6.3.1 Self Training:

6.3.1.1 Training conducted by one person and considered as a read and understanding session. Training shall be performed following these steps:

6.3.1.1.1 Overview the document briefly. Get familiarized with it. Review its sections and any additional parts of it (i.e., forms, charts, tables, etc.). Perform these activities before starting reading.

6.3.1.1.2 Read slowly and if possible loud enough that one can hear himself / herself.

6.3.1.1.3 Ensure to understand what it is read. Have a paper and pen to write down any question and/or suggestion to be later discussed with supervisor, co-worker, trainer, or designee.

6.3.1.1.4 A self training record (Form ITD-001-F2) is documented accordingly.

NOTE: Training curriculums and qualification techniques can be used to acknowledge the completion of self training. In these cases, Form ITD-001-F2 is not required.

6.3.1.2 Upon training completion, self training conducted by the employee is evaluated by discussing respective topic between employee and supervisor or designee (refer to section 6.5 for details of training evaluation). Respective evaluation is documented accordingly in the respective section of the training record as follows:

6.3.1.2.1 For self training using Form ITD-001-F2, supervisor or designee performs evaluation of respective topic (s) with employee by asking random questions of the topic (s) to the employee for discussion in order to measure the level of understanding. At the end of the evaluation, supervisor or designee acknowledges that the employee has understood respective material read on the appropriate section of the form.

6.3.1.2.2 For self training using training curriculums and qualification techniques, supervisor or designee performs evaluation of respective topic (s) with employee during the training period by asking random questions of the topic (s) to the employee for discussion and by assessing performance of the employee related to job functions and assigned tasks, in order to confirm the appropriateness of the extent of the training in line with the work responsibilities. Overall evaluation and acknowledgment of completion of the training is performed by the supervisor or designee

using the respective section of the training curriculums and qualification techniques at the end of the training period.

NOTE: If during the training evaluation performed by the supervisor or designee an opportunity of additional training is identified to enhance the level of understanding of the topic, the extent and method of training are determined and coordinated accordingly as per this SOP.

6.3.2 Group Training:

6.3.2.1 Training conducted between two or more persons and considered as a read, understand, and discussion session. Trainer can be the second person.

6.3.2.2 A training record (Form ITD-001-F1) is documented accordingly.

6.3.3 On The Job Training / Hands-on Training / Practical Training:

6.3.3.1 On the Job Training (OJT) is a training that takes place while employees are actually working; this means the skills are gained while trainees are carrying out their jobs. This training can be executed following below tasks. Equivalent approaches are considered acceptable as long as the process leads to proficiency for specific job tasks.

6.3.3.2 Department head or designee assigns a trainer to work with the trainee.

NOTE:

Authorized Trainers: BPI Labs employees or contractors who have the education, training and experience or any combination thereof, that enables them to conduct training. This includes but is not limited to:

a) The training coordinator.

b) External trainers upon approval of Quality Assurance via verification of their credentials.

c) All supervisors and managers after completion of their training curriculum unless pre-employment qualifications to conduct training are provided and approved by Quality Assurance.

d) Personnel designated by department managers or supervisors upon approval of Quality Assurance via verification of qualifications that include, but are not limited to:

- **Submission of a resume.**
- **Completion of the training curriculum for their position.**
- **Completion of the qualification technique for the unit operation, module or technique.**
- **Verifiable experience of outside training (certifications, diplomas, etc.)**

6.3.3.3 The trainer shall be an employee well experienced, knowledgeable, and fully trained on the topics to be covered and shall have good training / communication skills.

6.3.3.4 The trainee performs a self training according to section 6.3.1 for all documents included in the training curriculum in addition to others assigned by the Department head or designee.

6.3.3.5 The trainer performs the job and the trainee observes. The trainer goes over the procedure together with the trainee and in the work area showing where every equipment, files, documents, or any other item related to the training are located and, when applicable, its function and/or operation. Every practice, and method, is followed by the trainee with the written procedure and discussed / explained by the trainer, as needed. Trainer and trainee review the written procedures. This step can be repeated, as required. A training record (Form ITD-001-F1) is documented accordingly and identified as On the Job Training.

NOTE: As part of execution of qualification techniques, these documents are used to acknowledge the completion of this step. In these cases, Form ITD-001-F1 is not required.

6.3.3.6 Trainee performs the job with the reference of the written procedure, in presence of the trainer, and with the help and guidance of the trainer.

6.3.3.6.1 The trainer observes and verifies performance and execution against the written procedure. The activity or task performed are initialed / signed and dated by the trainee and trainer using appropriate records according to the activity. This record confirms that trainer has been present at the time of the task execution.

NOTE: During execution of qualification techniques, these documents are used to acknowledge the completion of this step. In these cases, Form ITD-001-F1 is not required.

6.3.3.6.2 Trainer conducts a question and answer session with the trainee. The trainer clarifies any doubt. Trainer verifies for comprehension.

6.3.3.6.3 This step can be performed as needed at the discretion of the trainer and department head according to performance observed and taking into consideration the trainee's performance, experience, and previous training. In case additional training is needed, trainer informs department head or designee for further instructions.

6.3.3.7 The trainer informs by any means (i.e., via e-mail) to the department head or designee about the completion of on the job training program.

6.4 Qualification Techniques:

6.4.1 Qualification techniques are used by department supervisors as a tool to qualify an employee in regards to a specific unit operation, module, or technique (i.e., sterile filtration, aseptic filling, sampling, HPLC analysis) and to acknowledge his / her competence and qualification on a continuous basis.

6.4.2 Qualification techniques records include, but are not limited to, the list of reference documents, the list of related equipment and measuring devices, the reference for the on the job training completion, and the approval of the exercise.

6.4.3 Each department supervisor prepares qualification techniques as needed based on the criticality of the unit operation, module, or technique, and coordinates execution with the selected employee.

6.4.4 Qualification techniques need to be executed by personnel at least once every three years according to the overall evaluation by the supervisor of the employee's performance throughout the entire certification process taking in consideration job performance, quality / accuracy of work, dependability, ability to work as part of a team, and compliance with company procedures. Acknowledgement of completion of training for the qualification technique unit operation / module is performed by placing employee and supervisor's signatures and date at the respective section of the Qualification Technique Form. Training and Development group assigns the re-certification due date for employees based on above criteria and supervisor's recommendations.

NOTES:

a) **Qualification Technique re-certification for production visual inspection of injections needs to be executed by personnel at least once every year according to the guidelines outlined on SOP IPD-017.**

b) **The qualification techniques for cGMP and Safety (i.e., QT-ITD-001 and QT-IEH-002, respectively) are executed once every two years and annual refreshment training is completed every year to be up to date on all the training needs from time to time.**

6.4.5 The qualification techniques matrix shows the core / primary activities that qualified personnel (i.e., subject matter experts) can perform unsupervised.

NOTES:

a) Training and Development group prepares a training folder by employee including the applicable qualification techniques to be executed during the respective certification period. Respective Qualification Technique Matrix is updated accordingly, and training folders are distributed to respective supervisor or designee upon request.

b) As a general practice, the employees should complete the initial qualification technique ideally within 3 months from the date of issuance.

c) Qualification Technique impact assessment is performed each time a qualification technique is revised via change control in order to assess that the respective document is not impacted by the change and to determine the need of distribution to respective training folders (i.e., if an additional SOP is added to the qualification technique, that qualification technique might not require to be distributed within the training period if respective training has been completed as part of change control).

d) As part of qualification technique recertification exercise, whenever the employee is unable to execute hands on / on the job training verification (Section – 4, Training Reference of Execution by Trainee) at the time of the recertification due period, then the employee must complete the self-training related to the respective qualification technique and inform Training and Development group accordingly to acknowledge this situation in the training system (i.e., Qualification Technique Matrix and corresponding qualification technique). The hands on / on the job training is executed once the activity / unit operation becomes available as per the department's needs.

e) The qualification technique recertification due date is assigned from the date of issuance of the qualification technique for the execution purposes. Whenever the qualification technique is recertified,

Training and Development group updates the Qualification Technique Matrix and re-issues the respective qualification technique for the next period.

f) On a quarterly basis, Training and Development group verifies the Qualification Technique Matrix for the employee's pending recertification for the next quarter. The Training and Development designee prepares a list of all the employees due for recertification and communicates to the employees and the supervisor to inform them about the qualification technique recertification. This list is monitored and updated on a monthly basis by the Training and Development group until completion.

6.5 Evaluation of Training:

6.5.1 Training and Development may, at its sole discretion, conduct an evaluation at any time of any part of the training process (i.e., training sessions, trainees, trainer, training material, retraining, repetitive human mistakes) to verify training effectiveness. Evaluation of training process involves the identification of unwanted trends that are discussed with supervisors and managers in order to determine the further action needed to enhance the performance of the personnel.

6.5.2 Supervisor or designee is fully responsible to evaluate training effectiveness of his / her employees routinely by assessing the job performance, quality and accuracy of work, consistency of work, among others, in order to understand the adequacy of the extent and method of training. The training evaluation is verified continuously and documented in all the available records in the quality system related to training and specific job functions.

6.5.3 In order to further measure the understanding of the training conducted to employees and as part of assessment check to ensure employees comprehend the SOPs related to their job function, Training and Development performs a quarter evaluation of the training system via verification of employee training records, and via review of quality system records such as but not limited to incidents, non-conformances, deviations, laboratory incidents, laboratory out of specifications, laboratory out of trends, CAPAs, and documentation errors with the purpose of identifying unwanted trends including repetitive human errors that may have been contributed due to lack of training understanding. The findings of this evaluation are discussed with supervisors and management to determine improvement plans for the specific employee in case a negative tendency is observed. The improvement plan, when needed, is designed between supervisor, employee, and Training and Development and executed accordingly to enhance the performance of personnel.

7.0 REVISION HISTORY

Revision No.	Effective Date	Description of Changes
01	SEP 22 2017	Original SOP
02	FEB 14 2018	1. Add a note for training record associated with training curriculums and qualification techniques under Sections 6.1.1 and 6.3.1.1.4 2. Update procedure of completion of training record in Sections 6.2.1.2.2 and 6.2.1.2.3 3. Add a note for preparation of training folder by employee under Sections 6.2.2.2 and 6.4.6 4. Remove statement related to training not required for other documents in Section 6.2.4.1 5. Update on the job training procedure after Section 6.3.3.4 6. Update re-certification frequency for qualification techniques in Section 6.4.4 7. Make editorial corrections throughout the whole document

SOP No.	Title	Revision No.
ITD-001	TRAINING SYSTEM	04

Revision No.	Effective Date	Description of Changes
03	MAR 19 2019	1.To mention qualification techniques into sections 1.0 and 3.0. 2. To update section 4.0 to include Training Curriculums TC-IGN-001, TC-IGN-002, and TC-IGN-003. 3. To add section 6.1.1.1.8 to mention that Acknowledgement of Training Understanding is not applicable for Form ITD-001-F1. 4. To remove section 6.1.2 and move the content to section 6.5 as section 6.5.1. 5. To update and combine section 6.2.1.2 and 6.2.1.3 to explain training and final release process as part of Training Curriculum TC-IGN-001. 6. To add section 6.2.2.3 to include acknowledgement of completion of training curriculum. 7. To Modify section 6.2.3 to explain the process of Annual Training as part of Training Curriculum TC-IGN-002. 8. To add section 6.3.1.2 to explain self training evaluation process. 9. To add a point on section d) of section 6.3.3.2 to mention completion of qualification technique verification. 10. To update section 6.4.4 to explain acknowledgment of completion of training for the qualification technique unit operation / module and qualification technique re-certification for visual inspection of Injections. 11. To update the "Notes" section on section 6.4 to mention qualification technique matrix, training folders, and qualification technique impact assessment. 12. To add section 6.5 to explain evaluation of training.
04	JUL 2 7 2022	1. Add qualification techniques in the Reference Section 4.0 2. Add 21 CFR Part 4, WHO Guidelines – Hormones, FDA Guidance – 503B, DBPR, DOH, internal audits, warning letters, and annual trend of 483s under Sections 6.2.1 New Employee Orientation and 6.2.3 Annual Training. 3. Add notes under Section 6.2.2 Biennial Training (Continuing Training Program) related to preparation, issuance, and tracking of training curriculums. 4. Add notes under Section 6.4 related to qualification techniques to explain the issuance tracking and completion of the qualification technique for initial and recertification purposes. 5. Remove Section 6.4.6 from Revision 03. 6. Editorial changes made throughout the entire procedure.

SOP No.	Title	Revision No.
IQC-002	STABILITY PROGRAM	05

Prepared By / Date	Reviewed By / Date	QA Approved By / Date	Effective Date
Vineela 03/03/21	03-05-21	M. Salazar 03/05/21	MAR 1 1 2021
			Change Control No.
Title: QC chemist	Title: Manager, QC	Title: CQCO	I-21090

1.0 PURPOSE

To establish a standard operating procedure that describes about the stability studies conducted at long term, accelerated, and intermediate storage conditions to establish the shelf life and labeled storage conditions of drug products and medical devices.

2.0 SCOPE

This procedure is applicable to drug products and medical devices manufactured by BPI Labs.

3.0 RESPONSIBILITY

3.1 Product Development designee is responsible to initiate the stability studies for R&D products.

3.2 Quality Assurance designee is responsible to initiate the stability studies for commercial products.

3.3 Quality Assurance and Quality Control management are responsible for proper implementation of this SOP.

4.0 REFERENCES

4.1 FDA Guidelines for Submitting Documentation for the Stability of Human Drugs and Biologics (1987)

4.2 FDA Guidance for industry Q1A (R2) Stability Testing of New Drug Substance and Products

4.3 FDA Guidance for Industry ANDAs: Stability Testing of Drug Substances and Products

4.4 ICH Guidance Q1A (R2) Stability Testing of New Drug Substances and Products

4.5 ICH Guidance Q1B Photostability Testing of New Drug Substances and Products

4.6 ICH Guidance Q1C Stability Testing for New Dosage Forms

4.7 ICH Guidance Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products

4.8 ICH Guidance Q1E Evaluation of Stability Data

4.9 Current USP

4.10 21 CFR 211.166 Stability Testing

4.11 Stability Protocol

4.12 SOP IQA-001 Change Control System

4.13 SOP IQC-001 Investigating Out of Specification (OOS) and Out of Trend (OOT) Test Results

4.14 SOP IQC-003 Standard Procedure for Sample Management in Analytical Development and Quality Control Department

4.15 SOP IGN-030 Operation of the Building Management System

4.16 Form IQA-006-F4 Initiation of Stability Study

4.17 Form IQC-002-F1 Discontinuation of Stability Study Form

4.18 Form IGN-030-F1 Security Monitoring of Environment Controlled Chambers

5.0 ATTACHMENTS

Not Applicable.

6.0 PROCEDURE

6.1 Definitions / Acronyms:

6.1.1 Stability:

The capacity of a drug product to remain within specifications established to ensure its identity, strength, quality, and purity.

6.1.2 Accelerated Testing:

Studies designed to increase the rate of chemical degradation or physical change of a drug substance or a drug product by using exaggerated storage conditions as part of the formal stability studies.

6.1.3 Long-term Testing:

Stability studies under the recommended storage condition for the retest period or shelf life proposed (or approved) for labeling.

6.1.4 Intermediate Testing:

If any "Significant Changes" occur at any time during testing at the accelerated storage condition, additional testing at the intermediate storage condition should be conducted.

6.2 Materials and Equipment:

6.2.1 Chambers or Walk-in Stability Room:

6.2.1.1 Controlled Room Temperature (CRT) / Long-term:

Environmental chamber / Walk-in Stability Room capable of controlling temperature to 25°C ± 2°C and relative humidity to 60%RH ± 5%RH.

6.2.1.2 Accelerated (AA):

Environmental chamber capable of controlling temperature to 40°C ± 2°C and relative humidity to 75%RH ± 5%RH.

6.2.1.3 Intermediate:

Environmental chamber capable of controlling temperature to 30°C ± 2°C and relative humidity to 65%RH ± 5%RH.

6.2.1.4 Refrigerator:

Environmental chamber capable of controlling temperature to 5 °C ± 3 °C.

6.2.2 Quality Assurance department shall arrange to calibrate the chambers / monitoring devices either in-house or coordinate with the external calibration consultants. Calibrate all the chambers every year.

6.3 Monitoring:

6.3.1 The actual temperature and relative humidity for all chambers and walk-in stability rooms will be monitored and recorded by Quality Assurance Department and Quality Control Department.

6.3.2 All monitoring devices (prints / charts / graphs) will be read and reviewed on a daily basis (business days) by the Quality Assurance Department.

6.3.3 The Quality Assurance Department shall inform to Quality Control Department whenever the temperature and relative humidity reading exceeds out of the temperature and relative humidity tolerances of ± 2°C and / or ± 5%RH, respectively.

6.3.4 All the chambers and walk-in stability rooms are connected to the Security System. This system sends a notification to Security System Operator in case any temperature and relative humidity reading exceeds out of the temperature and relative humidity tolerances of ± 2°C and / or ± 5%RH, respectively. The Security System Operator informs to concerned persons at BPI Labs immediately.

6.3.5 The Security monitoring system of Stability Chambers / Walk-in Stability Room is checked once in every six months by maintenance department in coordination with Security System Company.

6.3.6 After checking the Security monitoring system, details are entered in Form IGN-030-F1 Security Monitoring of Environment Controlled Chambers by maintenance department. The form is submitted to QA for final approval and filing.

6.4 Excursions:

6.4.1 Short term spikes due to opening of doors are acceptable as unavoidable.

6.4.2 If for any reason (e.g., power, equipment failures, etc.), chamber / walk-in stability room is in excursion that exceeds the defined tolerances for more than 24 hours, samples in the chamber / walk-in stability room shall be transferred into back-up chamber. If back-up chamber / walk-in stability room is not available, samples shall be stored at room temperature maximum up to three working days. Once the chamber / walk-in stability room is ready, the samples shall be moved to the original stability condition. If exceeds three working days, the pulling date shall be extended for Accelerated and Intermediate conditions. For CRT condition, it is not required to extend the pulling dates. The impact of such excursion will be assessed.

6.5 Storage Conditions (General Case):

6.5.1 Accelerated Stability (AA):

Samples are stored at 40°C ± 2°C and 75% RH ± 5% RH for a period of six (6) months (i.e., 180 days) for ANDA / ANADA / NDA / NADA. Test intervals are set at 1 month, 2 months, 3 months, and 6 months (i.e.,180 days).

6.5.2 Intermediate Stability (INT):

Samples are stored at 30°C ± 2°C and 65% RH ± 5% RH for a period of twelve (12) months for ANDA / ANADA / NDA / NADA. Test intervals are set at 1 month, 2 months, 3 months, 6 months (i.e.,180 days), 9 months, and 12 months.

6.5.3 Where "significant change" occurs in the samples of accelerated storage conditions, additional testing at the intermediate storage conditions (i.e., 30°C ± 2°C and 65% RH ± 5% RH) shall be conducted.

6.5.3.1 "Significant Change" at the accelerated condition is defined as:

A. A 5% potency loss from the initial assay value of a batch.

B. Any specified degradant exceeding its specification limit.

C. Dissolution exceeding the specification limits for 12 Dosage units (USP Stage 2).

D. Failure to meet specifications for appearance and physical properties.

E. Failure to meet the acceptance criterion for pH.

6.5.4 Long-term Stability (CRT):

Samples are stored at 25°C ± 2°C and 60% RH ± 5% RH (controlled room temperature) for up to shelf life for ANDA / ANADA and may be longer for NDA / NADA. Test intervals are at 3 months, 6 months (i.e., 180 days), 9 months, 12 months, 18 months, 24 months, and on an annual basis up to the proposed shelf life for NDA / NADA / ANDA / ANADA. Additional intervals can be assigned on a case-by-case basis.

6.6 Storage Conditions (Drug Product Intended for Storage in a Refrigerator):

6.6.1 Accelerated Stability (AA):

Samples are stored at 25°C ± 2°C and 60% RH ± 5% RH for a period of six (6) months for ANDA / ANADA / NDA / NADA. Test intervals are set at 1 month, 2 months, 3 months, and 6 months (i.e.,180 days).

6.6.2 Long-term Stability:

Samples are stored at 5°C ± 3°C in a refrigerator for a period of twelve (12) months for ANDA / ANADA / NDA / NADA. Test intervals are set at 3 months, 6 months (i.e.,180 days), 9 months, 12 months, 18 months and 24 months. Additional intervals can be assigned on a case-by-case basis.

6.7 Storage Conditions (Drug Product Intended for Storage in a Freezer):

6.7.1 Long-term Stability:

Samples are stored at - 20°C ± 5°C in a freezer for a period of twelve (12) months for ANDA / ANADA / NDA / NADA. Test intervals are set at 3 months, 6 months (i.e.,180 days), 9 months, 12

months, 18 months and 24 months. Additional intervals can be assigned on a case-by-case basis.

6.7.2 Testing on a single batch at an elevated temperature (e.g., 5°C ± 3°C or 25°C ± 2°C) for an appropriate time period should be conducted to address the effect of short-term excursions outside the proposed label storage condition.

6.8 Storage Conditions (Drug Product Intended for Storage Below - 20°C):

6.8.1 Drug products intended for storage below - 20°C should be treated on a case-by-case basis.

NOTE: If a drug product is required to be stored at condition different from above mentioned storage conditions, a separate stability protocol will be initiated that will contain all the critical information such as storage condition, test intervals, etc.

6.9 Preparation of Stability Protocol:

6.9.1 Stability protocols shall be prepared by Product Development for R&D products and by Quality Assurance for commercial products before the stability study is initiated.

6.9.2 Stability protocols shall include all specific details of the product and stability study such as, but not limited to, product name and strength, code number, active pharmaceutical ingredient associated, batch size, pack size and packaging configuration, study purpose, storage conditions, testing frequency, tests, number of containers to be pulled per sampling point, and number of samples to be collected.

6.9.3 Bracketing and Matrixing designs for stability testing of drug products can be applied according to ICH Guidance Q1D: Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products.

6.9.4 Stability protocols are approved in the quality system via change control following instructions documented in SOP IQA-001.

6.10 Initiation of Stability Study:

6.10.1 Stability study for R&D products is initiated by Product Development Department using the approved stability protocol. Stability samples are collected by Quality Assurance and submitted to Quality Control accordingly.

6.10.2 Stability study for commercial products (including validation) is initiated by Quality Assurance Department using the approved stability protocol and Form IQA-006-F4 (Initiation of Stability Study). Stability samples are collected by Quality Assurance and submitted to Quality Control accordingly.

6.10.3 Upon receipt, Quality Control Department verifies stability samples for correctness and integrity and ensures that an approved stability protocol associated with this stability study is available and that information documented in the protocol or Form IQA-006-F4 is accurate.

6.10.4 The stability samples shall be labelled as Upright (U), Inverted (I) and On the Side (OTS) orientations on the cartons as per stability protocol and the samples shall be loaded carefully into chambers as per orientation.

6.11 Scheduling:

6.11.1 The stability system scheduling shall be documented in stability protocol (i.e., R&D products) or using Form IQA-006-F4 (i.e., commercial products) upon initiations of any new stability studies for the products.

6.11.2 When the stability samples are loaded into the stability chamber, stability group or designee shall enter the initiating information into the stability logbook.

6.11.3 Stability samples (i.e., exhibit batches) can be loaded into the stability chambers after packaging without waiting for the release of time zero data to save the stability study time.

6.12 Sample Retrieval:

6.12.1 A monthly calendar with the products to be tested for that month will be generated from the Excel sheet / Microsoft outlook according to the approved stability protocol or Form IQA-006-F4.

6.12.2 The Stability Coordinator or designee will remove the appropriate quantity of samples according to stability protocol or Form IQA-006-F4 from storage, document such retrieval in the respective stability protocol or Form IQA-006-F4, and submit stability samples to the laboratory for testing.

6.12.3 When the stability samples are retrieved from the stability chamber, stability group or designee shall reflect this activity in the stability logbook.

6.12.4 The samples will be logged in the Stability Samples Logbook in Quality Control Department as per SOP IQC-003.

NOTE: Ensure to submit samples required for Microbiology testing (as per stability protocol) on the same day of retrieval (if applicable).

6.12.5 For pull dates, which fall on non-working days, samples will be pulled on the next working day.

6.13 Testing:

6.13.1 Samples will be tested in accordance with approved Stability Protocol using approved test methods, which are specific, and stability indicating.

6.13.2 For testing, sampling of dosage units from a given container should be done randomly with each individual unit having an equal chance to be selected. The chemist must inspect samples before testing and report any untoward appearance / findings to their supervisor or manager.

6.13.3 Accelerated and intermediate storage conditions samples testing should be completed within 15 calendar days of retrieval.

NOTE: In case of Microbiology testing, testing must be completed within 30 calendar days (excluding weekends / holidays) of retrieval.

6.13.4 Long term storage conditions samples testing should be completed within 15 working days.

NOTE: In case of Microbiology testing, testing must be completed within 30 calendar days (excluding weekends / holidays) of retrieval.

6.13.5 If testing is delayed, then the reasons and the impact for the delays shall be clearly documented and approved by the responsible Quality Control Manager or designee and submitted to Quality Assurance Department along with the stability data report.

6.14 Recording Results:

6.14.1 Results of testing are recorded as they are completed and checked against any previous data by group auditor or designee.

6.14.2 Test result failures shall be brought to the immediate attention of the Quality Control Manager or designee who shall notify the Quality Assurance Management consequently. Investigation of out of specifications or out of trends shall be conducted according to SOP IQC-001.

6.14.3 The SOP IQC-001 Investigating Out of Specification (OOS) and Out of Trend (OOT) Test Results, is not applicable for RLD and Experimental drug products.

6.15 Analysis Reporting Data:

6.15.1 Stability reports will be reported using product approved specification and analytical reports and according to stability data compilation sheets included in the stability protocol and will be submitted to Quality Assurance for review. The data should be submitted within 40 calendar days.

6.15.2 Stability reports will be provided to Regulatory Affairs for annual reports and other FDA submissions, as needed.

6.16 Documentation:

6.16.1 A stability project file will be maintained for each product initiated into the program.

6.16.2 Quality Control Manager or designee will ensure the current finished product specification is used for reporting purposes.

6.16.3 Initial release test results (time zero data) need to be available for all samples.

6.16.4 If more than 30 days have passed since the initial release date, stability initiator must submit additional samples for retest.

6.16.5 The Stability Chamber Logbooks as well as documentation included in the stability protocol or Form IQA-006-F4 will serve as documentation of the stability samples pulls.

6.17 Transportation of Stability Samples:

6.17.1 The Quality Control Manager or designee sending stability samples should ensure that the samples transported for loading into the stability chambers of any subsidiary or third party are transported as per the label storage conditions.

6.17.2 If there is any damage to the integrity of the container closure system of the sample during transit, the sample will not be loaded in the stability chambers.

6.17.3 The stability samples received for only loading into the stability chambers need to follow the stability conditions provided along with the samples.

6.18 Post-approval Stability Commitment:

6.18.1 If the submission does not include stability data on production batches, a commitment should be written in a specific stability protocol.

6.18.2 The stability protocol used for the studies on commitment batches should be the same as that for the primary batches, unless otherwise scientifically justified.

6.18.3 The commitment shall include the stability studies at intended long term storage conditions (at 25°C ± 2°C / 60% RH ± 5% RH) on the first three production batches in each packaging size.

6.18.4 In addition to the first three production batches, stability studies at 25°C ± 2°C / 60% RH ± 5% RH will be conducted on a minimum of one production batch per year for each packaging size.

6.18.5 The stability results for the drug product shall be reported in the annual report of the ANDA.

6.19 Changes or Cancellations:

6.19.1 Any change or termination of stability testing must be submitted in writing to the Quality Assurance Management with a completed Discontinuation of Stability Study Form (IQC-002-F1) in the stability Protocol. The stability system shall be updated immediately.

7.0 REVISION HISTORY

Revision No.	Effective Date	Description of Changes
01	JAN 10 2018	Original SOP
02	AUG 12 2019	1.Alignment was updated. 2.Added a note following point 6.12.4 detailing samples for microbiology laboratory must be submitted on same day of retrieval. 3.Added a note following point 6.13.3 and 6.13.4 describing microbiology testing must be completed in 30 working days.
03	NOV 22 2019	1. Changed 6.5.3.1 from "12 capsules or tablets" to "12 Dosage units" 2. Added 6.2.1.4 Refrigerator and its condition temperature. 3. Added Subsection E in section 6.5.3.1
04	SEP 29 2020	1. Added section 6.10.4 for introducing orientation of stability samples 2. Editorial changes were made throughout the SOP wherever applicable
05	MAR 1 1 2021	1.Removed the form IQC-002-F2 form sections 4.0 and 6.3.6 and added the form IGN-030-F1. 2.Added the SOP#IGN-030 and Form# IGN-030-F1 in the references section

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

Prepared By / Date	Reviewed By / Date	QA Approved By / Date	Effective Date
10/18/22	10/18/22	M Salazar 10/18/22	OCT 20 2022
Title: Process Engineer	Title: Director, Tech Ops	Title: CQCO	Change Control No. I-22608

1.0 PURPOSE

The purpose of this procedure is to provide standard operating instructions for the visual inspection of injections.

2.0 SCOPE

This procedure is applicable to personnel performing visual inspection of injections at BPI Labs facility, Suite #450.

3.0 RESPONSIBILITY

3.1 It is the responsibility of personnel performing visual inspection of injections to follow these instructions. It is also the responsibility of the Production Supervisor to implement and ensure that the procedure is being followed.

3.2 It is the responsibility of Production (PD) department and Production Supervisor to compile visual inspection results for trending. It is the responsibility of Quality Assurance (QA) department to prepare trending report.

4.0 REFERENCES

4.1 General Chapters USP <790> Visible Particulates in Injections

4.2 General Chapters USP <1790> Visual Inspection of Injections

4.3 USFDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice

4.4 PDA Survey 2014 Visual Inspection

4.5 PDA Survey 2015 Particulate Matter in Difficult to Inspect Parenterals

4.6 Technical Report No. 43 (Revised 2013) Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials

4.7 SOP IGN-001 Investigations

4.8 SOP IGN-020 Procedure for Repair and Maintenance of Equipment / Rooms

4.9 SOP IGN-024 Waste Disposal Authorization

4.10 SOP IMI-038 Determination of Particulate within Injectables Products using Filtration Method

4.11 SOP IPD-017 Qualification and Validation of Inspection Processes

4.12 SOP IPK-003 Brite Stock Handling

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

4.13 SOP IQA-006 Issuance of Batch Records, Packaging Records, Protocols, and In-House Computer Generated Labels

4.14 SOP IQA-016 Acceptable Quality Limit for Visual Inspection of Filled Product

4.15 SOP IWH-004 Storage and Disposal of Manufacturing and Laboratory Waste

4.16 Form IGN-001-F1 Investigation Report

4.17 Form IGN-024-F1 Waste Disposal Authorization Form

4.18 Form IPD-007-F1 Visual Inspection of Injections Report

4.19 Form IPD-007-F2 Visual Inspection Booth Light Intensity Verification Form

4.20 Form IPD-007-F3 Log for Visual Inspection of Injections

4.21 Form IQA-016-F1 Acceptable Quality Limit for Visual Inspection of Filled Product Report

4.22 IQA-016-F2 American National Standard (ANSI Z1.4) Sampling Plan

4.23 Respective Product Validated List (i.e., EOL I-034)

5.0 ATTACHMENTS

Not Applicable.

6.0 PROCEDURE

6.1 General:

6.1.1 In general, unless specified in the manufacturing batch record, Visual Inspection is performed for all cGMP Products. The inspection program is designed to understand the nature of defects and establish appropriate controls to eliminate them based on the product life cycle.

6.1.2 Personnel participating in Visual Inspection of Injections must be trained and qualified as per SOP IPD-017 Qualification and Validation of Inspection Processes.

6.1.3 Inspectors must have their eyes examined by an optometrist at least once a year as per specifications listed in SOP IPD-017. The frequency may be increased if the inspectors complain of headache, eye fatigue, or other complaints directly attributable to visual performance.

6.1.4 Supervisors must be informed if any inspectors are suffering from eye allergies, eye infections, eye fatigue, headache, or any other concerns that affect the performance of inspection.

6.1.5 Inspectors must gown with hair net, beard cover (if facial hair is present), lab coat, and gloves when entering the visual inspection room. Inspectors must degown within respective visual inspection room prior to exiting.

6.1.5.1 Gowning materials such as lab coat must be dedicated to a single batch. If inspections are performed in multiple rooms then separate gowning materials are required.

6.1.6 Avoid glare and direct viewing of the light source at high intensities as this may result in eye strain or fatigue.

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

6.1.7 Check the intensity of light before the start of a batch and after completion of each batch.

6.1.8 After every 55-65 minutes of visual inspection, a no less than 5-minute break MUST be taken to relax eyes. Document inspection and break times in Form IPD-007-F1 section II.

6.1.8.1 When a break is required, the inspector should finish the tub or tray they are inspecting before taking a break. If they are unable to finish, they must keep inspected and uninspected units separate and secure before taking a break and upon returning, must start with the same uninspected tub/tray.

6.1.8.2 The inspection times and break times should be sequential. For example, an inspector inspects on 07/24/19 from 11:00 to 12:03 and he/she takes a break from 12:03 to 12:08. This will be documented on one line, from left to right, in section II of IPD-007-F1 and initialed by the inspector.

6.1.8.3 All open entries in section II of form IPD-007-F1 should be closed on the same day of completion.

6.1.9 Visual inspection rooms must be locked if visual inspection personnel are not in the room. Visual inspection personnel are responsible for locking the visual inspection room door during breaks and at end of business day.

6.1.10 Visual inspectors are not required to use a magnifier or wear safety glasses during the inspection. Magnification should only be used for critical examination of a small number of units, as may be needed during an investigation. The use of the magnifier will be determined by a supervisor or designee.

6.1.11 There are three different categories of defects representing the risk to the patient, as defined below.

6.1.11.1 Critical Defect:

A defect which poses risk to the patient, especially risk of injury to patient and integrity breach of container closure (sterility of the product) and indicates the inspected article is likely to:

A. Result in hazardous or unsafe conditions for individuals using, maintaining, or relying on the product; or

B. May prevent performance of the product or material or failure to meet specifications. A critical defect is a unit of product that contains one or more critical defects.

Examples: Critical defects include cracks in the glass of the vial or syringe, missing stopper/plunger, etc.

6.1.11.2 Major Defect:

A condition/non-conformity, other than critical, that carries the risk of a temporary impairment or medically reversible reaction or involves a remote probability of a serious adverse reaction or reduce the usability of the unit of product for its intended purpose. A major defect is a unit of product that contains one or more major defects.

Examples: Major defects include contamination intrinsic to the manufacturing process such as fibers or particles and issues associated with the filling/stoppering process such as low fill, high fill, or empty container.

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

6.1.11.3 Minor Defect:

A minor defect is a condition/non-conformity that is not likely to reduce the usability of the unit of product for its intended purpose or is a departure from established standards having little bearing on the effective use, safety or operation of the unit of product. A minor defect is a unit of product that contains one or more defects. They are often cosmetic in nature, affecting only product appearance or pharmaceutical elegance.

Examples: Minor defects include cosmetic issues such as scratches/scuffs on the body of the vial/syringe, dents on the container/cap, etc.

6.2 Handling of the Visual Inspection Booths:

6.2.1 Setup:

6.2.1.1 Setup inspection booth on the workbench for safe and comfortable operation.

6.2.1.2 Connect to 120 Volts power source and turn ON the light switch and ensure lights are illuminating with no flickering. If the lights do not function properly, contact area supervisor and initiate a maintenance request as per SOP IGN-020.

6.2.2 Operation:

6.2.2.1 Log equipment usage into appropriate Cleaning, Use, and Maintenance Logbook.

6.2.2.2 Ensure the light is turned on and verify in the appropriate logbook that the Visual Inspection Booth is cleaned prior to use. If not, follow step 6.2.3 as applicable.

6.2.2.3 When inspecting filled product, hold the units approximately 8-10 inches below the light source and NMT 5 inches from the center line.

6.2.2.4 When finished with operation, ensure the light is turned off.

6.2.3 Cleaning:

6.2.3.1 Minor Cleaning:

A. Ensure the power is turned OFF.

B. Remove all evidence of the previous batch, including all filled product, both inspected and rejected.

C. Wipe down the interior of the inspection booth with 70% Isopropyl Alcohol (IPA).

D. Record the activities into the proper Cleaning, Use, and Maintenance logbook and ensure the cleaning is verified by a Supervisor or designee.

E. Place a "CLEAN" label on the Visual Inspection Booth

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

6.2.3.2 Major Cleaning:

A. Ensure the power is turned OFF.

B. Remove all evidence of the previous batch, including all filled product, both inspected and rejected.

C. Wipe down the interior and exterior of the inspection booth and the magnifying glass with a lint-free cloth and 70% IPA.

D. Record the activities into the proper Cleaning, Use, and Maintenance logbook and ensure the cleaning is verified by a Supervisor or designee.

E. Place a "CLEAN" label on the Visual Inspection Booth.

6.2.4 Verification of Light Intensity:

6.2.4.1 Light intensity verification will be performed annually for all Visual Inspection Booths using NIST calibrated standard Light Intensity Meter. Measure the light intensities at the locations specified in Form IPD-007-F2 and record values in Form.

6.2.4.2 Light intensity should be NLT 2100 lux at the furthest specified point. If the light intensity fails to meet the acceptance criteria, initiate a maintenance request as per SOP IGN-020 and repeat verification after maintenance is performed.

6.2.5 Corrective Maintenance:

6.2.5.1 In case of equipment break down, contact maintenance personnel for necessary actions. Refer to SOP IGN-020 for repair/maintenance procedure.

6.3 Visual Inspection Requirements per Product Type:

6.3.1 Manual visual inspection requirements are based on product type. Refer to Table 1 for inspection requirements per batch type and corresponding procedure section.

Table 1: General Visual Inspection Requirements Based on Product Type

Product Type	Inspection Requirement	Procedure Section
Research and Development (Exhibit / Stability / Pivotal)	100% Inspection (One Time)	6.4
Initial Commercial (i.e., Initial Process Validation)	First and Second 100% Inspections (Two Times)	6.5
Commercial Certified for Reduced Inspection	100% Inspection (One Time)	6.7
Difficult to Inspect (i.e., Colored Products for Research and Development & Commercial)	100% Inspection (One Time) Destructive Testing	6.8

6.3.1.1 Research and Development products (Exhibit / Stability / Pivotal) are one time 100% inspected by Production personnel.

6.3.1.2 Initial Commercial products (if not qualified under reduced inspection program) are two times (First 100% and Second 100%) inspected by Production personnel. Although regulatory expectations require only 100% inspection, Second 100% inspection is

performed to better understand the life cycle of the product, common defects types, and provide product quality assurance.

6.3.1.3 Commercial products certified for the Reduced Inspection Certification Program are one time 100% inspected by Production personnel. To determine if the product is qualified for reduced inspection program, refer to the respective Product Validated List (i.e., EOL I-034).

6.3.1.4 Difficult to inspect products (i.e., colored products for Research and Development & Commercial) are one time 100% inspected by Production personnel and then tested as per supplemental destructive testing.

NOTE: Whenever samples are required to be submitted to Quality Control and Microbiology for testing prior to the completion of visual inspection of the entire batch, visual inspection can be performed on representative tub or tray of filled units from beginning, middle, and end of the run using the appropriate procedure. Record inspection of such selected tub or tray using form IPD-007-F1, i.e., if a batch has 100 tub or tray, 10,000 units are filled (100 units per tub or tray), and 45 units of samples are required for Quality Control and Microbiology testing, select tub or tray 1, 50, and 100 for the inspection. Upon completion of the inspection of all units in the three tubs or trays, notify QA to collect representative samples as per SOP IQA-007.

6.3.2 Production department requests visual inspection forms with Batch Manufacturing Record using Form IQA-006-F1 "Batch / Packaging Record Request Form". Production department will verify the visual inspection requirements (either First 100% and Second 100% inspections or only First 100% inspection) using the respective Product Validated List (i.e., EOL I-034) to determine the amount of visual inspection forms needed.

6.3.3 Form IPD-007-F1 "Visual Inspection of Injections Report" is issued for each individual involved in visual inspection. Form IPD-007-F3 "Log for Visual Inspection of Injections" is issued per batch. These forms are issued with the Batch Manufacturing Record by QA department.

6.4 **Inspection of Research and Development Products:**

6.4.1.1 Research and Development (Exhibit / Stability / Pivotal) products are one time 100% inspected by Production personnel. Refer to Figure 1 for a general overview of research and development product inspections.

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

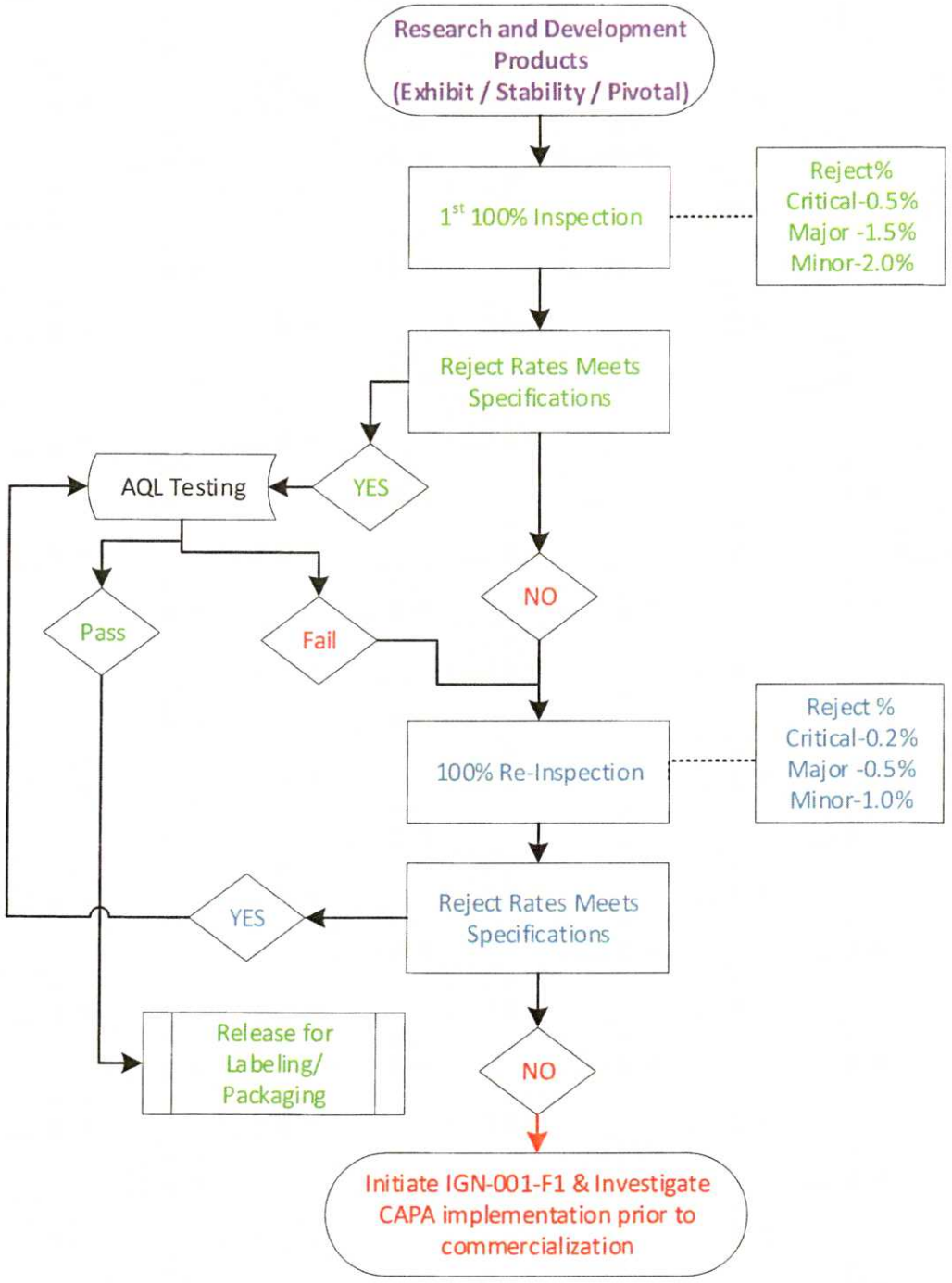


Figure 1: General Visual Inspection Process for Research and Development Products

6.4.1.2 Before QA issues line clearance, ensure the product is secured (e.g., cage with fastener and lock, rack that has been wrapped) and there is no sign of tampering. If there is evidence of tampering, notify supervisor or designee immediately to determine how to proceed.

6.4.1.3 Once line clearance has been given, bring product into the room and place a STATUS label on the rack/cage containing filled product (Status should be: To Be Inspected).

6.4.1.4 Place a STATUS label on the receiving rack/cage with appropriate status (e.g., First 100% inspected product, 100% re-inspected product)

6.4.1.5 Test light intensity using NIST calibrated standard Lux Meter prior to inspection start, and record results in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source. If the light intensity is less than 2100 lux the booth cannot be used for inspection, initiate a maintenance request as per SOP IGN-020.

6.4.1.6 Collect one Filled Units tub/tray to be inspected at a time from the batch of filled units. If filled units are in tubs count the number of units available for inspection and record number of units in the appropriate space on form IPD-007-F1 and check the First 100% inspection box. If filled units are in trays, prepare another empty tray to place inspected units.

6.4.1.7 Pick up and hold the units in between finger and thumb in horizontal position (with bottom of the vial/syringe touching the thumb) approximately 8-10 inches below the light source and NMT 5 inches from the center line. Rotate and observe the containers, slowly, for five seconds in such a way that the complete body of the containers, including neck and bottom, are visible for inspection. Observe the containers for following defects:

A. For inspection of vials with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on Flip-cap
d. Dirt on Exterior Surface
e. Empty Container
f. Cracked vial
g. Leakage
h. Missing Stopper
i. Missing Flip-cap
j. Incomplete seal/cap
k. Wrong color stopper/cap
l. Crimp defect (loose crimp or non-uniform crimp)

NOTE: When inspecting for incomplete seal/cap, rotate unit between fingers and ensure the cap is leveled with the vial and the seal is securely locked from all points. Holding in one hand, move the cap head side to side and ensure the securing flanges do not move past the crown of the vial.

B. For inspection of syringes with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on needle sheath or luer lock
d. Dirt on Exterior Surface
e. Empty syringe
f. Cracked or broken syringes
g. Missing stopper
h. Wrong stopper position (stopper upside down) with reference to standard
i. Liquid between stopper ribs
j. Partially Inserted Stopper, with reference to standard

6.4.1.8 Gently swirl or invert the vials/syringes making sure that minimal air bubbles are introduced and bring back to an upright position. Inspect the product in front of the **black background** for minimum five seconds and check for the defects mentioned below, as applicable for vials or syringes with liquid product.

A. For inspection of Liquid Product in either vials or syringes:

a. Low Fill Level
b. High Fill Level
c. Discolored, or Cloudy/Precipitate
d. Colored particles
e. Black Particles
f. White Particles
g. Glass Particles
h. Fibers

6.4.1.9 Invert the vials/syringes momentarily and bring to an upright position and inspect the product in front of the **white background** for minimum five seconds and check for the defects mentioned below.

A. Black/Brown Particles
B. Fibers
C. Colored Particles

NOTE: As each unit is inspected in front of black and white background each for a minimum of five seconds, and maximum of 2 containers are inspected at a time, it will take 20 seconds to inspect 2 units. No more than 360 units should be inspected per hour.

6.4.1.10 Accepted vials/syringes will be placed into their respective tub/tray. Rejected vials/syringes will be marked with the defect code number as listed in IPD-007-F1 form section III and placed into the appropriate labeled reject bin (i.e., critical reject bin, major reject bin, minor reject bin).

NOTE: If an inspector has a doubt about a defect category, another qualified inspector may inspect and confirm.

6.4.1.11 At the end of inspection process, test light intensity using NIST calibrated standard Lux Meter, and record in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source; if the light intensity does not meet specification, initiate a maintenance request as per SOP IGN-020. All units inspected in this booth must be re-inspected after taking corrective action/repair or perform inspection in any other inspection booth.

6.4.1.12 Individual operators will reconcile the inspected units and rejects in his/her form and attach to the batch record.

6.4.1.13 Review total reject rates from the First 100% inspection through respective inspection forms. If it is within the specified limits from batch record, coordinate with Quality Assurance for Acceptable Quality Level (AQL) Inspection. If the reject rates are not specified in the Batch Manufacturing Record, follow the limits specified in Table 2.

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

Table 2: Research and Development Products Visual Inspection Acceptance Criteria

Type of Defects	% Reject Rates (Action Level)	
	First 100% Inspection	100% Re-inspection
Critical Defects	0.5	0.2
Major Defects	1.5	0.5
Minor Defects	2.0	1.0

A. If the reject rates from the first 100% inspection are NOT within the specified limits, request Quality Assurance Document Control to issue respective Batch record pages and Form IPD-007-F1 for 100% re-inspection as per SOP IQA-006.

B. Review total reject rates from 100% re-inspection. If it is within the specified limits from batch record or Table 2 "**100% Re-inspection**", coordinate with Quality Assurance for Acceptable Quality Level (AQL).

C. If first AQL inspection fails, re-inspection of complete batch is performed with "100% Re-inspection" limits in Table 2. Once re-inspection is complete, a second AQL inspection can be performed with tightened inspection limits, as per SOP IQA-016. If it is NOT within the specified limits, inform supervisor. An investigation must be initiated as per IGN-001, corrective and preventive actions must be implemented prior to commercial batch manufacturing.

6.4.1.14 Once AQL inspection is complete and the batch record has been updated, the filled product can be further released for labeling and packaging.

A. If product is left unattended, ensure the product is secure (e.g., secured in a cage with fastener and lock).

6.4.1.15 If the filled product needs transfer to the warehouse, prepare the transfer by following the procedure in SOP IPK-003.

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

6.5 Inspection of Initial Commercial Products:

6.5.1.1 Initial Commercial products (i.e., initial process validation batches) are First 100% inspected and then Second 100% inspected, unless they are qualified for Reduced Inspection Program. To determine if the product is qualified for reduced inspection program, refer to the respective Product Validated List (i.e., EOL I-034).

NOTE: Refer to section 6.7 for Inspection of Commercial Products Certified for Reduced Inspection Program.

A. Refer to Figure 2 for the general inspection process for initial Commercial batches.

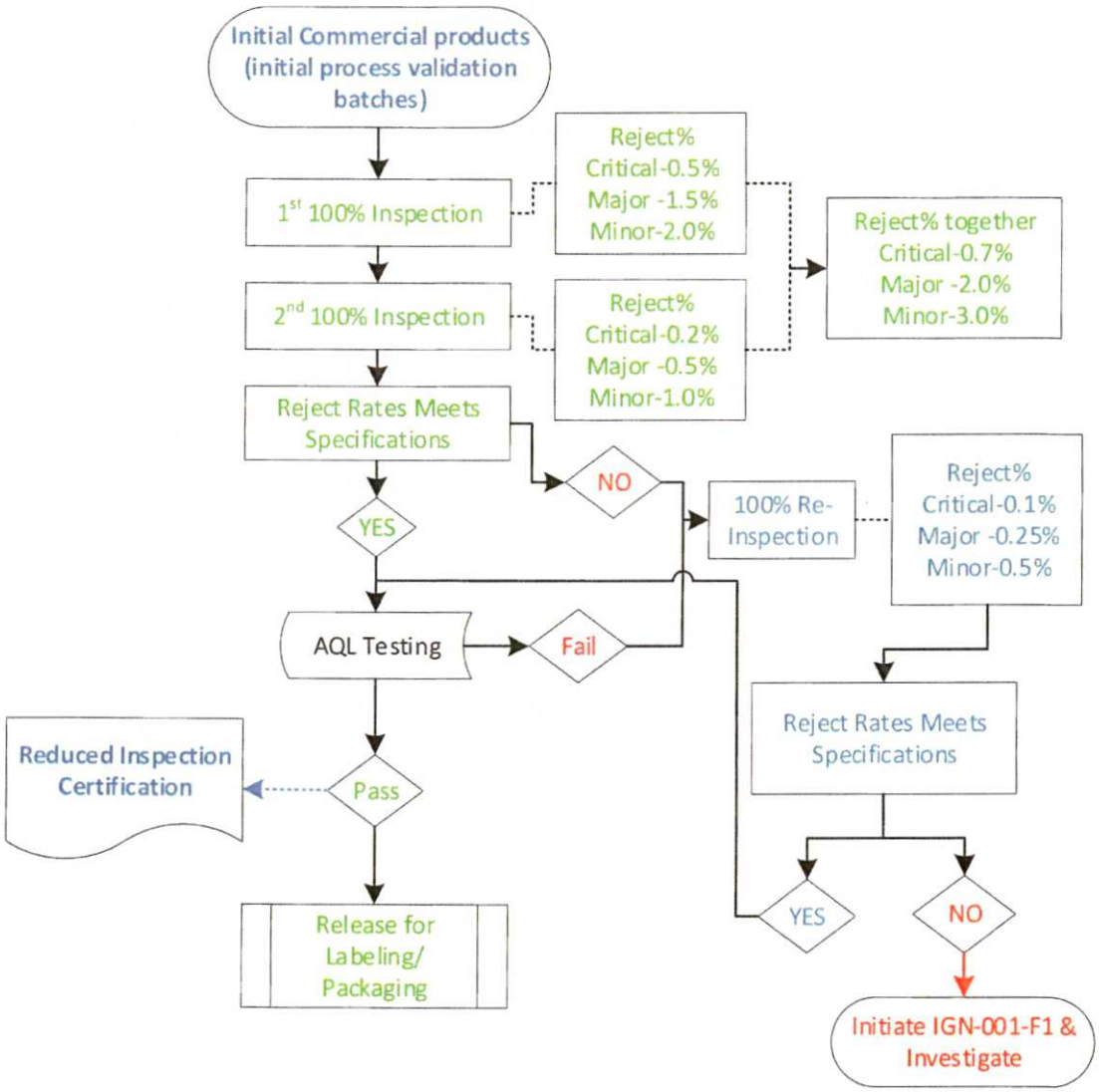


Figure 2: General Visual Inspection Process for Commercial Batches Prior to Reduced Inspection Certification

6.5.1.2 Before QA issues line clearance, ensure the product is secured (e.g., cage with fastener and lock, rack that has been wrapped) and there is no sign of tampering. If there is

evidence of tampering, notify supervisor or designee immediately to determine how to proceed.

6.5.1.3 Once line clearance has been given, bring product into the room and place a STATUS label on the rack/cage containing filled product (Status should be: To Be Inspected).

6.5.1.4 Place a STATUS label on the receiving rack/cage with appropriate status (e.g., First 100% inspected product, Second 100% inspected product, 100% re-inspected product)

6.5.1.5 Test light intensity using NIST calibrated standard Lux Meter prior to inspection start, and record results in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source. If the light intensity is less than 2100 lux the booth cannot be used for inspection, initiate a maintenance request as per SOP IGN-020.

6.5.1.6 Collect one Filled Units tub/tray to be inspected at a time from the batch of filled units. If filled units are in tubs count the number of units available for inspection and record number of units in the appropriate space on form IPD-007-F1 and check the First 100% inspection box. If filled units are in trays, prepare another empty tray to place inspected units.

6.5.1.7 Pick up and hold the units in between finger and thumb in horizontal position (with bottom of the vial/syringe touching the thumb) approximately 8-10 inches below the light source and NMT 5 inches from the center line. Rotate and observe the containers, slowly, for five seconds in such a way that the complete body of the containers, including neck and bottom, is visible for inspection. Observe the containers for following defects:

A. For inspection of vials with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on Flip-cap
d. Dirt on Exterior Surface
e. Empty Container
f. Cracked vial
g. Leakage
h. Missing Stopper
i. Missing Flip-cap
j. Incomplete seal/cap
k. Wrong color stopper/cap
l. Crimp defect (loose crimp or non-uniform crimp)

NOTE: When inspecting for incomplete seal/cap, rotate unit between fingers and ensure the cap is leveled with the vial and the seal is securely locked from all points. Holding in one hand, move the cap head side to side and ensure the securing flanges do not move past the crown of the vial.

B. For inspection of syringes with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on needle sheath or luer lock
d. Dirt on Exterior Surface
e. Empty syringe
f. Cracked or broken syringes
g. Missing stopper

h. Wrong stopper position (stopper upside down) with reference to standard
i. Liquid between stopper ribs
j. Partially Inserted Stopper, with reference to standard

6.5.1.8 Gently swirl or invert the vials/syringes making sure that minimal air bubbles are introduced and bring back to an upright position. Inspect the product in front of the **black background** for minimum five seconds and check for the defects mentioned below, as applicable for vials or syringes with liquid product.

A. For inspection of Liquid Product in both vials and syringes:

a. Low Fill Level
b. High Fill Level
c. Discolored, or Cloudy/Precipitate
d. Colored particles
e. Black Particles
f. White Particles
g. Glass Particles
h. Fibers

6.5.1.9 Invert the vials/syringes momentarily and bring to an upright position and inspect the product in front of the **white background** for minimum five seconds and check for the defects mentioned below.

A. Black/Brown Particles
B. Fibers
C. Colored Particles

NOTE: As each unit is inspected in front of black and white background each for a minimum of five seconds, and maximum of 2 containers are inspected at a time, it will take 20 seconds to inspect 2 units. No more than 360 units should be inspected per hour.

6.5.1.10 Accepted vials/syringes will be placed into their respective tub/tray. Rejected vials/syringes will be marked with the defect code number as listed in IPD-007-F1 form section III and placed into the appropriate labeled reject bin (i.e., critical reject bin, major reject bin, minor reject bin).

NOTE: If an inspector has a doubt about a defect category, another qualified inspector may inspect and confirm.

6.5.1.11 At the end of inspection process, test light intensity using NIST calibrated standard Lux Meter, and record in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source; if the light intensity does not meet specification, initiate a maintenance request as per SOP IGN-020. All units inspected in this booth must be re-inspected after taking corrective action/repair or perform inspection in any other inspection booth.

6.5.1.12 Individual operators will reconcile the inspected units and rejects in his/her form and attach to the batch record.

6.5.1.13 Review total reject rates from the first 100% inspection through respective inspection forms, typical "**First 100% Inspection**" % Rejects Rates are listed in Table 3.

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

Table 3: Initial Process Validation/Commercial Products Visual Inspection Acceptance Criteria

Type of Defects	% Reject Rates (Action Level)			
	First 100% Inspection	Second 100% Inspection	Together First & Second Inspection	100% Re-inspection
Critical Defects	0.5	0.2	0.7	0.1
Major Defects	1.5	0.5	2.0	0.25
Minor Defects	2.0	1.0	3.0	0.5

6.5.1.14 Perform a Second 100% inspection following the same procedure as the First 100% inspection, typical "**Second 100% Inspection**" % Rejects Rates are listed in Table 3.

6.5.1.15 Rejected vials/syringes will be marked with the defect code number as listed in IPD-007-F1 form section III and placed into the appropriate labeled reject bin (i.e., critical reject bin, major reject bin, minor reject bin).

6.5.1.16 At the end of inspection process, test light intensity using NIST calibrated standard Lux Meter, and record in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source; if the light intensity does not meet specification, initiate a maintenance request as per SOP IGN-020. All units inspected in this booth must be re-inspected after taking corrective action/repair or perform inspection in any other inspection booth.

6.5.1.17 Individual operators will reconcile the inspected units and rejects in his/her form and attach to the batch record.

6.5.1.18 Once the Second 100% inspection is complete, inform supervisor or designee to summarize overall inspection results in Form IPD-007-F3 and Batch Manufacturing Record.

6.5.1.19 Review total reject rates "**Together First & Second Inspection**" in respective inspection forms. If it is within the specified limits listed in batch record or Table 3, coordinate with Quality Assurance for Acceptable Quality Level (AQL) Inspection.

A. If the reject rates from the "**Together First & Second Inspection**" are NOT within the specified limits, request Quality Assurance Document Control to issue respective Batch record pages and Form IPD-007-F1 for 100% re-inspection as per SOP IQA-006.

B. Review total reject rates from 100% re-inspection. If it is within the specified limits from batch record or Table 3, coordinate with Quality Assurance for Acceptable Quality Level (AQL). If it is NOT within the specified limits, inform supervisor and an investigation must be initiated as per IGN-001.

C. If first AQL testing fails, re-inspection of complete batch is performed with "100% Re-inspection" limits from Table 3. Once re-inspection is complete, a second AQL inspection can be performed with tightened inspection limits, as per IQA-016.

NOTE: Only one re-inspection is allowed. If the reject rates are still NOT within the specified limits, an investigation must be initiated as per IGN-001.

6.5.1.20 Once AQL inspection is complete and the batch record has been updated, the filled product can be further released for labeling and packaging.

A. If product is left unattended, ensure the product is secure (e.g., secured in a cage with fastener and lock).

6.5.1.21 If the filled product needs transfer to the warehouse, prepare the transfer by following the procedure in SOP IPK-003.

6.6 **Reduced Inspection Certification Program for Commercial Products:**

6.6.1 Manufacturing Science & Technology or Production Lead/designee are responsible for compiling results and report for the Reduced Inspection Certification Program.

6.6.2 Reduced Inspection Certification is performed based on the following criteria:

6.6.2.1 Execute First 100% and Second 100% Visual Inspections for three consecutive cGMP commercial manufacturing batches per container closure system or product and filling process line.

6.6.2.2 Once three consecutive cGMP visual inspection results are available, a summary report will be prepared evaluating if the process is well understood, visible particulates type and characteristics are determined, and the visual inspection process is in control to maintain reject rates.

6.6.2.3 The summary report will compare the consistency of results between the batches and ensure the results meet the following criteria.

A. Each defect category in each inspection meets the criteria in Table 3.

B. Defect types are consistent between the batches.

C. The reject rate from the Second 100% inspection is significantly lower than First 100% inspection (typically 50% less than First 100% inspection).

6.6.2.4 The summary report will be reviewed and approved by Quality Assurance Management through change control request.

6.6.2.5 Upon approval of change control, the respective Product Validated List (i.e., I-034) will be updated with reduced inspection for all future cGMP batches.

6.6.2.6 First 100% and Second 100% Visual Inspection should be performed for reduced inspection certified products if:

A. First 100% visual inspection reject rates are significantly higher and any new particle types are identified which originated from the process.

B. Primary container or closure manufacturer changes their process, which may affect particulates from packaging component.

C. Major changes are made in the aseptic fill process/equipment which may impact either particulate generation or particulate retention.

6.6.2.7 If the visual inspection results for certified products do not comply with above requirements, an investigation as per SOP IGN-001 is conducted and the product must be removed from the Reduced Inspection Program. The respective Product Validated List (i.e., EOL I-034) must be updated via change control to remove the product from the Reduced Inspection Program. The product will then be First and Second 100% inspected until the criteria is met once again as per the requirements of this SOP.

6.7 Inspection of Commercial Products Certified for Reduced Inspection Program:

6.7.1.1 All commercial products certified for Reduced Inspection Certification Program are one time 100% inspected (i.e., First 100% Inspection). To determine if the product is qualified for reduced inspection program, refer to the respective Product Validated List (i.e., EOL I-034).

A. Refer to Figure 3 for the general inspection process of commercial products certified for reduced inspection.

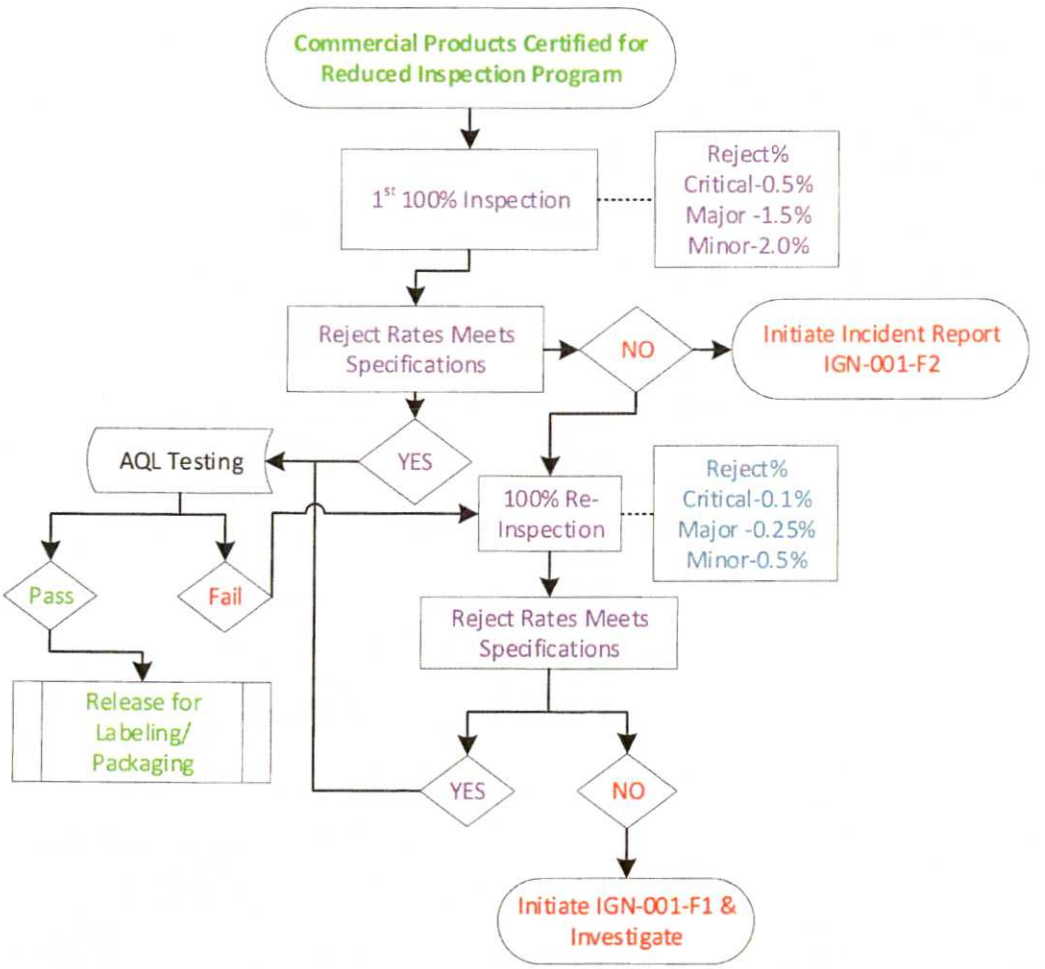


Figure 3: General Visual Inspection of Commercial Products Certified for Reduced Inspection

6.7.1.2 Before QA issues line clearance, ensure the product is secured (e.g., cage with fastener and lock, rack that has been wrapped) and there is no sign of tampering. If there is

evidence of tampering, notify supervisor or designee immediately to determine how to proceed.

6.7.1.3 Once line clearance has been given, bring product into the room and place a STATUS label on the rack/cage containing filled product (Status should be: To Be Inspected).

6.7.1.4 Place a STATUS label on the receiving rack/cage with appropriate status (e.g., First 100% inspected product)

6.7.1.5 Test light intensity using NIST calibrated standard Lux Meter prior to inspection start and record results in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source. If the light intensity is less than 2100 lux the booth cannot be used for inspection, initiate a maintenance request as per SOP IGN-020.

6.7.1.6 Collect one Filled Units tub/tray to be inspected at a time from the batch of filled units. If filled units are in tubs count the number of units available for inspection and record number of units in the appropriate space on form IPD-007-F1 and check the First 100% inspection box. If filled units are in trays, prepare another empty tray to place inspected vials/syringes.

6.7.1.7 Pick up and hold the units in between finger and thumb in horizontal position (with bottom of the vial/syringe touching the thumb) approximately 8-10 inches below the light source and NMT 5 inches from the center line. Rotate and observe the containers, slowly, for five seconds in such a way that the complete body of the containers, including neck and bottom, is visible for inspection. Observe the containers for following defects:

A. For inspection of vials with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on Flip-cap
d. Dirt on Exterior Surface
e. Empty Container
f. Cracked vial
g. Leakage
h. Missing Stopper
i. Missing Flip-cap
j. Incomplete seal/cap
k. Wrong color stopper/cap
l. Crimp defect (loose crimp or non-uniform crimp)

NOTE: When inspecting for incomplete seal/cap, rotate unit between fingers and ensure the cap is leveled with the vial and the seal is securely locked from all points. Holding in one hand, move the cap head side to side and ensure the securing flanges do not move past the crown of the vial.

B. For inspection of syringes with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on needle sheath or luer lock
d. Dirt on Exterior Surface
e. Empty syringe
f. Cracked or broken syringes
g. Missing stopper

h. Wrong stopper position (stopper upside down) with reference to standard
i. Liquid between stopper ribs
j. Partially Inserted Stopper, with reference to standard

6.7.1.8 Gently swirl or invert the vials/syringes making sure that minimal air bubbles are introduced and bring back to an upright position. Inspect the product in front of the **black background** for minimum five seconds and check for the defects mentioned below, as applicable for vials or syringes with liquid product.

A. For inspection of Liquid Product in both vials and syringes:

a. Low Fill Level
b. High Fill Level
c. Discolored, or Cloudy/Precipitate
d. Colored particles
e. Black Particles
f. White Particles
g. Glass Particles
h. Fibers

6.7.1.9 Invert the vials/syringes momentarily and bring to an upright position and inspect the product in front of the **white background** for minimum five seconds and check for the defects mentioned below.

A. Black/Brown Particles
B. Fibers
C. Colored Particles

NOTE: As each unit is inspected in front of black and white background each for a minimum of five seconds, and maximum of 2 containers are inspected at a time, it will take 20 seconds to inspect 2 units. No more than 360 units should be inspected per hour.

6.7.1.10 Accepted vials/syringes will be placed into their respective tub/tray. Rejected vials/syringes will be marked with the defect code number as listed in IPD-007-F1 form section III and placed into the appropriate labeled reject bin (i.e., critical reject bin, major reject bin, minor reject bin).

NOTE: If an inspector has a doubt about a defect category, another qualified inspector may inspect and confirm.

6.7.1.11 At the end of inspection process, test light intensity using NIST calibrated standard Lux Meter, and record in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source; if the light intensity does not meet specification, initiate a maintenance request as per SOP IGN-020. All units inspected in this booth must be re-inspected after taking corrective action/repair or perform inspection in any other inspection booth.

6.7.1.12 Individual operators will reconcile the inspected units and rejects in his/her form and attach to the batch record.

6.7.1.13 Review total reject rates from the first 100% inspection through respective inspection forms. If the reject rate acceptance criteria are not specified in the Batch Manufacturing

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

Record, follow the limits specified in Table 4. If it is within the specified limits, coordinate with Quality Assurance for Acceptable Quality Level (AQL) Inspection.

Table 4: Reduced Inspection Certified Products Visual Inspection Acceptance Criteria

Type of Defects	% Reject Rates (Action Level)	
	First 100% Inspection	100% Re-inspection
Critical Defects	0.5	0.1
Major Defects	1.5	0.25
Minor Defects	2.0	0.5

NOTE: If First 100% Inspection reject rates are within the specified limits, then a comment should be made in the Batch Manufacturing Record for Second 100% Inspection results referring to the Reduced Inspection Certification.

A. If the reject rates from the first 100% inspection are NOT within the specified limits, initiate an incident report as per SOP IGN-001 and request Quality Assurance Document Control to issue respective Batch record pages and Form IPD-007-F1 for 100% Re-inspection as per SOP IQA-006.

B. Review total reject rates from 100% re-inspection. If it is within the specified limits from batch record or Table 4 "**100% Re-inspection**", coordinate with Quality Assurance for Acceptable Quality Level (AQL).

C. If first AQL testing fails, re-inspection of complete batch is performed with "100% Re-inspection" limits from Table 4 after initiating an incident report as per SOP IGN-001. Once re-inspection is complete, a second AQL inspection can be performed with tightened inspection limits, as per SOP IQA-016. If it is NOT within the specified limits, inform supervisor. An investigation must be initiated as per IGN-001.

NOTE: Whenever the "100% re-inspection" and final AQL pass the requirements, the decision of removing the commercial product from the reduced inspection program is assessed and discussed in the respective incident / investigation report based on the nature of the defect.

6.7.1.14 Once AQL inspection is complete and the batch record has been updated, the filled product can be further released for labeling and packaging.

A. If product is left unattended, ensure the product is secure (e.g., secured in a cage with fastener and lock).

6.7.1.15 If the filled product needs transfer to the warehouse, prepare the transfer by following the procedure in SOP IPK-003.

6.8 Handling of Difficult to Inspect Products:

6.8.1 Some products may be difficult to inspect for particulates (e.g., colored products for Research and Development & Commercial). If a product cannot be reliably inspected following the procedures above, the following method will be used for inspection.

6.8.1.1 The product will undergo first 100% inspection, AQL inspection, and destructive testing. Refer to Figure 4 for the general inspection process for difficult to inspect products.

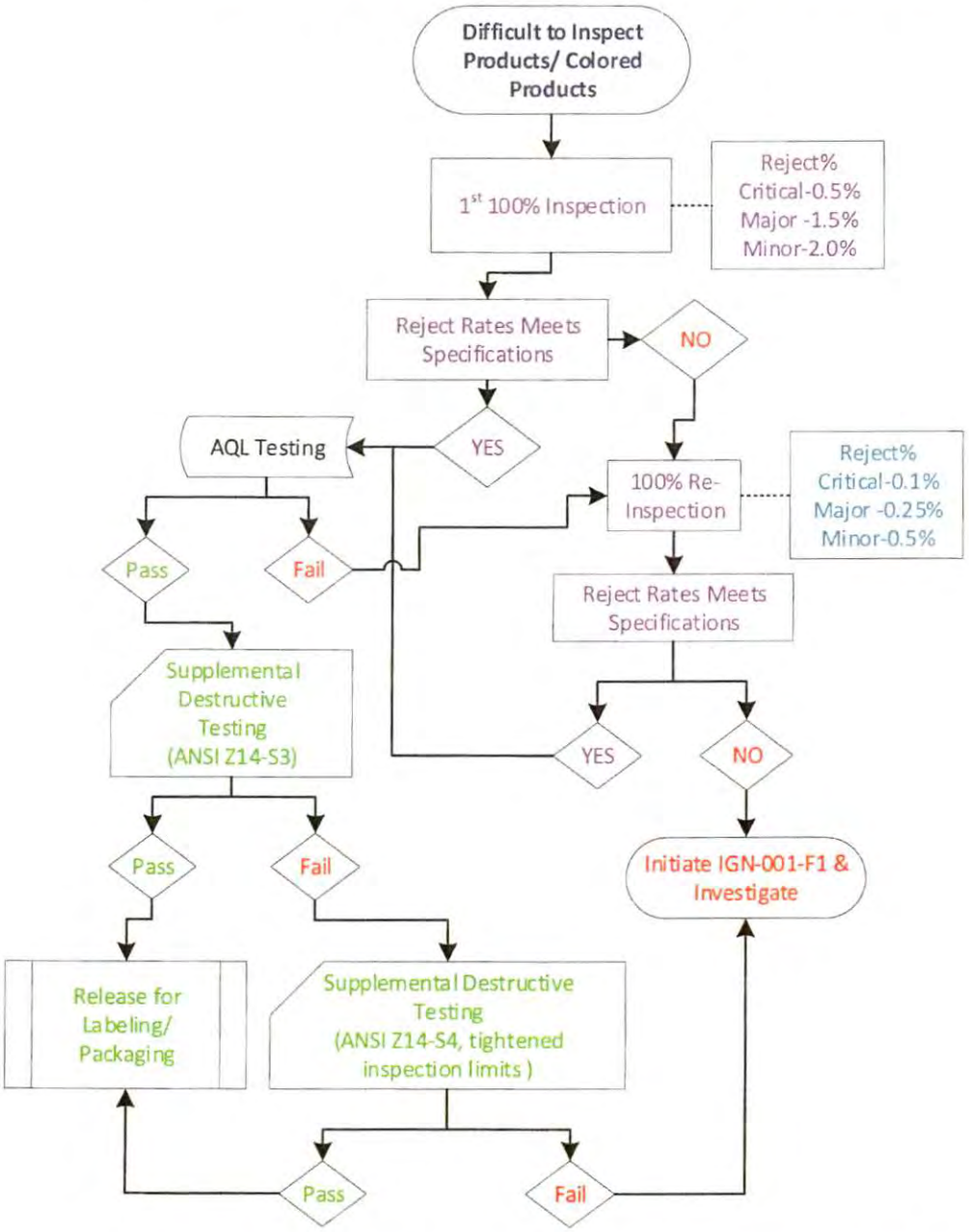


Figure 4: General Visual Inspection Process for Difficult to Inspect Products

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

6.8.1.2 Review total reject rates from the first 100% inspection through respective inspection forms. If the reject rate acceptance criteria are not specified in the Batch Manufacturing Record, follow the limits specified in Table 5. If it is within the specified limits, coordinate with Quality Assurance for Acceptable Quality Level (AQL) Inspection.

Table 5: Difficult to Inspect Products Visual Inspection Acceptance Criteria

Type of Defects	% Reject Rates (Action Level)	
	First 100% Inspection	100% Re-inspection
Critical Defects	0.5	0.1
Major Defects	1.5	0.25
Minor Defects	2.0	0.5

A. If the reject rates from the first 100% inspection are NOT within the specified limits, request Quality Assurance Document Control to issue respective Batch record pages and Form IPD-007-F1 for 100% re-inspection as per SOP IQA-006.

B. Review total reject rates from 100% re-inspection. If it is within the specified limits from batch record or Table 5 "**100% Re-inspection**", coordinate with Quality Assurance for Acceptable Quality Level (AQL).

C. If first AQL testing fails, re-inspection of complete batch is performed with "100% Re-inspection" limits from Table 5. Once re-inspection is complete, a second AQL inspection can be performed with tightened inspection limits, as per SOP IQA-016. If it is NOT within the specified limits, inform supervisor. An investigation must be initiated as per IGN-001.

6.8.1.3 Once production and AQL inspections are complete, QA department will take samples following Form IQA-016-F2 American National Standard (ANSI Z1.4) Sampling Plan, Special Inspection level S3 for supplemental destructive testing, by either an in-house or outside laboratory.

6.8.1.4 Transfer the samples to in-house laboratory for testing or to Warehouse to prepare samples for shipping.

A. In-house testing is performed as per SOP IMI-038 "Determination of Particulate within Injectables Products using Filtration Method".

B. If supplemental destructive testing does not meet the acceptance criteria, retesting is performed with tightened parameters.

At this time, QA department will take additional samples following Form IQA-016-F2 American National Standard (ANSI Z1.4) Sampling Plan, Special Inspection level S4 with tightened inspection limits for retesting of supplemental destructive testing.

If retesting does not meet the acceptance criteria, an investigation is initiated as per SOP IGN-001.

6.8.1.5 Once AQL inspection and supplemental testing are complete and the batch record has been updated, the filled product can be further released for labeling and packaging.

A. If product is left unattended, ensure the product is secure (e.g., secured in a cage with fastener and lock).

6.8.1.6 If the filled product needs transfer to the warehouse, prepare the transfer by following the procedure in SOP IPK-003.

6.9 Reconciliation of Visually Inspected Product:

6.9.1 After complete inspection, Production Supervisor or designee will review each IPD-007-F1 with IPD-007-F3 to ensure each tub/tray was inspected as per established inspection program and all units are accounted for.

6.9.2 Production Supervisor or designee will check each tub/tray's inspections and acknowledge in respective space in Form IPD-007-F3.

6.9.3 Production Supervisor or designee will then check the number of units available for each inspection, number of units rejected in each inspection, and number of units available after complete inspection.

6.9.4 Form IPD-007-F3 and Batch Manufacturing Record inspection results must be reviewed and found acceptable by Production Supervisor or designee prior to labeling or packaging of visually inspected product.

6.10 Handling of Rejected Units:

6.10.1 Once Visual Inspection is finished and the appropriate forms and Batch Record pages are complete, the rejected units will be placed into a storage container (e.g., box, resealable bags). Production will complete the label shown in Figure 5 and place it on the storage container.

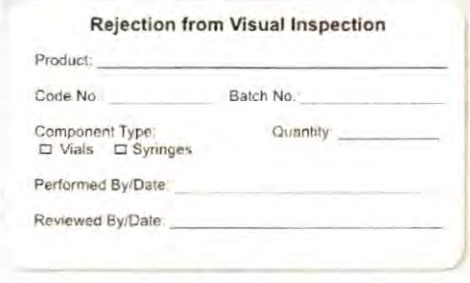


Figure 5: Rejection from Visual Inspection Label Template

6.10.2 Production will take labeled storage container to warehouse. Warehouse and production will place the storage container into the "REJECT" cage and production will document in the appropriate logbook.

6.10.3 Once the batch has been released by QA and no further testing is needed, QA will notify production and warehouse personnel.

6.10.4 Production designee will complete form IGN-024-F1 for the rejected units and give the completed form to warehouse.

6.10.5 Warehouse personnel will follow the waste procedure outlined in IWH-004 to dispose of the rejected units.

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

6.10.6 If the inspection is outside the specified acceptance criteria, production supervisors may determine that testing and identification of particulates is needed for a product. If so, production will send samples from the respective batch to either an in-house or outside laboratory using the following procedure.

6.10.6.1 Take the rejected units from warehouse to appropriate inspection room.

6.10.6.2 Separate the units into groups of similar particulate types (e.g., colored fiber, white fiber, dark fiber).

6.10.6.3 Choose a representative sample from each particulate type to send for testing.

6.10.6.4 Transfer the representative sample to QC laboratory for testing or to Warehouse to prepare samples for shipping. Return remaining rejected units to the warehouse.

6.11 Trending of Visual Inspection Results:

6.11.1 Visual inspection results for each cGMP batch will be tabulated and trended on a quarterly basis (once every three months) to ensure that manufacturing and inspection processes are operating in control.

6.11.2 Trending is performed to compile results and identify possible anomalies such as abnormal defect type or number of defects observed in a single product or container/closure system.

6.11.3 A report of the trend will be written and reviewed accordingly.

6.11.4 Visual inspection results for products certified for reduced inspection program are reviewed to ensure the product still qualifies for reduced inspections. In case a product no longer qualifies for the reduced inspection program, the product must be removed through change control procedure and revision of respective Product Validated List (i.e., EOL I-034).

6.11.5 Based on the results obtained, Corrective and Preventive Action (CAPA) may be proposed as per SOP IQA-024 if required.

7.0 REVISION HISTORY

Revision No.	Effective Date	Description of Changes
01	FEB 05 2019	Original SOP
02	JUL 29 2019	1. Added IWH-004, IQA-006, IPK-003, IGN-024, and IGN-024-F1 to reference section. 2. Add Second 100% inspection in Figure 1. 3. Clarified section 6.1.7 for taking and documenting breaks 4. Clarified section 6.1.8 for use of the magnifier. 5. Clarified section 6.2.2.2 for verifying cleanliness on the Visual Inspection Booth. 6. Changed section 6.2.4.2 to initiate a maintenance request as an incident is not needed. 7. Updated section 6.3 title to Procedure for Manual Visual Inspection and modified and realigned section for a Second 100% Inspection. 8. Removed duplicate defects in section 6.3.5.1.J and 6.3.5.1.K. 9. Added note after section 6.3.3.3.A for inspecting incomplete seal/cap 10. Modified Section 6.3.6.1 to include syringes and removed section 6.3.6.2. 11. Added 6.4 Handling of Rejected Units.
03	DEC 11 2019	1. Added note after section 6.3.4.1 for use of tray partitions when packing units into trays. 2. Added section 6.4 for handling of difficult to inspect products. 3. Added section 6.5.6 for testing and identification of particulates procedure.

SOP No.	Title	Revision No.
IPD-007	VISUAL INSPECTION OF INJECTIONS	09

Revision No.	Effective Date	Description of Changes
04	OCT 15 2020	1. Included Note between steps 6.3.2 and 6.3.3 to explain procedure for sample collection when they must be taken prior to completion of visual inspection.
05	DEC 02 2020	1. Included Note between steps 6.3.3.8 and 6.3.3.9 to establish a limit on the number of units inspected per hour.
06	MAR 16 2020	1. Updated Section 3.0 for Trending Responsibilities. 2. Moved procedure for placing inspected units into Tray to Section 6.3.4.10. 3. Added Section 6.6 for Trending of Visual Inspection Results.
07	FEB 07 2022	1. Changed wording from "tub" to "container" in case of inspection of units in tubs, trays, etc. 2. Note was added in Section 6.4 for taking samples of difficult to inspect products. 3. Added Section 6.3.5 for Reconciliation of Visually Inspected Product.
08	MAY 19 2022	1. Entire SOP is re-arranged to accommodate visual inspection based on product stage of life cycle. 2. Change in % Reject Rates based on industry standards and guidance. 3. Introduced "Reduced Inspection Certification Program". 4. Other minor changes to maintain the flow of inspection requirements depending on batch type.
09	OCT 2 0 2022	1. Change syringe defect description from "Distance between stopper and top liquid level" to "Partially Inserted Stopper", in respective sections

SOP No.	Title	Revision No.
IGN-025	ASEPTIC PROCESS SIMULATION (APS) OR MEDIA FILL PROGRAM	04

Prepared By / Date	Reviewed By / Date	QA Approved By / Date	Effective Date
04/07/23	PMK 04/07/23	M. Salazar 04/10/23	APR 26 2023
Title: Asst. Manager	Title: Manager-MS	Title: CQCO	Change Control No. I-23296

1.0 PURPOSE

The purpose of this SOP is to establish and implement the Aseptic Process Simulation (APS), also called Media Fill Validation to support sterile drug products manufacturing.

The purpose of an Aseptic Process Simulation (APS) is to:

1.1 Assess the capability of an aseptic process under a given manufacturing environment and process controls.

1.2 Demonstrate that appropriately designed and implemented process changes are acceptable.

1.3 Demonstrate compliance with current Good Manufacturing Practices.

1.4 Demonstrate the appropriateness of operating practices used in support of aseptic processing.

1.5 Challenge the aseptic process for microbial contamination vulnerabilities.

2.0 SCOPE

The procedure is applicable for Sterile Drug Products Manufacturing facility at BPI Labs.

3.0 RESPONSIBILITY

3.1 Manufacturing Science & Technology (MS) / Production (PD):

3.1.1 Prepare, review, and execute the media fill Batch Record, Protocol, and the Final Report.

3.1.2 Provide the environmental summary report for non-viable particulate air, relative humidity, temperature, and differential pressure monitoring conducted during the media fill.

3.2 Microbiology:

3.2.1 Incubate and inspect incubated media filled units and remaining bulk media at the completion of incubation.

3.2.2 Provide the summary report for the examination of the media filled units to MS for inclusion with the media fill report.

3.2.3 Provide the environmental summary report for viable air and surface monitoring conducted during the media fill.

3.3 Quality Assurance:

3.3.1 Review and approve the media fill batch record and final media fill report.

3.3.2 Maintain the media fill schedule (every 6 months per filling line and process) to maintain bracketing and ensure the qualified status of the aseptic processing is maintained.

4.0 REFERENCES

4.1 CFR Title 21 Part 211.113 Control of microbiological contamination

4.2 USP General Chapters: <1116> MICROBIOLOGICAL CONTROL AND MONITORING OF ASEPTIC PROCESSING ENVIRONMENTS

4.3 USP General Chapters: <1208> STERILITY TESTING-VALIDATION OF ISOLATOR SYSTEMS

4.4 USP General Chapters: <1211> STERILITY ASSURANCE

4.5 Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice FDA, September 2004

4.6 PDA Technical Report No. 22 (Revised 2011), Process Simulation for Aseptically Filled Products

4.7 Food and Drug Administration Compliance Program Guidance Manual Chapter 56 – Drug Quality Assurance - Subject-Sterile Drug Process Inspections

4.8 SOP IGN-001 Investigations

4.9 SOP IQA-024 Corrective and Preventive Actions

4.10 SOP IWH-004 Storage and Disposal of Manufacturing and Laboratory Waste

4.11 VMP-I01 Validation Master Plan for BPI Labs

4.12 IPD-RA-1-IPD-FM01-01 Risk Assessment Aseptic Process Simulations (Media Fills) for Robotic Aseptic Fill Machine (ID. 1-PD-FM01-01)

4.13 IPD-RA-1-IPD-FM02-01 Risk Assessment Aseptic Process Simulations (Media Fills) for FlexPro Robotic Aseptic Fill Machine (ID. 1-PD-FM02-01)

5.0 ATTACHMENTS

Not Applicable.

6.0 PROCEDURE

6.1 General:

6.1.1 BPI Labs aseptic fill process is designed to perform within a Grade ISO 5 environment, through use of robotic isolators, both gloved and gloveless.

6.1.2 Gloveless isolators eliminate human interventions and human originated microbial contamination risk is eliminated from aseptic fill in Sterile Drug Products fill finish. Due to this reason, some traditional elements of aseptic process are not applicable, such as, but not limited to, personnel gowning qualification and personnel monitoring during fill.

6.1.3 Gloved Isolators are designed to fill with no direct human interaction. Isolator designed with gloves ports are used in the event of necessary adjustments to the fill machine within ISO 5 environment.

6.1.4 Sterile Drug Products Manufacturing is designed either by means of aseptic filling or aseptic filling followed with terminal sterilization of product in its final container/closure system.

6.1.5 APS is only required for all products manufactured using aseptic process. If terminal sterilization is used, no media fill support is required since these products are subjected to subsequent terminal sterilization. This provides the necessary Sterility Assurance Level (SAL) for those products, provided sufficient pre-sterilization hold time studies have been established.

6.1.6 Processes to be challenged in process simulation:

The conduct of process simulations for aseptically produced parenteral products entails simulation of the process from the point of sterilization of the product and product contact surfaces, including containers and closures, through sealing of the filled container. Process such as weigh dispensing, mixing, pre-sterilization/filtration, and post sealing does not require to be simulated, similarly to the product process.

6.1.6.1 Compounding/Mixing and Sterile Filtration Operation: After sterilization, the medium should be passed through the equipment train. as though it were an actual production batch, and all routine aseptic procedures used in the manufacture of a batch should be performed, e.g., sampling, aseptic connection. Any aseptic manipulations performed during and at the end of the holding period should be simulated as well.

6.1.6.2 Filling Operation: The containers and closures (if necessary), product contact equipment, and filling parts should be prepared using standard operating procedures (SOPs). The filling machine should be operated at the pre-determined conditions for the container size being utilized based on risk assessment and "worst case" conditions.

A. For a process conducted in an isolator or robotic aseptic operations, where there is a low risk of contamination because of the lack of direct human intervention, a standard quantity of NLT 3,500 containers is sufficient to perform operations and interventions. For container formats with larger sizes and less containers per nest (formats greater than 10mL filling volume), a standard of NLT 1,200 containers is sufficient. This would yield a similar or greater number of nests required to complete the batch, similarly allowing for all required operations and interventions to be performed.

B. For traditional aseptic fills under Laminal Air Flow hoods, with manual aseptic operations and interventions:

a. When the production batch size is above 10,000 units, a minimum of 10,000 units is sufficient to perform all operation and interventions.
b. When the production size is below 5,000 units, at least equal the maximum batch size.

6.2 APS Strategy:

6.2.1 Media fill runs and required frequencies are listed in Table 1.

Table 1: Media Fill Strategy

When to Perform	How Many	Action	Reporting System
When a processing line is being initially qualified, including new facility construction and new filling line installation.	At least three separate, consecutive, successful runs	Any one size container	Protocol & Report
When introducing new container/closure size outside of the established bracket.	At least three separate, consecutive, successful runs	Specific container/closure	Protocol & Report
When introducing new container/closure type (e.g. syringes).	At least three separate, consecutive, successful runs	Specific container/closure	Protocol & Report
Once initially qualified, every six (6) months ± 1 month (semi-annually).	One successful run	Alternating with each end of the bracket (e.g., largest, smallest)	Protocol & Report
Facility and equipment modifications, such as breach to the sterile/aseptic area/isolator and line configuration changes.	Revalidation as per Change Control assessment	Impact assessed via Change Control	Protocol & Report
When using alternate filtration or filling assembly, such as Multi-Use flow path instead of Single-Use flow path.	One successful run	Impact assessed via Change Control	Protocol & Report
Minor modifications in Flow paths or sterile filtration/filling assembly, such as alternate use of sterile connector or change in product holding container size, material, etc.	One successful run	Impact assessed via Change Control	Protocol & Report
Anomalies in environmental testing results from filling operation, container closure system changes, extended shutdowns, or sterility testing failure due to fill system failures.	Impact assessed via Change Control	Impact assessed via Change Control	Impact assessed via Change Control

6.2.2 A detailed APS strategy and guidance written in the Validation Master Plan of BPI Labs should be followed to perform media fills.

6.3 Risk Assessment (RA):

6.3.1 Risk Assessment is performed per fill line to determine container closure configurations, identify, and evaluate the aseptic process steps, interventions, and worst-case conditions that can potentially adversely affect the sterility assurance risk to the product and incorporate in the APS.

6.4 Media Fill Matrix:

6.4.1 A matrix will be prepared based on the Risk Assessment to include validated Media Fills.

6.4.2 Specific conditions that represent the worst case(s) will be identified within the matrix. The matrix and specific criteria for assessment and inclusion of Media Fills must be documented and approved by Quality Assurance or designee.

6.5 Execution of Media Fill Validation:

6.5.1 Batch Record preparation and execution:

6.5.1.1 It should be written in the same format as a normal production batch record and contain all the routine data and sign-off requirements. All information applicable to the process simulation, which normally would be attached to a batch record, also should be attached to the simulation batch record, e.g., cleaning and sterilization records for pieces of equipment used, release stickers for the containers and closures, etc. All interventions, whether inherent (integral component of the process) or corrective (required to maintain operation), and stoppages, should be documented in the batch record as the type of intervention, time the intervention occurred, aseptic operators involved with the duration of the intervention or stoppage, and the number of the tub or tray being filled. The executed batch record should include information which is relevant to the performance and completion of the study. This includes but is not limited to:

A. Names of individuals participating in the simulation

B. Media sterilization/filtration

C. Filter identification and membrane integrity test results

D. Record or log of routine and non-routine occurrences including those in the filling room, which may have an effect on the outcome of the study

E. Number of units filled

F. Number of units rejected for cause during pre-incubation inspection (e.g. damaged container, defective seal)

G. Number of units incubated

H. Filled unit incubation time, temperature, and duration

I. Number of units positive and tub or tray number of any positive unit(s)

J. Growth promotion of medium (after incubation)

K. Filled unit accountability

L. Environmental and personnel monitoring (if applicable) results

M. The description and resolution of any discrepancies or deviations to the protocol

N. The executed batch record should be approved, signed, and dated

SOP No.	Title	Revision No.
IGN-025	ASEPTIC PROCESS SIMULATION (APS) OR MEDIA FILL PROGRAM	04

6.5.2 Validation Protocol and Report Preparation:

6.5.2.1 A formal written protocol or procedure should be prepared, approved, and issued prior to the start of the study. The document should include but not limited to the following information:

A. Groups responsible for execution, microbial testing, and approval of study

B. Rationale for the "worst case" parameters chosen as appropriate simulation of routine operations

C. Identification of the process to be simulated

D. Identification of the room or rooms to be used

E. Identification of the filling line and equipment to be used, including fluid path configuration details if multiple configurations are available

F. Type of container/closure to be used

G. Line speed

H. Minimum number of units to be filled

I. Number and type of interventions and stoppages

J. Identification of units to be excluded from incubation and rationale

K. Media to be used

L. Volume of medium to be filled into the containers

M. Incubation time, temperature, and duration for the filled units

N. Environmental monitoring to be performed

O. Accountability requirements

P. Acceptance criteria for all activities

Q. Description of the documentation required for the final report

R. Duration of the aseptic process simulation

S. Duration of routine production fills being simulated

T. Definition of conditions that may cause the simulations to be invalidated and decision-making authority

6.5.3 Pre-Incubation Container Inspection:

6.5.3.1 Prior to incubation 100% media filled units are visually inspected for non-integral units (e.g., missing, or misaligned closures, cracks in container) due to the possible breach of product sterility, according to the Master Batch Manufacturing Record instructions.

6.5.4 Incubation:

6.5.4.1 All pre-inspected media filled units must be incubated for at least 7 days at 22.5°C ± 2.5°C (where vials will be inverted), followed with another at least 7 days at 32.5°C ± 2.5°C (where vials will be upright), in temperature-controlled incubators. Syringes are always incubated upright as product is always in contact with the stopper.

6.5.5 Post-Incubation Container Inspection:

6.5.5.1 At the end of each incubation condition, visual inspection of all units for growth is performed by microbiologist or qualified operator.

6.5.6 Acceptance Criteria:

6.5.6.1 When filling fewer than 5000 units, no contaminated units should be detected.
A. One (1) contaminated unit is considered cause for revalidation, following an investigation.

6.5.6.2 When filling from 5,000 to 10,000 units:

A. One (1) contaminated unit should result in an investigation, including consideration of a repeat media fill.

B. Two (2) contaminated units are considered cause for revalidation, following investigation.

6.5.6.3 When filling more than 10,000 units:

A. One (1) contaminated unit should result in an investigation.

B. Two (2) contaminated units are considered cause for revalidation, following investigation.

6.5.6.4 Leftover Media in the container/bags:

A. Samples are taken from the leftover media in the container/bags and are submitted for incubation. The samples from the leftover media are representative of the container they were attached to, but are not directly representative of the final units being filled as part of the media fill.

6.5.6.5 Investigations should be performed per SOP IGN-001.

6.6 Initial APS:

6.6.1 Initial APS is performed in the events discussed in Table 1.

6.6.2 Upon completion of facility, utility, and equipment qualification, risk assessment is prepared by MS and approved to all departments involved, along with Quality Assurance.

6.6.3 Three (3) consecutive, separate, successful, runs are executed and included in an Effective Official List.

6.6.4 Quality Assurance controls the schedule to re-qualify each media fill based on a six-month period. Schedule is circulated to the concerned departments every month to ensure media fill program to the specific container closure systems are in valid state.

6.7 Continued Process Simulation Verification:

6.7.1 The bracketing approach will be maintained as the basis for requalification. APS is to be performed every six months for each processing line / fill machine, alternating between smallest and largest, as well as alternating container/closure systems, to maintain qualification of the aseptic filling operations.

Example:

Process Simulations for Vanrx Formats are bracketed by 2R vials and 50R vials, as well as 1mL syringes and 10mL syringes. As such, process simulations can be performed in the following order: 2R Vials -> 10mL Syringe -> 1mL Syringe - > 50R Vials. This would repeat back to 2R Vials and the order repeats.

6.7.2 An Initial Protocol will be created for initial qualification. A verification Protocol will be created and reissued for requalification, when applicable. These protocols will be used for execution of media fill runs for the specific run.

6.7.3 Quality Assurance updates media fill history and schedule to ensure that the process bracketing is maintained.

6.8 Disposal of Media Filled Containers and leftover media:

6.8.1 After completion of the incubation, media filled containers are disposed of per SOP IWH-004, unless there is a pending investigation related to the media fill or GPT failure of the media used.

6.9 Media Fill Failure Investigation:

6.9.1 Any contaminated unit cause for an investigation (as per IGN-001) should include a comparison, and analysis, of environmental monitoring performed during the media fill. If an assignable cause is identified, a single re-validation run will be planned. If no root cause is found for a process simulation failure, three consecutive, successful process simulations are required for re-qualification.

6.9.2 The investigation into a failed APS will include the following activities:

6.9.2.1 Identification of microorganisms, preferably to species level, to aid in the determination of the possible sources of the contamination.

6.9.2.2 Review of the data of microbial environmental monitoring and airborne particulate monitoring.

6.9.2.3 Review of the sterilization / depyrogenation cycles of container / closures, components, equipment, and filter integrity test data of filters used for filtration.

6.9.2.4 Review qualification documents of the HEPA Filters (integrity when challenged with aerosol, airflow direction, velocity measurements, air flow patterns, and pressure differentials).

6.9.2.5 Review of interventions and batch report from filler for any unusual events that occurred during the media fill.

6.9.2.6 Review of the procedure adopted during the intervention.

6.9.2.7 Storage condition of sterile items, disinfection procedures, and training.

6.9.2.8 Review of the equipment qualification, such as autoclave sterilization performance qualifications.

6.9.2.9 Post filter integrity test data of the filters used in the media fill.

6.9.2.10 Evidence of power failure and all deviations that occurred during the process.

6.9.2.11 Evaluation of incubated bulk media.

6.9.2.12 The investigation must be directed towards identification of the root cause of the failure and suggest the corrective and preventive actions to be taken in order to prevent failure. Refer to SOP IQA-024.

6.9.2.13 Based on investigation performed by manufacturing, QA will perform a risk assessment and assess the impact on all product filled on the affected fill line since the last acceptable APS, and determine the disposition of released product, as well as the product in-process.

6.9.2.14 After incubation is underway, any unit found to be damaged should be included in the data for the media fill run, because the units can be representative of drug product released to the market. Any decision to exclude such incubated units (i.e., non-integral) from the final run must be fully justified through a deviation. If a correlation emerges between difficult to detect damage and microbial contamination, a thorough investigation should be conducted to determine its cause.

6.10 Invalidation of APS or abortion of media fill will occur in the following conditions:

6.10.1 When growth promotion test (GPT) of media fails.

6.10.2 When filtered media shows mass growth in bulk solution.

6.10.3 Under circumstances in which written procedures require commercial lots to be equally handled, such as:

6.10.3.1 Filter integrity test failure which would have resulted in product re-filtration or rejection.

6.10.3.2 Failure of physical conditions in the isolator (e.g., power outage).

6.10.3.3 Any major breakdown in the fill equipment, which requires to open the isolator.

6.10.4 If for any reason the media fill run is considered invalid/aborted, containers should not be incubated.

6.10.5 All media filled units filled before an incident that would cause an aborted fill must be incubated.

6.10.6 Invalidation of APS or abortion of media fill will be documented through the respective section in the appropriate protocol. Investigation should be performed per SOP IGN-001.

6.11 New Product or Container Closure Introduction:

6.11.1 Change control will be initiated for new product and container closure introduction. The team, including Quality Assurance, will evaluate the need for a media fill.

6.11.2 If the product being evaluated falls in the already validated container closure configuration, no additional media fills are required, e.g. Product "A" container closure system is 2R vial, 13mm neck with 13mm stopper cap as closure, and the new product "B" introduced is also is 2R vial, 13mm neck with 13mm stopper cap as closure.

6.11.3 If the new container closure is out of the bracketing range established, media fill must be performed for at least three consecutive separate successful runs for that container closure. For example, if bracketing is for 2R vial with 13mm neck and 13mm stopper cap, and 10R vial with 20mm neck and 20mm stopper cap, the 4R, 6R, and 8R vials with 20mm neck and 20mm stopper cap do not require media fill, however the 100R vial with 32mm neck with 32mm stopper cap does require 3 consecutive successful media fills.

6.11.4 New product manufacturing process is evaluated for aseptic operations and any additional interventions or process conditions, other than the previously validated, must be reviewed for criticality.

7.0 REVISION HISTORY

Revision No.	Effective Date	Description of Changes
01	DEC 07 2018	Original SOP
02	FEB 04 2011	1. Include Risk Assessment in references section. 2. Include different scenarios in Table 1. 3. Expand on continued process simulation verification in step 6.7.1. Procedure and example included for alternating container closure system.
03	JAN 31 2023	1. Include Risk Assessment for new fill machine (FM02) in references section 2. Split up section 6.1.1 to elaborate the use of both gloved and gloveless isolators 3. Include sections under new 6.1.6.2 detailing the required amount of containers to be challenged during process simulation.
04	APR 2 6 2023	1. Modified Step 6.1.6.2.A to specify that 1,200 containers is sufficient for container/closure formats with a fill volume greater than 10mL 2. Step 6.5.6.4.A reworded to specify that leftover media is incubated from samples taken from the containers. 3. Clarified wording for example in Step 6.7.1

SOP No.	Title	Revision No.
IGN-033	HANDLING OF 503B PRODUCTS	08

Prepared By / Date	Reviewed By / Date	QA Approved By / Date	Effective Date
Kirtan R Patel 08/31/21	08/31/21	M. Salazar 08/31/21	AUG 3 1 2021
			Change Control No.
Title: QA Specialist	Title: Pharmacist	Title: CQCO	I-21419

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1.0 PURPOSE

The purpose of this SOP is to establish general guidelines for the handling of 503B Injectable Sterile Drug Products at BPI Labs facility Suite 450.

2.0 SCOPE

This procedure is applicable to 503B Injectable Sterile Drug Products manufactured at BPI Labs facility Suite 450.

For Solid Dosage Products manufactured at Suite 420A, refer SOP GN-040 Handling of 503B Products (Solid Dosage).

3.0 RESPONSIBILITY

3.1 It is the responsibility of every department listed in this procedure to follow instructions delineated in each section.

3.2 It is the responsibility of Operations and Quality Assurance Management to ensure that all activities included in this procedure are followed in the development of 503B drug products.

4.0 REFERENCES

4.1 Guidance for Industry Sterile Drug Products Produced by Aseptic Processing Current Good Manufacturing Practice Sept 2004

4.2 Contract Manufacturing Arrangements for Drugs: Quality Agreements

4.3 Bulk Drug Substances Used in Compounding Under Section 503B of the FD&C Act

4.4 Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act

4.5 Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act

4.6 Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

4.7 Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food Drug and Cosmetic Act

4.8 21 CFR Part 310 – New Drugs, Subpart D – Records and Reports, Section 310.305

4.9 Florida Department of Health Board of Pharmacy Rule 64B16-28.100 Pharmacy Permits – Applications and Permitting

4.10 ICH Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products

SOP No.	Title	Revision No.
IGN-033	HANDLING OF 503B PRODUCTS	08

4.11 Protocol IFC-PQ-T-1-AH-02,1-AH-03,1-AH-04 HVAC System (ID No. 1-AH-02, 1-AH-03, 1-AH-04) Performance Qualification Protocol

4.12 SOP GN-040 Handling of 503B Products (Solid Dosage)

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4.13 SOP ICB-001 Calibration Procedure

4.14 SOP IGN-001 Investigations

4.15 SOP IGN-003 Creation and Modification of Code Numbers and National Drug Code Numbers (NDC)

4.16 SOP IGN-006 Development of Products

4.17 SOP IGN-010 Personnel Gowning, Sanitation, Health Habits, Health Conditions

4.18 SOP IGN-017 Personnel Flow in BPI Labs Suite 450

4.19 SOP IGN-018 Material Flow in BPI Labs Suite 450

4.20 SOP IGN-019 Handling of Purified Water, Water for Injection, Pure Steam, and City Water

4.21 SOP IGN-023 Preparation of Master Batch and Packaging Records

4.22 SOP IGN-025 Aseptic Process Simulation (APS) or Media Fill Program

4.23 SOP IGN-027 Preparation of Cleaning Agents, Detergents, and Disinfectants Used in Manufacturing

4.24 SOP IGN-028 Cleaning of Processing and Non-Processing Rooms

4.25 SOP IGN-030 Operation of the Building Management System

4.26 SOP IGN-036 Serialization Procedure

4.27 SOP IMI-003 Out of Specification Microbiology Results

4.28 SOP IMI-005 Preparation, Maintenance, and Growth Promotion of Culture Media

4.29 SOP IMI-006 Growth Promotion Test

4.30 SOP IMI-020 Environmental Monitoring Program (Viable) for Sterile Drug Manufacturing Area

4.31 SOP IMI-034 Handling of Microbiology Laboratory Incidents

4.32 SOP IPC-001 Purchasing System

4.33 SOP IPD-002 Dispensing of Raw Material and Packaging Material

4.34 SOP IPD-006 Time Limitations for Production and Cleaning

4.35 SOP IPD-007 Visual Inspection of Injections

4.36 SOP IPD-FM01-1 Set Up and Operation of the Robotic Aseptic Fill Machine (Model # SA25)

4.37 SOP IPD-SS01-1 Set Up and Operation of the Steam Sterilizer (Model # FOAF3/AG)

4.38 SOP IPK-001 Labeling and Packaging Operation

4.39 SOP IPK-002 Issuance, Reconciliation, Destruction, and Return of Printed Labeling Material

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4.40 SOP IPK-003 Brite Stock Handling

4.41 SOP IPH-001 503B - Research and Development Experimental Trial Batches

4.42 SOP IPH-002 BPI Policy for Essentially Copies of Approved Drug Products

4.43 SOP IQA-001 Change Control System

4.44 SOP IQA-002 Document Control System

4.45 SOP IQA-003 Identification and Numbering System

4.46 SOP IQA-005 Monitoring of Environmental Conditions

4.47 SOP IQA-006 Issuance of Batch Records, Packaging Records, Protocols, and In-House Computer-Generated Labels

4.48 SOP IQA-007 Sampling System

4.49 SOP IQA-009 Handling of Complaints

4.50 SOP IQA-010 Vendor Qualification Program

4.51 SOP IQA-011 Disposition Procedure

4.52 SOP IQA-012 Retesting of Materials and Products

4.53 SOP IQA-013 Quality Control Unit and Management

4.54 SOP IQA-020 Retention Samples

4.55 SOP IQA-021 Procedure for Reviewing Executed cGMP Documents

4.56 SOP IQA-024 Corrective and Preventive Actions

4.57 SOP IQA-025 Statistical Techniques

4.58 SOP IQC-001 Investigating Out of Specification (OOS) and Out of Trend (OOT) Test Results

4.59 SOP IQC-002 Stability Program

4.60 SOP IQC-003 Standard Procedure for Sample Management in Analytical Development and Quality Control Department

4.61 SOP IQC-004 Handling of Contract Laboratories

4.62 SOP IQC-005 Method Validation / Method Verification Guidelines

4.63 SOP IQC-021 Analytical Method Transfer

4.64 SOP IRA-001 Reporting of Adverse Drug Experiences

4.65 SOP IRA-004 Drug Product Registration Requirements

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4.66 SOP IRA-006 Creating or Changing Drug and Device Product Labeling

4.67 SOP IRA-010 Medical Devices Registration Requirements

4.68 SOP ITD-001 Training System

4.69 SOP IVD-001 Cleaning Validation

4.70 SOP IVD-002 Process Validation

4.71 SOP IVD-003 Swab Procedure

4.72 SOP IVD-007 Heating, Ventilation, and Air Conditioning (HVAC) Validation

4.73 SOP IWH-001 Receiving of Materials and Products

4.74 SOP IWH-004 Storage and Disposal of Manufacturing and Laboratory Waste

4.75 STM IMV-I01 Validation of Bacterial Endotoxin Testing

4.76 STM IMV-I02 Method Validation of Sterility Test

4.77 STM IMV-I03 Suitability of Microbial Enumeration Tests and Tests for Specified Microorganisms

4.78 PLN-I01 Project Plan for BPI Labs

4.79 EOL I-030 503B – Active Raw Materials List – BPI Labs

4.80 EOL I-031 503B – Finished Products Code Number List – BPI Labs, Human Drug Products

4.81 EOL I-033 503B – Inactive Raw Materials List – BPI Labs

4.82 EOL I-036 503B – Miscellaneous List – BPI Labs

4.83 EOL I-037 503B – Packaging Components List – BPI Labs

5.0 ATTACHMENTS

Not applicable.

6.0 PROCEDURE

6.1 Quality Assurance Activities:

6.1.1 It is the responsibility of the Quality Assurance Control Unit to ensure that Quality System requirements are effectively established and maintained in accordance with 21 CFR parts 210, 211, and 820.

6.1.1.1 The Quality Assurance Control Unit is comprised of all Quality Assurance (QA) Department members / associates that have authority and responsibility to ensure that Quality System requirements are effectively established and maintained (refer to SOP IQA-013 for details).

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6.1.1.2 All departments are responsible for reviewing assigned Quality System documents such as Standard Operating Procedures (SOP), Forms, Job Descriptions, and Training Curriculum as well as ensure technical documentation is current and accurate.

6.1.1.3 QA department is responsible for ensuring all official documents such as SOP and Batch Records are approved, implemented, and distributed and that all obsolete editions of revised documents are retrieved (refer to SOPs IQA-001 and IQA-002 for details).

6.1.2 It is the responsibility of Quality and Operation Management to ensure all employees are qualified through a combination of training and experience to complete and maintain their assigned responsibilities (refer to SOP ITD-001 for details).

6.1.3 QA is responsible for the sampling and approval or rejection of raw materials (components), containers, closures, in-process materials, packaging materials, labeling, and finished products as per applicable specification (SPC) and respective quality system procedures (refer to SOPs IQA-007 and IQA-011 for details).

6.1.4 Analytical Chemistry Quality Control (QC) and Microbiology (MI) departments are responsible for the testing of raw material and finished products as per applicable SPC. QC and MI will review these results before release of material and products.

6.1.5 Retention of finished product reserve samples for applicable analytical and microbial SPC testing is the responsibility of QA, QC, and MI departments.

6.1.6 The results from environmental monitoring, water system testing, and media fill program are reviewed and scrutinized by QA department (refer to SOPs IMI-020, IGN-019, and IGN-025 for details).

6.1.7 Personnel monitoring is not applicable because of the nature of the manufacturing process.

6.1.7.1 After compounding, human intervention with the drug product and possibility of contamination is limited because of the use of peristaltic pumps, sterilized components, aseptic connections, sterilizing grade in-line filtration, and robotic aseptic filling and stoppering.

6.1.8 All documentation related to the manufacturing, labeling, and packaging operations of a product such as, but not limited to, Master Batch Manufacturing Record, Master Batch Labeling Record, Master Batch Packaging Record, and laboratory analytical reports shall be reviewed thoroughly before a batch is released (refer to SOP IQA-021 for details).

6.1.8.1 It is mandatory that all the data in all documents comply with the established SOP and product applicable SPC.

6.1.9 In the event of non-conformance or incidence, QA department is responsible for facilitating investigation of root cause and implementation of Corrective and Preventive Actions (CAPA) following guidelines of SOPs IGN-001, IQC-001, IMI-003, IMI-034, and IQA-024, among others.

6.1.10 In the event of formal product complaint or adverse event, QA department is responsible for facilitating investigation of root cause and implementation of CAPA following guidelines of SOPs IQA-009 and IRA-001, among others.

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6.2 Facility Design:

6.2.1 The manufacturing facility within 12393 Belcher Road, Suite 450, Largo, Florida is designed to prevent contamination and mix ups, segregate zones of differing cleanliness classification, and facilitate ease of cleaning, maintenance, and operations. Refer to the Project Plan for BPI Labs PLN-I01 for more details.

6.2.1.1 The facility prevents contamination and mix ups by designating areas for specific unit operations for a single product at a time. This is controlled by use of equipment and area labeling, QA line clearance, and Manufacturing Batch Record review.

6.2.2 The facility consists of sealed modular cleanroom walls, ceilings, and walkable ceiling panels to maintain ISO 14644 Class 8 conditions throughout the facility.

6.2.3 Potential risks have been identified and applicable controls have been implemented as per facility design Risk Assessment.

6.2.4 The facility has been qualified through the execution of Performance Qualification Protocol to maintain no less than ISO Class 8 cleanliness by controlling non-viable particulate, viable particulate, number of air changes, and directional airflow in cleanrooms.

6.2.4.1 Clean and ample airflow within the facility is controlled by ensuring all supplies and returns are clear, all HEPA filters are leak tested, and the supply airflow is sufficient for the required number of room changes.

6.2.4.2 Manufacturing Science and Technology (MS) department is responsible for validation, requalification, and calibration of facility control systems (refer to SOP IVD-007 for details).

6.2.5 The facility is designed to aseptically fill and stopper syringe and vial 503B drug products within ISO 5 isolators surrounded by a qualified ISO 8 environment.

6.2.5.1 The temperature, relative humidity, and air pressure differentials of all cleanroom environments are continuously monitored during production and periodically revalidated (refer to SOP IQA-005 for details).

6.2.6 Terminally sterilized 503B products are filled under ISO 5 environment surrounded by ISO 8 environment.

6.2.6.1 Terminal sterilization cycles are validated using appropriate biological indicator challenge for 6-log reduction.

6.2.7 Controls are available to maintain and monitor the facility design including, but not limited to, those documented in SOPs IGN-030, IQA-005, and IMI-020.

6.3 Control Systems and Procedures for Maintaining Suitable Facilities:

6.3.1 The facility is designed to limit the possibility of mix ups and cross contamination by establishing defined areas per unit operation and procedures for personnel flow, material flow, and cleaning (refer to SOPs IGN-017, IGN-018, and IGN-028).

6.3.2 The possibility of cross contamination of hazardous and non-hazardous drugs is limited by designating separate sampling rooms and equipment for dispensing of different drug types.

6.3.2.1 Hazardous drugs are dispensed within containment and dispensing isolators to prevent cross contamination and ensure the safety of operators.

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6.3.3 Production equipment follow cleaning schedules based on production schedule and Time Limitations.

6.3.3.1 Time Limitations are established for production and cleaning of process equipment and areas (refer to SOP IPD-006).

6.3.4 Processing, non-processing areas, and cleanroom support areas are kept clean and sanitary with cleaning schedule of WFI, disinfectant, and weekly sporicidal cleaning agent (refer to SOPs IGN-027 and IGN-028 for details).

6.3.4.1 Cleaning technicians are required to be trained on and review facility cleaning SOP, with an emphasis on cleaning schedule and rotating use of disinfectant / sporicidal cleaning agents.

6.3.4.2 Cleaning, Use, and Maintenance Logbooks are designated for each area to ensure the facility is being cleaned on the established schedule.

6.3.4.3 As with all received materials, disinfectant / sporicidal cleaning agents are inspected by QA department and verified with applicable SPC.

6.3.5 Temperature, relative humidity (RH), and pressure differentials within the manufacturing facility are maintained by the central heating, ventilation, and air conditioning (HVAC) system and monitored through Building Management System (BMS) to maintain product quality. The BMS provides trend reports of each condition and alerts personnel in case of an excursion (refer to SOP IGN-030).

6.3.5.1 The facility is designed to maintain 20 ± 2°C, less than 60% RH, and pressure differentials across rooms of differing classification.

6.3.5.2 These conditions are continuously monitored during production and are a requirement of room release (refer to SOP IQA-005).

6.3.5.3 In case of an excursion, impact is assessed, and incident is initiated when necessary.

6.3.6 Calibration schedule for critical instruments such as temperature, relative humidity, and pressure differential sensors in processing areas and equipment is maintained by QA and executed by MS (refer to SOP ICB-001).

6.3.7 Water systems (purified water, water for injection, and pure steam) are monitored every day of production and frequently as per applicable SPC (refer to SOP IGN-019).

6.3.7.1 In case of an excursion from the applicable SPC, impact is assessed, and investigation is initiated when necessary.

6.4 Personnel Qualification:

6.4.1 All personnel involved with the compounding of 503B drug products have been trained on established SOP for the dispensing, mixing, and filtration of compounded sterile products (CSP).

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6.4.2 Training Curriculums (TC) are established for initial and periodic GMP refreshment training of employees. This curriculum includes on-the-job and self-training on general and department specific roles (refer to SOP ITD-001 for details).

6.4.2.1 Prior to engaging in any commercial batch manufacturing, personnel must have completed their initial qualification for the applicable unit operation.

6.4.3 GMP trainers must be qualified through completion of the Qualification Technique (QT) prior to new employee or refreshment training.

6.4.4 Personnel, production process, container / closure type, and production equipment have been challenged through Aseptic Processing Simulation (APS) media fill studies prior to engaging in commercial batch manufacturing (refer to SOP IGN-025).

6.4.4.1 APS media fill studies must be successfully performed in worst case scenarios to validate routine manufacturing parameters.

A. For example, validating the use of one (1) in-line filter during compounding of successful APS media fill study validates the use of two (2) in-line filters during routine manufacturing.

6.5 Environmental and Personnel Monitoring:

6.5.1 Environmental conditions such as temperature, relative humidity, and air pressure differentials are continuously monitored by Building Monitoring System (BMS) (refer to SOPs IGN-030 and IQA-005).

6.5.1.1 BMS creates trends of environmental conditions able to be monitored and reviewed by trained personnel. QA reviews these trends prior to each unit operation room release.

6.5.1.2 Air pressure differential limits ensure that cascading pressure differentials are maintained during compounding of sterile drug products.

6.5.1.3 BMS automatically notifies Management / responsible personnel in the event of an excursion from ideal conditions.

6.5.2 Passive air (settle plate) and active air Environmental Monitoring (EM) are conducted daily during compounding, filling, and sterilization operations. Surface (contact plate) sampling is conducted at the end of operation, prior to cleaning (refer to SOP IMI-020).

6.5.2.1 The procedure, locations, actions limits, and justification of locations for EM are established (refer to SOP IMI-020).

6.5.2.2 The results from EM are completed in the applicable Forms and results are reviewed with the Master Batch Manufacturing Record.

6.5.3 Sampling data is reviewed after each batch and an extensive review is conducted periodically to identify any issues and scrutinize existing procedures.

6.5.3.1 In the event of results near or above action levels, QA department is responsible for facilitating investigation of potential product impact and root cause.

6.5.4 Personnel monitoring is not implemented because of the nature of the production process. Refer to the Project Plan PLN-I01 for BPI Labs for more details.

6.5.4.1 After compounding, human intervention with the drug product and possibility of contamination is limited because of the use of peristaltic pumps, sterilized components, aseptic connections, sterilizing grade in-line filtration, and robotic aseptic filling and stoppering.

6.5.5 Personnel gowning, sanitation, health habits, and health conditions are controlled and established (refer to SOP IGN-010).

6.5.6 Personnel flow and personal protective equipment requirements within the facility are established (refer to SOP IGN-017). It is the responsibility of Production personnel to follow this procedure and Management's responsibility to ensure this procedure is being followed.

6.5.6.1 These procedures control the safety of operators, cleanliness of processing rooms, and limit the possibility of cross contamination.

6.6 Equipment:

6.6.1 Process equipment used for batch production are qualified for use and calibrated on a scheduled maintained by the QA department (refer to SOP ICB-001).

6.6.1.1 The calibration schedule for production equipment and instruments are maintained by QA department and implemented by Manufacturing Science and Technology (MS) department.

6.6.1.2 Product contact surfaces of production equipment must be certified (i.e., certified 316 stainless steel) as non-reactive, non-adsorptive, and non-additive.

6.6.1.3 All documentation concerning material certification and current calibration performed in-house by MS with executed Form or by a third party is maintained by QA department.

6.6.2 Equipment qualifications and validations are approved by QA and executed by MS through Installation, Operation, and Performance Qualification Protocol.

6.6.3 SOP are established for the set up and operation, cleaning, and maintenance of major production equipment and implemented by Production personnel prior to use.

6.6.4 Production department is responsible for training, review, and execution of production equipment cleaning SOPs.

6.6.4.1 Training Record forms are executed at the time of training and maintained by QA department once complete.

6.6.5 Production department is responsible for the use of Cleaning, Use, and Maintenance logbooks to ensure the status of production equipment prior to use.

6.6.6 Refrigerators, freezers, and incubators are monitored with use of calibrated thermometer and, when applicable, relative humidity sensor.

6.6.7 Single-use disposable utensils and components are used for the dispensing, mixing, filtration, and filling of sterile drug products.

6.6.7.1 Inspection and certificate of analyses are used in the verification of these components prior to use.

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6.6.7.2 Components are inspected for damage or contamination prior to and after use via respective batch record.

6.7 Containers and Closures:

6.7.1 Pharmacist / Product Development / Production identifies vendors and materials required for a new project following SOP IPC-001. Materials can be ordered as samples for trial / experimental use; these materials are unaccounted. Once materials and vendors are identified and approved, a code number is requested per SOP IGN-003.

6.7.2 Upon creation of a code number using the appropriate official list, the following activities are coordinated:

6.7.2.1 Pharmacist / Analytical Research / Quality Control Department generates specification (SPC) and standard test method (STM) following instructions delineated in SOP IQA-025. Refer to Table 1 for suggested specification testing for primary and secondary packaging components.

Table 1 – Suggested Specification Testing for Containers and Closures

Type of Material	Suggested Testing Types
Primary Packaging (e.g., vial, syringe, cap, stopper)	Description, Physical Tests, Sterility (if applicable), Endotoxin (if applicable), and Certificate of Compliance Check
Secondary Packaging (e.g., carton)	Description (Visual Inspection), Physical Tests

6.7.2.2 Purchasing Department orders material upon management request following SOP IPC-001.

6.7.3 Warehouse Department receives materials following SOP IWH-001.

6.7.4 QA samples and inspects cGMP materials received following SOP IQA-007. Product Development can use these materials in quarantine for formulation trials only, ensuring sampling has been performed and an identification test has been completed, if required, as a discretion of the user.

6.7.5 Pharmacist / Analytical Research / Quality Control Department tests samples received according to the material specification and standard test method. Full testing is performed for all materials unless vendor has been qualified per SOP IQA-010; if this is the case, reduced testing is coordinated based on the tests specified in the specification. If during testing activities, Analytical Research / Quality Control / Microbiology Department finds that any test does not conform to established specifications, an investigation is performed in accordance with SOPs IQC-001 and IMI-003. Upon testing completion, results and data generated are submitted to Quality Assurance for final disposition.

6.7.5.1 Reduced specification testing is performed for containers and closures as suggested by SOP IQA-010 and applicable packaging component SPC, as seen in Table 2.

Table 2 – Suggested Reduced Specification Testing for Containers and Closures

Type of Material	Suggested Reduced Testing Types
Primary Packaging (e.g., vial, syringe, cap, stopper)	Description, Physical Tests, Sterility (if applicable), Endotoxin (if applicable), and Certificate of Compliance Check
Secondary Packaging (e.g., carton)	Description (Visual Inspection)

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6.7.6 In case the Product Development Department needs to use a material that is under testing for a cGMP batch, a conditional release request is coordinated as per SOP IQA-011.

6.7.7 The Quality Assurance Department performs final disposition for materials and assigns a retest date (when applicable) and expiration date once inspection and testing is completed as per SOP IQA-011.

NOTE: Analytical testing methods for active raw materials are validated / verified by the Pharmacist / Analytical Research / Quality Control / Microbiology Department based on method validation guidelines.

NOTE: All formal documents are routed for approval using SOP IQA-001.

6.7.8 As a general practice, retesting is not performed for containers and closures.

6.7.9 Containers and closures are stored in the climate-controlled warehouse monitored by BMS.

6.7.10 Quality Agreements must be established with each primary container and closure vendor to ensure the quality of the finished drug product.

6.7.10.1 Only pre-sterile ready to use (RTU) containers and closures are used for batch production. Vendors must perform sterilization cycle validation proven by Certificate of Analysis.

6.7.10.2 The primary packaging of pre-sterile containers and closures are only removed in ISO 5 areas once ready to be filled and stoppered.

6.7.11 Vendors of primary and secondary packaging materials are routinely evaluated as per SOP IPC-001.

6.8 Components:

6.8.1 Pharmacist / Product Development / Production identifies vendors and materials required for a new project following SOP IPC-001. Materials can be ordered as samples for trial / experimental use; these materials are unaccounted. Once materials and vendors are identified and approved, a code number is requested per SOP IGN-003.

6.8.2 The Active Pharmaceutical Ingredient (API) must be manufactured by an establishment that is FDA registered. Quality Agreements must be made with the API suppliers to ensure product quality and that FDA establishment registration is maintained.

6.8.3 Upon creation of a code number using the appropriate official list, the following activities are coordinated:

6.8.3.1 Pharmacist / Research and Development (R&D) / QC / MI Department generates SPC and STM following instructions delineated in SOP IQA-025. Refer to Table 3 for suggested SPC testing for active and inactive components.

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Table 3 – Suggested Specification Testing for Active and Inactive Components

Type of Material	Suggested Testing Types
Active (e.g., API)	Description, Identification, Loss on Drying (water), Assay, Microbial Enumeration Test, Endotoxin
Inactive (e.g., excipient)	Description, Identification, Microbial Enumeration Test (if applicable), Endotoxin (if applicable)

6.8.3.2 Purchasing Department orders materials upon management request as per SOP IPC-001.

6.8.4 Warehouse Department receives materials as per SOP IWH-001.

6.8.5 Active and inactive pharmaceutical ingredients are stored in the climate-controlled warehouse monitored by BMS.

6.8.6 QA Department samples and inspects cGMP materials received as per IQA-007. Pharmacist / Product Development can use these materials in quarantine for formulation trials only, ensuring sampling has been performed and an identification test has been completed, if required, as a discretion of the user.

6.8.6.1 Sampling is conducted within the manufacturing facility with use of complete gowning, Personal Protective Equipment (PPE), and dispensing hood or isolator.

6.8.7 Cleaning validation is not performed for components because of the use of single use systems.

6.8.8 Pharmacist / Analytical Research / Quality Control Department tests samples received according to the material specification and standard test method. Full testing is performed for all materials unless vendor has been qualified per SOP IQA-010; if this is the case, reduced testing is coordinated based on the tests specified in the specification. If during testing activities, Analytical Research / Quality Control / Microbiology Department finds that any test does not conform to established specifications, an investigation is performed in accordance with SOPs IQC-001 and IMI-003. Upon testing completion, results and data generated are submitted to Quality Assurance for final disposition.

6.8.8.1 Reduced specification testing is performed for active and inactive pharmaceutical ingredients as suggested by SOP IQA-010 and applicable packaging component SPC, as seen in Table 4.

Table 4 – Suggested Reduced Specification Testing for Active and Inactive Components

Type of Material	Suggested Reduced Testing Types
Active (e.g., API)	Description, Identification, Loss on Drying (water), Assay, Microbial Enumeration Test (if applicable), Endotoxin (if applicable)
Inactive (e.g., excipient)	Description, Identification, Microbial Enumeration Test (if applicable), Endotoxin (if applicable)

6.8.9 In case the Product Development Department needs to use a material that is under testing for a cGMP batch, a conditional release request is coordinated as per SOP IQA-011.

6.8.10 The Quality Assurance Department performs final disposition for materials and assigns a retest date (when applicable) and expiration date once inspection and testing is completed as per SOP IQA-011.

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NOTE: Analytical testing methods for active raw materials are validated / verified by the QC / MI Department based on method validation guidelines.

NOTE: All formal documents are routed for approval through Change Control System.

6.8.11 Retesting is performed for active and inactive components as per SOP IQA-012.

6.8.12 Vendor of active and inactive materials are routinely evaluated as per SOP IPC-001 (i.e., active materials ever year and inactive materials every two years).

6.9 Production and Process Controls:

6.9.1 General Controls:

6.9.1.1 Master batch records prepared for R&D products, proposed commercial products, and scale-up/validation/commercial product products are prepared by Product Development, Pharmacist, and/or Production department.

A. Master batch and packaging records for 503B products should be prepared as per SOP IGN-023.

6.9.1.2 All master batch and packaging records must be reviewed by Pharmacist / Production / Product Development departments and approved by Regulatory Affairs and QA departments.

6.9.1.3 All batch and packaging records are requested by Production designee and issued by QA department as per SOP IQA-006.

6.9.1.4 It is the responsibility of Production department to request room release per production unit operation and the responsibility of QA department to follow clearance procedure as per SOP IQA-014.

6.9.1.5 Time Limitations (refer to SOP IPD-006) and Hold Times must be followed for production process and in-process product as validated through media fill validation program.

A. The storage time limitation of bulk solution is validated through successful results of Hold Time study protocol.

6.9.1.6 503B drug products are aseptically handled by use of peristaltic pumps, aseptic connections, and pre-sterile components, among others.

6.9.1.7 Terminally sterilized 503B products are filled under ISO 5 environment surrounded by ISO 8 environment.

A. Terminal sterilization cycles are validated using appropriate biological indicator challenge for 6-log reduction.

6.9.1.8 Production parameters such as production equipment, process parameters, hold times, and time limitations or validated under worst-case scenario simulation during media fill validation program.

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6.9.2 General Production Process:

6.9.2.1 503B manufacturing and packaging operations follow the general production process of documentation release, line clearance, weigh and dispense, mixing, filtration, filling, terminal sterilization (when applicable), packaging, and labeling.

6.9.2.2 Documentation such as batch manufacturing record and applicable forms are requested by Production designee and issued by QA department as per IQA-006.

6.9.2.3 Line clearance / room release is requested by Production department prior to each operation and issued by QA department as per SOP IQA-014.

6.9.2.4 Weighing and dispensing of raw pharmaceutical ingredients (e.g., API, excipient) is performed by use of restricted access isolator or dispensing hoods as per batch record and SOP IPD-002.

6.9.2.5 Raw pharmaceutical ingredients are mixed with pharmaceutical grade Water for Injection (WFI) as per batch record.

6.9.2.6 Mixed unfiltered intermediate product is aseptically filtered by use of sterilizing grade filters into pre-sterile fill path or intermediate bags.

6.9.2.7 Filters used during filtration are sterilizing grade 0.2µ hydrophilic filters. 100% of filters used for batch manufacturing are filter integrity tested, with the results from these tests included within the Batch Manufacturing Record.

6.9.2.8 Filling will occur within controlled ISO 5 environment surrounded by ISO 8 environment.

6.9.2.9 When applicable, terminal sterilization will be performed by use of validated cycle and qualified equipment.

6.9.2.10 Packaging and labeling operation is performed as per packaging record and SOPs IPK-001 and IPK-002.

6.9.3 Research and Development Products:

6.9.3.1 Pharmacist identifies new projects to be developed in the company based on, but not limited to, company and marketing needs, and opportunities nominated by FDA "Bulk Drug Substances Nominated for use in Compounding under Section 503B of Food, Drug, and Cosmetic Act".

6.9.3.2 Pharmacist shall use SOP IPH-002 to determine if the proposed new project is essentially a copy of an approved or unapproved drug product. New projects shall be in compliance with "FDA Guidance for Industry Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act".

6.9.3.3 Pharmacist / Product Development Department prepares the marketing trade dress for the project with the purpose of understanding all aspects of the formulation, process, and labeling, among others, of the product. Pharmacist / Product Development Department prepares the R&D checklists for covering project planning and execution activities and ensuring that all project activities have been completed and that the FDA expectations, needs, and requirements have been met.

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6.9.3.4 Pharmacist designs experimental batches in order to analyze product behavior and test different formulations and processes (refer to SOP IPH-001 for details). Generally, these batches are documented and tracked via notebook. At this stage, Pharmacist / R&D / QC Department can analyze experimental samples and coordinate informal stability of the product. All experimental data generated by the Laboratory is submitted to the Pharmacist / Product Development Department for analysis and further action. Experimental batches are disposed according applicable SOP when required.

6.9.3.5 QA Validation Department incorporates the product into the cleaning validation matrix in order to swab cGMP equipment to look for active residue content (if equipment is shared between products). Pharmacist / R&D / QC Department prepares documented method in the laboratory to analyze active residue content of swab samples (refer to SOPs IVD-001, IVD-003, and IQC-005), when applicable.

6.9.3.6 QA Department swabs product contact cGMP equipment following cleaning validation matrix and submits swab samples to R&D / QC Department for analysis as per SOPs IVD-001 and IVD-003.

6.9.3.7 Once Pharmacist / Product Development develops the formulation and processes that are going to be used in the manufacturing of the product for stability / Beyond-use-Dating (BUD) or batch, a code number is requested via SOP IGN-003.

6.9.3.8 Upon creation of code number using the appropriate official list, the following activities are coordinated:

A. Pharmacist / R&D / QC Department generates specification for intermediates and bulk finished products, and STM (refer to SOP IQA-025 for details).

B. Pharmacist / Product Development prepares master batch records and master packaging records for stability batches, ensuring formula number is traceable. The sampling plan requirements are included as part of the master batch records and master packaging records where all instructions are clearly sequentially identified and step by step process is implemented and executed at all times (refer to SOP IGN-023 for details).

C. Pharmacist / R&D / QC / Microbiology Department coordinates method validation of analytical, microbial testing (i.e., Description, Assay, Sterility, Bacterial Endotoxins Test) only for stability products (refer to STMs IMV-I01 and IMV-I02 as well as SOP IQC-005).

6.9.3.9 Pharmacist / Production requests issuance of master batch record and executes batch using a cGMP qualified and validated facility and equipment. Samples of the intermediate and bulk finished products are submitted to Pharmacist / R&D / QC Department for testing. If during testing activities Pharmacist / R&D / QC Department finds that any test does not conform to established specifications, an investigation is performed. Upon testing completion, results and data generated are submitted to QA for final disposition.

SOP No.	Title	Revision No.
IGN-033	HANDLING OF 503B PRODUCTS	08

6.9.3.10 Pharmacist / Production submits executed batch record to QA Department for review and final disposition.

6.9.3.11 Pharmacist / Production requests conditional release of the Bulk Finished Product to QA before packaging operation in case final disposition has not been determined by QA at the time of performing the packaging operation.

6.9.3.12 Pharmacist / Production requests issuance of master packaging record, executes a batch using a cGMP qualified and validated facility and equipment, and submits executed packaging record to QA Department for final disposition.

6.9.4 Scale-up of Products:

6.9.4.1 Pharmacist with the help of Production coordinates the scale-up activities (when required) and prepares the commercial master batch record and the master packaging record (ensuring formula number is traceable with stability batch).

6.9.4.2 Pharmacist / R&D / QC Department coordinates method transfer of the analytical testing during the scale-up activities, if required (refer to SOP IQC-021).

6.9.4.3 The QA Department prepares cleaning validation protocol to be executed accordingly, if necessary (refer to SOP IVD-001 for details).

6.9.4.4 QA Department coordinates preparation of Stability Protocol for commercial batches (refer to SOP IQC-002 for details).

6.9.4.5 Labeling group or designee coordinates preparation of printed labeling material (i.e., product label) to be used in the commercial products (refer to SOP IRA-006 for details).

NOTE: Product checklist is prepared to plan and execute all activities related to the commercial launch.

6.9.5 Validation of Commercial Products:

6.9.5.1 Pharmacist / Production Department requests issuance of commercial master batch records, commercial master packaging records, and process validation protocols (refer to SOP IVD-002 for details).

6.9.5.2 Pharmacist / Production Department with the help of Pharmacist and QA Department executes data requested usually in the first batch using a cGMP qualified and validated facility and equipment.

6.9.6 Commercial Products:

6.9.6.1 Production Department executes validated product and processes based on production schedule using cGMP qualified and validated facility and equipment.

6.9.6.2 Product contact components (filters, tubing, aseptic connections, fill path) are sterilized by use of validated cycles.

A. In-house sterilization cycle validation is performed by use of Biological Indicators (BI) and calibrated thermocouples. The sterilization time of these validated cycles are increased for routine manufacturing overkill potential.

B. Product container / closure are pre-sterile and sealed components sterilized with validated cycles by the manufacturer.

6.9.6.3 The details (BPI receiving number, expiration date, etc.) of each component used in batch manufacturing are logged within Master Batch Manufacturing Record.

A. These details include the expiration date for depyrogenated glassware (vials, syringes, etc.) used in the manufacture of a batch.

6.9.6.4 Upon completion of the batch, the finished drug product will remain in quarantine until being released through inspection, testing, and release facilitated by QA.

A. Visual inspection is conducted by qualified individuals who undergo annual eye exams to ensure 20/20 vision (refer to SOP IPD-007).

6.9.6.5 QA Department reviews all data generated including Master Batch Manufacturing Record and analytical testing from the commercial batches and performs final disposition of each batch before distribution (refer to SOPs IQA-011 and IQA-021).

A. Complete records are maintained with Quality Assurance Control Unit's Document Control (refer to SOP IQA-002).

6.9.6.6 In the event of non-conformance or incidence, QA department is responsible for facilitating investigation of root cause and implementation of Corrective and Preventive Actions (CAPA) following guidelines of SOPs IGN-001, IQC-001, IMI-003, and IQA-024, among others.

6.10 Release Testing:

6.10.1 Specification for each finished 503B drug product is created as per SOP IQA-025 to ensure finished drug product quality.

6.10.2 Generally, product specific SPC tests include chemical, microbial, and physical tests listed in Table 5.

Table 5 - General Release Specification Testing for 503B Finished Drug Products

Test	Specification
Description	As per applicable SPC
Identification A (by HPLC)	As per applicable SPC
pH <USP 791>	As per applicable SPC
Container Content USP <697>	As per applicable SPC
Particulate Matter USP <1>	Foreign matter (Visible particulates): Free from foreign matter.
	Subvisible Particles USP <788> Particles ≥ 10µm: NMT 6000 per container Particles ≥ 25µm: NMT 600 per container
Assay	As per applicable SPC
Bacterial Endotoxins Test USP <85>	As per applicable SPC
Sterility Tests USP <71>	No evidence of microbial growth

6.10.3 Antimicrobial effectiveness test is only performed as necessary for 503B drug products labeled as multiple dose.

6.10.4 Product specification testing may be outsourced to contract laboratory, as needed as per IQC-004.

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6.10.5 Prior to product release, it is the responsibility of Pharmacist and QA department to review the executed batch records, microbial environmental monitoring results, and finished product testing results as per SOP IQA-021.

6.10.6 Specification test results are reviewed and finished 503B drug products are released as per SOP IQA-011.

6.11 Laboratory Controls:

6.11.1 Sampling of raw material and finished products is conducted by QA department.

6.11.2 Testing is conducted by QC and MI departments as per product / material specific validated standard test method (STM) and specification (SPC) criteria.

6.11.3 Clear and complete records of laboratory data is kept in laboratory notebook, analytical worksheet, reports, and logbooks for QC, R&D, and MI Departments.

6.11.4 United States Pharmacopoeia (USP) and European Pharmacopoeia (EP) standards are followed for the procedure of preparation, qualification, storage, handling, and use of laboratory analytical standards.

6.11.5 The procedure for approval of contract laboratories, receiving and shipping of samples, coordination of testing, receiving of results and submission of data to QA department is established by SOP IQC-004.

6.11.5.1 Contract laboratory is a BPI qualified and FDA approved independent company that has entered into a Quality Agreement with BPI to test pharmaceutical products such as raw material, in-process samples, and finished products.

A. Quality Agreements are established as per FDA Guidance Contract Manufacturing Agreements for Drugs: Quality Agreements and ISO 17025.

6.11.5.2 Pharmacist / QC department is responsible for reviewing the data for accuracy, completing analytical report and specification, and submitting analytical report to QA department.

6.11.5.3 QA department is responsible for final disposition of product based on the received results.

6.12 Stability / Expiration Dating for Compounded Drug Products:

6.12.1 The expiration date for all products, is established through the conduct of a stability program that includes testing to assess the product's performance against specifications after aging to the desired expiration date (§ 211.137); the conditions are outlined in ICH guidance for industry 4 Q1A(R2) Stability Testing of New Drug Substances and Products.

6.12.1.1 Beyond use Date (BUD), like expiration date, is the number of days or date at which a drug product is no longer acceptable for use. BUD is calculated from the date of manufacture (i.e., compounding date).

6.12.2 The expiration date is presented as month/date/year using the format MM/DD/YY (i.e., 08/20/19) or equivalent.

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6.12.3 A listing of established products and their corresponding expiration dating intervals is included in Finished Products Code Number List.

6.12.4 The expiration dating interval is established by obtaining stability data conducted by following an established stability protocol specific for the product (refer to SOP IQC-002 for additional details), as per SOP IQA-019 assignment of expiration dates are given, within requirements listed below.

6.12.4.1 At least 10 percent of the proposed maximum size commercial batch (i.e., pilot scale size) or at least commercial batch size.

6.12.4.2 Stability study condition and test intervals can be found in Table 6.

NOTE: As a general policy, Accelerated (AA) stability studies are only conducted for Stability batches. Long Term (CRT) stability studies are conducted for Stability and Commercial batches.

Table 6 - Temperature, Relative Humidity, Test Interval Conditions for Stability Studies

	Temperature	Relative Humidity	Test Intervals
Long Term (CRT)	25°C ± 2°C	60%RH ± 5%RH	2, 4, 6, 8 months
Accelerated (AA)	40°C ± 2°C	75%RH ± 5%RH	1, 2 months

6.12.4.3 Accelerated studies, combined with basic information of the components, drug products, and container / closure system, may be used to establish a tentative BUD interval provided shelf life studies are not available and are being conducted.

6.12.4.4 For product stored in accelerated conditions that yield acceptable stability results after 30 days (1 month), BUD / expiration dating interval of 240 days (8 months) from the manufacturing date of the batch can be assigned.

Example: If the batch was manufactured on 08/20/19 and stability data shows that the product is stable for 30 days in the accelerated conditions, a tentative BUD/expiration date of 04/15/20 can be assigned to the product, as follows.

Manufacturing Date (Compounding Date): 08/20/19

Beyond Use Date Interval: 240 days

Beyond Use Date (BUD): 08/20/19 + 240 days - 1 day = 04/15/20

NOTE: In case the BUD / expiration dating interval is assigned as 360 days, then the test intervals for the long term stability are adjusted accordingly, i.e., 3, 6, 9, and 12 months.

6.12.4.5 When a tentative expiration dating interval has been established using accelerated test data and the product has been marketed based on that interval, if the product stored at a controlled room temperature fails to conform to all acceptance criteria during stability testing, an investigation is conducted following SOP IGN-001.

6.12.4.6 All official data generated in the development phase is filed by Document Control.

NOTE: Preparation and approval activities of all formal documents are performed using Change Control System.

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6.12.4.7 All data generated from the validation including analytical testing are submitted to QA for final disposition and assignment of beyond use date (BUD) based on results of stability data.

6.13 Packaging and Labels:

6.13.1 All units should be packaged and labeled in accordance with SOPs IPK-001 and IPK-002 as well as Master Batch Packaging Record created in Quality System as per SOP IGN-023.

6.13.1.1 Product labels and Master Batch Packaging Record are controlled and released by QA department as per SOP IQA-006.

6.13.2 Labels must contain the following information:

6.13.2.1 The statement: "This is a compounded drug." Or a reasonable comparable alternative statement that prominently identifies the drug as a compounded drug.

6.13.2.2 Name, address, and phone number of the facility.

6.13.2.3 The statement: "Rx Only."

6.13.2.4 The following details of the drug:

A. Established name.
B. Quantity or volume, dosage form, and strength.
C. The date the drug was compounded.
D. Expiration or beyond use date.
E. Lot or Batch Number.
F. Storage and handling instructions.
G. National Drug Code Number (NDC No.) when available.
H. The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individually identified patient, the statement "Office Use Only".
I. A list of active and inactive ingredients identified by established name and the quantity or proportion of each ingredient.

6.13.2.5 FDA website and phone number: "www.fda.gov/medwatch" and "1-800-FDA-1088".

6.13.3 Labeling operation is performed in-house either manually or with use of automated labeler.

6.13.3.1 A specimen label is placed in the master labeling batch record for reference prior to Labeling operation.

6.13.3.2 Labels are placed on the units and labeled units are inspected throughout labeling process as per Master Batch Labeling Record.

6.13.3.3 Labeled units are placed in trays and trays are labeled with "STATUS" label.

NOTE: Serialization as per SOP IGN-036 is not applicable for 503B drug products.

6.13.4 Packaging operation is performed in-house or by an outside packaging contractor.

6.13.4.1 In-house, labeled units will be manually placed in carton holders, filled carton holders will be placed into cartons, and filled cartons will be manually placed into shipping boxes.

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6.13.4.2 This series of packaging containers as well as labeling equipment inspection ensures stability of containers, prevents mix-up, mechanical abrasion to product containers, and possible product contamination.

6.13.4.3 Unlabeled product or "brite stock" can be stored into inventory for future labeling and packaging (refer to SOP IPK-003 for details).

6.13.5 When labeling process is complete, a reconciliation of the used filled product, labeling materials, and labeling units is performed as per Master Batch Labeling Record.

6.13.5.1 Discrepancies during reconciliation are investigated as per SOP IGN-001.

6.13.5.2 Excess of labels with Lot and control numbers printed are destroyed.

6.14 Reserve Samples:

6.14.1 Retention samples will be taken for each batch of 503B product inline with guidelines included in SOP IQA-020.

6.14.2 As a general practice, the quantity of the retention sample is determined to cover no less than twice the quantity necessary for all analytical and microbial tests as per the applicable specification. The quantity of the retention sample for each product is listed in applicable EOL.

6.14.3 Reserve samples must be retained and stored under the labeled storage conditions and in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics (e.g., same material, same headspace for liquids).

6.14.4 Reserve samples must be held for no less than 30 days following the established expiration date.

6.14.5 Reserve samples are collected from the beginning, middle, and end of a packaging run.

6.14.6 Generally, QA department pulls retention samples of packaged product according SOP IQA-020.

6.15 Product Complaint Handling:

6.15.1 The procedure to handle (receipt, logging, investigation, monitoring, trending, and resolution) written and oral product complaints received by the company concerning any of the distributed drug products is established as per SOP IQA-009.

6.15.2 All complaints received are logged into "Complaints" logbook and assigned a complaint number.

6.15.3 Depending on the nature of the complaint, QA or designee may request concerned department for investigation, along with complaint sample if available.

6.15.4 QA or designee will investigate through review of batch record, packaging record, and analytical data looking for deviations, issues, or nonconformance to evaluate the impact and cause of the complaint.

6.15.5 QA or designee will arrange for appropriate physical, chemical, and/or microbial testing of complaint sample.

6.15.6 Once the results are reviewed, an Investigation report is prepared indicating the detailed investigation, most probable root cause, corrective and preventive actions, and conclusions. Corrective and preventive actions are addressed as per applicable SOP.

6.16 Adverse Event Handling:

6.16.1 The procedure for the surveillance, receipt, evaluation, and reporting of Adverse Drug Experiences (ADEs) associated with human and veterinary drug products manufactured at BPI Labs must follow the FDA guideline "Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act".

6.16.2 It is the responsibility of Regulatory Affairs personnel to assure all ADEs (i.e., all serious and unexpected adverse drug experiences) are properly documented, investigated by appropriate personnel, and reported to the FDA (i.e., 15-day Alert Report) as per SOP IRA-001.

6.16.3 Regulation requires reporting of each ADE as soon as possible, but in no case later than 15 calendar days from initial receipt.

6.16.4 All reported ADE must be promptly investigated and a follow-up report must be submitted within 15 calendar days of receipt of new information or as requested by the FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information.

6.16.5 Reports to the FDA concerning ADE must include pertinent identifying details:

6.16.5.1 An identifiable patient.

A. Information on the names and addresses of patients should not be included. A unique code should be assigned for each individual patient.

6.16.5.2 An identifiable reporter.

A. Defined as a patient, consumer, family member, doctor, pharmacist, other health care professional or related individual.
B. A reporter can be identified by one or more of the following: personal identifier (e.g., name), professional identifier (e.g., doctor, nurse, pharmacist), contact information (e.g., e-mail address, phone number).

6.16.5.3 A suspect drug product.

A. Defined as a product suspected as associated with the adverse event.
B. In the case that an adverse event involves multiple suspect drug products compounded by the same facility, the facility should only submit one report with all drug products listed.

6.16.5.4 A serious adverse event.

A. Defined as a patient outcome involving death, life-threatening ADE, inpatient hospitalization, disability or incapacity, or a congenital anomaly or birth defect.

6.16.6 Reports must be submitted with current labeling of drug product, hospital summaries, autopsy/death certificate, relevant laboratory data, and clinical data.

6.16.7 Reports can be submitted through the Safety Reporting Portal (SRP) or the Electronic Submissions Gateway (ESG).

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6.16.8 Before submitting electronically for the first time, facilities should notify the FDA Adverse Event Reporting System (FAERS) Electronic Submission Coordinator to assist the facility in its submission.

6.16.9 Regulations require firms to maintain records relating to all ADEs (including raw data and any correspondence relating to the adverse drug experiences) for no less than 10 years and to permit any authorized FDA employee, at all reasonable times, to have access to and copy and verify the records established and maintained under 21 CFR Part 310.305.

6.17 Regulatory Requirements:

6.17.1 Registration with FDA:

6.17.1.1 Refer to the FDA Guidance "Registration of Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act" for all suggestions regarding electronic 503B registration with the FDA.

6.17.1.2 Outsourcing facilities must register initially and each year thereafter during the registration period between October 1st and December 31st.

6.17.1.3 To register as an outsourcing facility, a compounder must provide the following information:

A. Name
B. Place of business.
C. Unique facility identifier.
D. Point of contact email address.
E. Indication whether the facility intends to compound products on FDA's drug shortage list.
F. Indication whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile or nonsterile drugs from bulk drug substances.

6.17.1.4 Facilities intending to register as outsourcing facilities should submit registration using existing Structured Product Labeling (SPL) format.

A. Refer to Section IV of FDA Guidance "Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing" for complete details for SPL submission.

6.17.1.5 FDA is required to publish a list of registered outsourcing facilities and the facilities' status, as well as, update the list weekly.

6.17.2 Registration with Florida Department of Health Board of Pharmacy:

6.17.2.1 Refer to Rule 64B16-28.100 "Special Sterile Compounding Permit Application and Information" for a complete guidance on application and permitting requirements for special compounding facilities established by Florida Department of Health under Florida Statute Chapter 465.

6.17.2.2 Permits are only valid for the name and physical location to which it is issued. Any changes to facility name or location must be requested through Florida Department of Health Board of Pharmacy.

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6.17.2.3 An initial onsite inspection is required for issuance of a new permit. The board inspector will document the facility's compliance with all applicable rules and statues.

6.17.2.4 Outsourcing facilities engaged in sterile compounding must obtain and maintain a Special Sterile Compounding Permit by filing an application with form DH-MQA 1270 "Special Sterile Compounding Permit Application and Information".

6.17.2.5 Applicants for a Special Sterile Compounding Permit must comply with all permitting requirements in subsection (1) of Rule 64B16-28.100 and designate a prescription department manager or consultant pharmacist on record.

6.17.2.6 Florida Department of Health reserves the right to inspect outsourcing facilities at any time after the initial inspection.

6.17.3 Reporting to FDA:

6.17.3.1 Outsourcing facilities must submit a product report upon initial registration and twice each year thereafter, once in June and once in December, for products produced during the previous six-month period.

A. Drug product reports submitted between June 1 and June 30 of each year must report products produced from December 1 through May 31.

B. Drug product reports submitted between December 1 and December 30 of each year must report products produced from June 1 through November 30.

6.17.3.2 Each semiannual report must identify all sterile and non-sterile drugs compounded at the outsourcing facility during the previous six-month period and provide the following information for each compounded drug:

A. The active ingredient and strength of active ingredient per unit.
B. The source of the active ingredient.
C. The 10-digit National Drug Code (NDC) number of the source drug or bulk active ingredient, if available.
D. The dosage form and route of administration.
E. The package description.
F. The number of individual units produced.
G. The 10-digit NDC number of the final product, if assigned.

6.17.3.3 Outsourcing facilities must submit drug product reporting electronically in SPL format. Refer to FDA guidance "Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food Drug and Cosmetic Act" for more information about drug product reporting.

SOP No.	Title	Revision No.
IGN-033	HANDLING OF 503B PRODUCTS	08

7.0 REVISION HISTORY

Revision No.	Effective Date	Description of Changes
01	AUG 29 2019	Original SOP
02	OCT 02 2019	Section 4.39 SOP No. IPT-006 503B Research and Development Experimental Trial Batches updated to new SOP No. IPH-001 503B Research and Development Experimental Trial Batches. Section 6.9.3.2 SOP No. IPT-006 503B Research and Development Experimental Trial Batches updated to new SOP No. IPH-001 503B Research and Development Experimental Trial Batches. Sections 6.4.4, 6.4.5, and 6.5.3 Removed from SOP, redundancy
03	NOV 27 2019	Section 6.12 Table 6 to Include 9 Month Long Term Testing Interval, and 2 Month Accelerated Testing Interval. Section 6.12.4.4 to change expiration dating to 240 days (8 months), and tentative BUD date to 04/15/20.
04	MAY 12 2020	A note added under Section 6.12.4.2. Section 6.12 Table 6 to replace 9 Month Long Term Testing Interval with 8 Month Long Term Testing Interval.
05	JAN 22 2021	Added References SOPs GN-040 "Handling of 503 Products" and IQA-012 "Retesting of Materials and Products" Minor editorial changes to Purpose, Scope, and Sections 6.1.4, 6.9.2.3, and 6.15.2
06	APR 28 2021	Added References SOP IPH-002 BPI Policy for Essentially Copies of Approved Drug Products. Section 6.9.3.2 changed to discuss use of new SOP IPH-002. Section numbering is modified to reflect this change.
07	MAY 06 2021	1. Add 21 CFR Part 310 – New Drugs, Subpart D – Records and Reports, Section 310.305 in the Reference section. 2. Section 6.8.2 updated to reflect FDA establishment registration for APIs. 3. Revise SOP Section 6.16 to clarify the reporting and handling of ADEs according to 21 CFR Part 310.305.
08	AUG 3 1 2021	Clarify Section 6.12.4.4 in regards to BUD calculation and stability test intervals for long term in case of 360 days BUD interval.

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	Category: BPI SOP Title: IGN-033 Handling of 503B Products		
Version 01	**State** Effective	**Effective Date** 29-MAR-2023	**Document ID** 834697

REVISION HISTORY

Version 01 Effective on 29-Mar-2023
Initial Migration

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

ZenQMS System — This document was an already EFFECTIVE document that was migrated from legacy systems on this date.
Signed 10:52:44 PM UTC 03-Apr-2023

SOP No.	Title	Revision No.
IGN-028	CLEANING OF PROCESSING AND NON-PROCESSING ROOMS	08

Prepared By / Date	Reviewed By / Date	QA Approved By / Date	Effective Date
PMK 01/20/23	01/23/23	M. Salazar 01/23/23	JAN 27 2023
Title: Manager.	Title: COO	Title: CQCO	Change Control No. I-23027

1.0 PURPOSE

The purpose of this SOP is to describe procedures for cleaning of the manufacturing processing and non-processing rooms, including cleanroom support areas, laboratories, warehouse, and utility areas.

2.0 SCOPE

This procedure is applicable for the cleaning of processing areas (such as samples, formulations, and filling), non-processing areas (such as utility areas, non-cleanroom corridors, laboratories, warehouse, and change rooms), and cleanroom support areas (such as cleanroom corridors, clean equipment room, and cleaning supplies room) located in BPI Labs.

3.0 RESPONSIBILITY

It is the responsibility of the Production Cleaner to follow this procedure and it is the responsibility of the Production / Laboratory Manager or designee to implement and monitor the procedure.

4.0 REFERENCES

4.1 21 CFR Part 211.42 Design and Construction Features

4.2 21 CFR Part 211.56 Sanitation

4.3 USP <1072> Disinfectants and Antiseptics

4.4 USFDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice

4.5 PDA Technical Report 70 Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities

4.6 SOP IGN-027 Preparation of Cleaning Agents, Detergents, and Disinfectants Used in Manufacturing

4.7 EOL I-003 Miscellaneous List

5.0 ATTACHMENTS

Not Applicable.

6.0 PROCEDURE

6.1 General Requirement:

6.1.1 When performing cleaning, ensure hazardous energy sources are tagged and locked out.

6.1.2 Review the applicable SDS for handling, instructions, personal protective equipment requirements, and disposal instructions for any chemicals and materials involved in this process.

6.1.3 Use gloves, masks, and safety goggles / face shields while cleaning.

NOTE: After shut-down activities, all rooms must be cleaned as per procedure mentioned in Weekly Cleaning (steps 6.3.9) before being utilized.

6.1.4 All areas under the scope of this SOP are listed in Table 1 below.

Table 1: Processing, Non-Processing, and Cleanroom Support Areas

Processing Areas	Non-Processing Areas
Filling Rooms (Rooms 312 and 317)	Non-Cleanroom Corridors (Corridors 201, 207, and 409)
Formulation Rooms (Rooms 311 and 316)	Change Rooms / Lockers (Rooms 202 and 203)
Autoclave Load (Room 313)	Quality Control Laboratory (Rooms 103, 104, and 107)
Autoclave Unload (Room 319)	Microbiology Laboratory (Room 205)
Tank WIP Room (Room 315)	MLT Laboratory (Room 211)
Samples Rooms (Rooms 308 and 308A)	Warehouse (Shipping and Receiving) (Rooms 408 and 411)
Sterility Isolator Room (Room 210)	Utility Area / Boiler Room (Rooms 403 and 404)
Cleanroom Support Areas	Tech Space (Room 208)
Cleanroom Corridors (Corridors 310 and 301)	Vestibule (Room 101)
Personnel Gowning Airlock (Room 304)	Restrooms (Rooms 105 and 106)
Personnel De-Gowning Airlock (Room 303)	Inspection and Packaging Rooms (Rooms 405 and 407)
Material Airlocks (Rooms 305, 306, and 309)	Labeling and Packaging Room (Room 412)
Clean Equipment Room (Room 318)	
Component Preparation Room (Room 314)	
Cleaning Supplies Room (Room 302)	
Anteroom (Room 204)	
Airlocks (Rooms 307 and 209)	

6.1.5 Types of Areas:

6.1.5.1 Processing Areas include rooms in cleanroom area that may be used for Production.

6.1.5.2 Cleanroom Support Areas include rooms and corridors that are within cleanroom area but where a Production process would not occur.

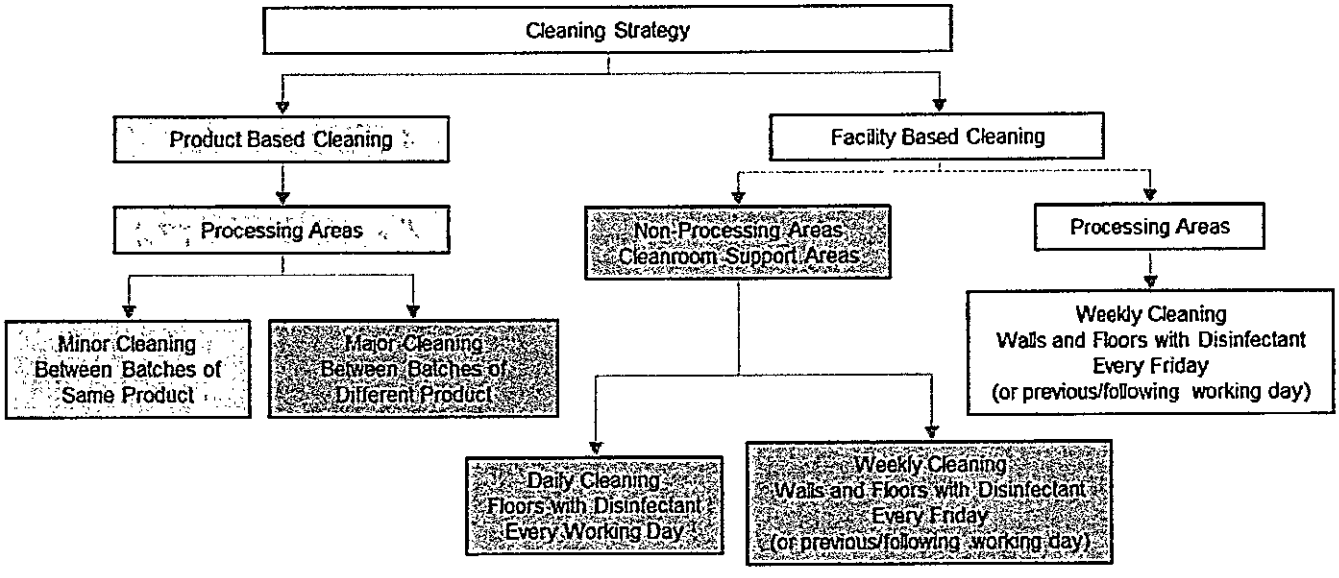
6.1.5.3 Non-Processing Areas are rooms and corridors outside the cleanroom area, and where open product would not be exposed.

A. Inspection and Packaging Rooms and Labeling and Packaging Room are areas outside the cleanroom where Finished Product is processed, but always in a sterile, sealed state. As there is no open product, routine Facility Based Cleaning is

performed as per Table 4 and Product Based Cleaning is performed as per Step 6.2.5.

6.1.6 BPI's cleaning strategy is designed considering cross contamination and microbial bioburden. Product Based Cleaning revolves around manufacturing areas and reducing the risk of contamination of the product. Facility Based Cleaning involves areas of all classifications and ensuring there is no introduction of microbial contaminants from lower to higher classified areas. See Figure 1 below.

Figure 1: Cleaning Strategy Flow



6.1.7 Cleaning Strategy:

6.1.7.1 Mops and cleaning supplies used in Non-Processing Areas will NOT be used in Processing Areas or Cleanroom Support Areas, however the same mops and cleaning supplies can be used between Processing Areas and Cleanroom Support Areas. Ensure mops and cleaning supplies are labeled accordingly.

6.1.7.2 Ensure the correct cleaning supplies are used for their respective area by reviewing the labels before the start of cleaning.

6.1.7.3 Production Cleaner should refer to the cleaning schedule posted in accessible areas for use of the appropriate disinfectant as per rotation.

6.1.7.4 To ensure water ports and transfer equipment are not incidentally contaminated, care should be taken when collecting WFI or Purified Water for cleaning.

A. If a hose or pipe is needed to transfer water, ensure it is securely connected to the water port without leaks. Do not touch the water port directly with bare hands as this may contaminate the water port.
B. Before collecting or using water for cleaning, direct the hose to a drain and flush for NLT 1 minute.
C. Collect water or use for cleaning, then close the water port valve tightly to avoid leaks.

D. Remove the water hose and place it in a designated area to air dry. Ensure the hose is placed in a position that will drain any residual water.

6.1.7.5 Prepare disinfectants as per SOP IGN-027. Document the amount of disinfectant used in the appropriate Preparation of Disinfectant Dilutions Logbook.

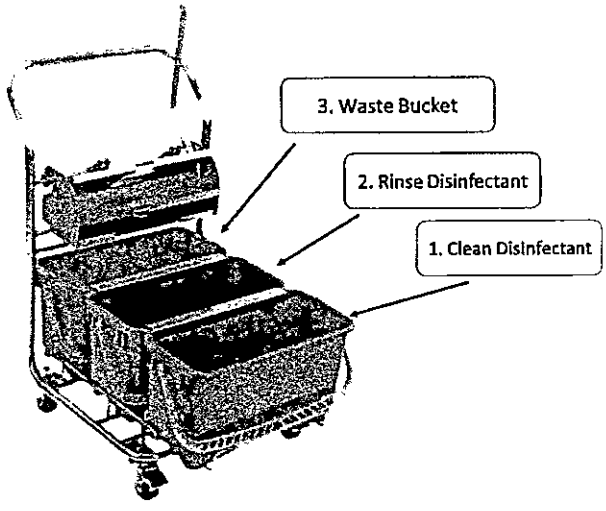
6.1.7.6 Production Cleaner should refer to the approved Facility Based Cleaning Flows for Cleanrooms as a guide to which rooms should be cleaned for Daily and Weekly cleaning, as well as provide direction where cleaning should begin and end.

NOTE: Cleaning Flows are only a recommendation. When a specific room cannot be cleaned per the approved flow, due to unavoidable circumstances, cleaning can proceed in the following available room, as needed.

6.1.7.7 The "Three Bucket System" works as follows: first bucket contains a clean disinfectant (or WFI/PW as applicable), second bucket contains a rinse disinfectant and is used to rinse the cleaning agent (or WFI/PW as applicable) from dirty mop, and third bucket is a waste bucket used to wring the mop. See Figure 2.

6.1.7.8 The flow for the "Three Bucket System" is as follows: dip mop into clean disinfectant, then wring mop into waste bucket to remove excess liquid and begin mopping. After mopping, insert mop into rinse bucket to remove dirty liquid, then wring mop to remove excess liquid. Repeat process until cleaning is finished.

Figure 2: Three Bucket System



6.1.7.9 Cleaning should be performed from the highest surface point to the lowest surface point (i.e., walls, equipment, and then floors, in sequential order), as well as, from the furthest surface point to the closest surface point (i.e., farthest corner of the room towards the exit that will be used to leave the room).

6.1.7.10 Cleaning should be performed uniformly in single overlapping strokes, ensuring all areas are reached by the mop without going over a single area multiple times.

6.2 Product Based Cleaning:

6.2.1 Product Based Cleaning is applicable to Process Equipment and Processing Rooms to avoid cross contamination majorly. It is separated as Minor Cleaning and Major Cleaning, and they are performed between batches.

NOTE: Whenever cleaning a processing room along with multiple equipment located in the same room, open each related logbook (i.e., equipment and room) and document the type of cleaning (i.e., major cleaning / minor cleaning) under the "Description" column. Whenever the cleaning of each specific equipment is initiated, log such information in the respective logbook using only the "Start Date" and "Start Time" columns. Additionally, whenever the cleaning of each equipment is completed, document such information in the respective logbook using only the "Finish Date" and "Finish Time". Finally, the room should be cleaned last and the corresponding entries in the logbook related to the initiation and completion of the cleaning process need to be documented accordingly whenever the operation is started and completed. In case of cleanroom supporting areas, enter cleaning details in one single logbook.

6.2.2 Before starting minor or major cleaning, put a check mark against the appropriate box on status label of the room, as applicable.

6.2.3 Minor Cleaning:

6.2.3.1 Minor cleaning is performed between batches of the same product type.

6.2.3.2 Ensure all evidence of the previous batch, including the batch record, all containers produced, and all raw materials, is cleared from the room. Ensure debris is removed off floor, and trash is removed from room.

6.2.3.3 Equipment should be cleaned per respective equipment cleaning SOP.

6.2.3.4 Using sterile 70% IPA, wipe down scales, tables, carts, windows, and doors.

6.2.3.5 Mop the floors using a mop wetted in WFI/PW following the "Three Bucket System" method and allow to dry.

6.2.3.6 After cleaning, sign the Cleaning, Use, and Maintenance Logbook for minor cleaning. Call the supervisor or designee to verify the cleaning.

6.2.3.7 Place a "CLEAN" label on the door with cleaning details.

6.2.3.8 Discard leftover cleaning agents through the drains in the Component Preparation Room, or designated areas. Clean buckets thoroughly with Purified Water after use.

6.2.4 Major Cleaning:

6.2.4.1 Major cleaning is performed between batches of different product type.

6.2.4.2 Ensure all evidence of the previous batch, including the batch record, all containers produced, and all raw materials, is cleared from the room. Ensure debris is removed off floor and trash is removed from room.

6.2.4.3 Cover room temperature / relative humidity monitoring probe in polyethylene bag to avoid water spill and physical damage to probe.

6.2.4.4 Equipment should be cleaned per respective equipment cleaning SOP.

NOTE: Never spray WFI/PW directly on opening of exhaust duct, inlet supply grills, electrical fixtures, and light fixtures.

6.2.4.5 Clean ceilings using a mop wetted in WFI/PW following the "Three Bucket System" method.

6.2.4.6 Clean walls and floors, using a mop wetted in WFI/PW following the "Three Bucket System" method and allow to dry.

6.2.4.7 Using sterile 70% IPA, wipe down scales, tables, carts, windows, and doors.

NOTE: While performing the cleaning of the processing rooms, ensure the personnel and material flow are done in a way that avoids any cross contamination (i.e., do not enter the cleaned rooms while cleaning an un-cleaned room).

6.2.4.8 After cleaning, sign the Cleaning, Use, and Maintenance Logbook for major cleaning and call the Supervisor or designee to verify the cleaning.

6.2.4.9 Place a "CLEAN" label on the door with cleaning details.

6.2.4.10 Discard leftover cleaning agents through the drains in the Component Preparation Room. Or designated areas. Clean buckets thoroughly with Purified Water after use.

6.2.5 Product Based cleaning for **Inspection and Packaging Rooms and Labeling and Packaging Room are** different as they are outside the cleanroom area but there is not open product exposed:

6.2.5.1 Minor cleaning is performed between batches of the same product type as below:

A. Ensure all evidence of the previous batch, including the batch record, all containers produced, and all raw materials, is cleared from the room. Ensure debris is removed off floor and trash is removed from room.

B. Equipment should be cleaned per respective equipment cleaning SOP.

C. Using sterile 70% IPA, wipe down scales, tables, carts, windows, and doors. If any debris or spills are present, mop floor using a mop wetted in WFI/PW.

D. After cleaning, sign the Cleaning, Use, and Maintenance Logbook for minor cleaning. Call the supervisor or designee to verify the cleaning.

E. Place a "CLEAN" label on the door with cleaning details.

F. Discard leftover cleaning agents through the drains in the Utilities Area, or designated areas. Clean buckets thoroughly with Purified Water after use.

6.2.5.2 Major cleaning is performed between batches of different product as below:

A. Ensure all evidence of the previous batch, including the batch record, all containers produced, and all raw materials, is cleared from the room. Ensure debris is removed off floor and trash is removed from room.

B. Equipment should be cleaned per respective equipment cleaning SOP.

SOP No.	Title	Revision No.
IGN-028	CLEANING OF PROCESSING AND NON-PROCESSING ROOMS	08

C. Using sterile 70% IPA, wipe down scales, tables, carts, windows, and doors.
D. Clean floors, using a mop wetted in WFI/PW and allow to dry.
E. After cleaning, sign the Cleaning, Use, and Maintenance Logbook for major cleaning. Call the supervisor or designee to verify the cleaning.
F. Place a "CLEAN" label on the door with cleaning details.
G. Discard leftover cleaning agents through the drains in the Utilities Area, or designated areas. Clean buckets thoroughly with Purified Water after use.

6.3 Facility Based Cleaning:

6.3.1 Facility Based Cleaning is applicable to Processing Areas only when production is inactive. If Production is active, cleaning may be performed in rooms that are not in use and areas that are in use must been cleaned whenever the activity is done. When production is active, refer to Product Based Cleaning as per section 6.2.

NOTE: Production cleaner should not enter a room with cleaning utensils where production process is occurring.

6.3.2 The different types of cleanings are detailed in Table 2. Types of Cleanings are defined by the frequency of the specific procedure required.

Table 2: Types of Cleanings

Type of Cleaning	Identification	Main Surfaces	When Required
Daily	D	Floors	Every scheduled working day with Decon-Phene or Decon-Quat
Weekly	W	Ceilings, Walls, and Floors	Every Friday, or next working day if it is a holiday/not scheduled with Decon-Phene, Decon-Quat, or Decon-Spore

NOTE: Cleaning types should not overlap (i,e. Daily cleaning and Weekly cleaning should not be performed on the same day).

6.3.3 Daily Cleaning is performed only in Non-Processing Areas and Cleanroom Support Areas (Refer to Table 1) using a disinfectant. Daily Cleaning is not performed in Processing Areas.

6.3.4 Weekly cleaning is performed in Processing Areas, Non-Processing Areas, and Cleanroom Support Areas, using disinfectants and sporicidal agents to reduce microbial bioburden majorly.

6.3.5 Weekly Cleaning supersedes Product Based Major cleaning and can be documented as equals when releasing a room for production.

6.3.6 Disinfectant Type use is determined by the disinfectant rotation as per SOP IGN-027 and approved rotation schedule posted in accessible areas. Table 3 shows an example of four-week period of Disinfectant Rotation.

Table 3: Example of Disinfectant Rotation

M	T	W	T	F
Decon-Phene Daily Cleaning	Decon-Phene Daily Cleaning	Decon-Phene Daily Cleaning	Decon-Phene Daily Cleaning	Decon-Phene Weekly Cleaning
M	T	W	T	F
Decon-Phene Daily Cleaning	Decon-Phene Daily Cleaning	Decon-Phene Daily Cleaning	Decon-Phene Daily Cleaning	Decon-Spore Weekly Cleaning
M	T	W	T	F
Decon-Quat Daily Cleaning	Decon-Quat Daily Cleaning	Decon-Quat Daily Cleaning	Decon-Quat Daily Cleaning	Decon-Quat Weekly Cleaning

SOP No.	Title	Revision No.
IGN-028	CLEANING OF PROCESSING AND NON-PROCESSING ROOMS	08

M	T	W	T	F
Decon-Quat Daily Cleaning	Decon-Quat Daily Cleaning	Decon-Quat Daily Cleaning	Decon-Quat Daily Cleaning	Decon-Spore Weekly Cleaning

6.3.7 Non-Processing Areas, Cleanroom Support Areas, and Processing Areas are cleaned as per the schedule in Table 4.

Table 4: Non-Processing Areas, Cleanroom Support Areas, and Processing Areas Routine Schedule

Cleaning Agents	Sterile 70% IPA	Decon-Phene or Decon-Quat	Decon-Spore	WFI
Surfaces	**Windows, Handles, Doors**	**Floors**		**Ceilings**
Non-Processing Areas				
Non-Cleanroom Corridors	D, W	D, W	W	N/A
Change Rooms / Lockers	D, W	D, W	W	N/A
Microbiology Laboratory	D, W	D, W	W	N/A
MLT Laboratory	D, W	D, W	W	N/A
Quality Control Laboratory	D, W	D, W	W	N/A
Vestibule	D, W	D, W	W	N/A
Restrooms	D, W	D, W	W	N/A
R & D Laboratory	W	W	W	N/A
Warehouses (Shipping and Receiving)	W	W	W	N/A
Inspection and Packaging	W	W	W	N/A
Labeling and Packaging	W	W	W	N/A
Tech Space	N/A	W	W	N/A
Utility Area / Boiler Room	N/A	W	W	N/A
Surfaces	**Windows, Handles, Doors**	**Walls and Floors**		**Ceilings**
Cleanroom Support Areas				
Cleanroom Corridors	D, W	D, W	W	W
Personnel Gowning and De-Gowning Rooms	D, W	D, W	W	W
Material Airlocks	D, W	D, W	W	W
Component Preparation Room	D, W	D, W	W	W
Clean Equipment Room	D, W	D, W	W	W
Cleaning Supplies Room	D, W	D, W	W	W
Processing Areas				
Filling Rooms	W	W	W	W
Formulation Rooms	W	W	W	W
Autoclave Load	W	W	W	W
Autoclave Unload	W	W	W	W
Samples Rooms	W	W	W	W
Sterility Room	W	W	W	W
Tank WIP Room	W	W	W	W

NOTE: Certain rooms may have different cleaning frequencies than what is stated in Steps 6.3.8 and 6.3.9. Always follow what is specified in Table 4 as a default.

6.3.8 Daily Cleaning:

6.3.8.1 Daily cleaning is performed every scheduled working day in Non-Processing Areas and Cleanroom Support Areas, with exceptions, as listed in Table 4.

6.3.8.2 Prior to cleaning, sweep away dust and debris, and dust-off surfaces as needed.

6.3.8.3 Prepare appropriate cleaning solution and document the amount of disinfectant used in the Preparation of Disinfectant Dilutions Logbook.

NOTE: Cleanroom Cleaning should begin in the highest classified areas (i.e., filling rooms, formulations room) and should end in the least classified areas (i.e., corridor 301, anteroom), as possible. However, ensure personnel and material flow are in a way that avoids cross contamination (i.e., do not enter cleaned rooms from an un-cleaned room). Refer to approved Facility Based Cleaning Flows for Cleanrooms.

6.3.8.4 Using sterile 70% IPA, wipe down windows, handles, and doors. Also wipe any chairs, tables, phones, racks, carts, etc., when applicable.

6.3.8.5 Mop the floors using a mop wetted in disinfectant solution (refer to EOL I-003 Miscellaneous List and refer to SOP IGN-027 for preparation of disinfectant solution), following the "Three Bucket System" method, or other bucket system when applicable, and allow a minimum contact time of 10 minutes. Once contact time has been allowed, confirm the action within the Cleaning, Use, and Maintenance Logbook.

6.3.8.6 Mop the floors using a mop wetted in WFI following the "Three Bucket System" method, or other bucket system when applicable, to remove disinfectant residues and allow to dry.

6.3.8.7 After cleaning, sign the Cleaning, Use, and Maintenance Logbook for daily cleaning and call the Supervisor or designee to verify the cleaning.

6.3.8.8 Discard leftover cleaning agents through the drains in the Component Preparation Room, or designated areas. Clean buckets thoroughly with Purified Water after use.

6.3.9 Weekly Cleaning:

6.3.9.1 Weekly cleaning is performed every Friday (or previous/next working day, as necessary) in Non-Processing Areas, Cleanroom Support Areas and Processing Areas, with exceptions, as listed in Table 4 (if Friday is in production, clean upon completion or next working day). In addition to the daily cleaning procedure performed as per section 6.3.8, ceilings and walls are included as part of weekly cleaning.

NOTE: If management is aware the Weekly cleaning cannot be completed for all rooms on Friday, cleaning may be performed Thursday and Friday. If cleaning is started on Friday but cannot be completed, cleaning may be continued on Monday followed by routine schedule starting on Tuesday or the next working day, as required.

6.3.9.2 Prior to cleaning, sweep away dust and debris, and dust-off surfaces as needed.

6.3.9.3 Prepare appropriate cleaning solution and document the amount of disinfectant used in the Preparation of Disinfectant Dilutions Logbook.

NOTE: Cleanroom Cleaning should begin in the highest classified areas (i.e., filling rooms, formulations room) and should end in the least classified areas (i.e., corridor 301, anteroom), as possible. However, ensure personnel and material flow are in a way that avoids cross contamination (i.e., do not enter cleaned rooms from an un-cleaned room). Refer to approved Facility Based Cleaning Flows for Cleanrooms.

6.3.9.4 Clean ceilings using a mop wetted in WFI following the "Three Bucket System" method.

6.3.9.5 Clean the walls using a mop wetted in disinfectant solution (refer to EOL I-003 Miscellaneous List and refer to SOP IGN-027 for preparation of disinfectant solution), following the "Three Bucket System" method, or other bucket system when applicable, and allow a minimum contact time of 10 minutes.

6.3.9.6 Mop walls using a mop wetted in WFI following the "Three Bucket System" method, or other bucket system when applicable, to remove disinfectant residues and allow to dry.

6.3.9.7 Using sterile 70% IPA, wipe down windows, handles, and doors. Also wipe any chairs, tables, phones, racks, carts, etc., when applicable.

6.3.9.8 Mop the floors using a mop wetted in disinfectant solution (refer to EOL I-003 Miscellaneous List and refer to SOP IGN-027 for preparation of disinfectant solution), following the "Three Bucket System" method, or other bucket system when applicable, and allow a minimum contact time of 10 minutes. Once contact time has been allowed, confirm the action within the Cleaning, Use, and Maintenance Logbook.

6.3.9.9 If any Pass box present in room, clean as per section 6.5.

6.3.9.10 Mop the floors using a mop wetted in WFI following the "Three Bucket System" method, or other bucket system when applicable, to remove disinfectant residues and allow to dry.

6.3.9.11 After cleaning, sign the Cleaning, Use, and Maintenance Logbook for weekly cleaning and call the Supervisor or designee to verify the cleaning.

6.3.9.12 Place "CLEAN" label on the door if cleaning in a Processing Area. Do not place labels in Non-Processing Areas and Cleanroom Support Areas.

NOTE: Label Inspection and Packaging Room and Labeling & Packaging Room after all cleanings.

6.3.9.13 Discard leftover cleaning agents through the drains in the Component Preparation Room. Clean buckets thoroughly with Purified Water after use.

6.4 Return all cleaning products, mops, and pails to the cleaning supplies area after cleaning and sanitizing.

6.4.1 Clean buckets and pails thoroughly inside and out until no visible residue is observed, using Purified Water in the Component Preparation Room, or designated areas. Invert items to allow removal of excess water and wipe with a lint free cloth.

6.4.2 Mop heads should be discarded daily. Discard and replace mop head if it becomes visibly dirty at any point.

6.4.3 Wipe "Three Bucket System" cart with sterile 70% IPA prior to replacing buckets on it.

6.5 Cleaning of Production Passbox:

6.5.1 If any room within Production contains a Pass box for material transfer between two classified rooms or between a classified room and an unclassified room, cleaning for this Pass box is required to be performed on a Weekly Basis.

6.5.1.1 Prior to cleaning, dust-off surfaces as needed.

6.5.1.2 Wipe down interior and exterior surfaces from top to bottom using sterile 70% IPA and a lint free cloth.

7.0 REVISION HISTORY

Revision No.	Effective Date	Description of Changes
01	AUG 29 2018	Original SOP
02	FEB 12 2019	1. Include Room numbers in Table 1 for further description 2. Remove 6.1.8 and 6.1.9 as 6.1.10 covers the same information to advise user that different areas have different supplies that should not be mixed and should be labeled appropriately to prevent that 3. Edit sections 6.2.3.7, 6.2.4.10, 6.3.6.7, and 6.3.7.10 to update the location of where buckets are cleaned as utensils for processing areas should not be taken to non-processing areas. 4. Include disinfectant types in Table 2 5. Edit Tables 3 and 4 for clarification that walls and floors use disinfectant and processing areas should include windows, handles, and doors 6. Note included under section 6.3.7 to address the procedure if weekly cleaning cannot be completed solely on Friday 7. Update section 6.4.1 and 6.4.3 to include the cleaning of buckets in wash room as utensils for processing areas should not be taken to non-processing areas and wipe Three Bucket system cart with 70% IPA 8. Rearrange steps 6.2.4.3 and 6.3.7.3 so that ceilings and walls are cleaned prior to wiping windows with IPA as water streaks from walls may fall on the windows 9. Include section 6.1.10 and 6.1.11 to mention cleaning schedule that will be posted and documenting disinfectant dilution in appropriate logbook. 10. Include wiping of carts, rack, phones, and other items inside rooms, when applicable in sections 6.3.6.3 and 6.3.7.6.
03	SEP 23 2019	1. Table 1 updated to ensure all missing rooms are included. 2. Clarify types of areas in step 6.1.5. 3. Figure 1 updated to better explain room cleaning flow. 4. Step 6.1.7 included for general cleaning strategies. 5. Include Step 6.2.5 to detail cleaning for Visual Inspection and Labeling/Packaging Room as they are outside cleanroom but still used for process. 6. Clarify step 6.3.1 to clarify cleaning may be performed in unused rooms when production is active. 7. Include Step 6.3.5 to specify the Weekly Cleaning supersedes Major cleaning. 8. Table 2 was updated to remove Bi-weekly cleaning as a type of cleaning since it is the same as Weekly procedure wise. Disinfectant rotation is the only difference which is explained in step 6.3.2. Bi-weekly cleaning removed from entire SOP. 9. Note under Table 2 added to clarify that Daily cleaning and Weekly cleaning procedures should not occur on the same day. 10. Table 3 was added to show example of disinfectant rotation. 11. Table 4 updated to include missing rooms and update cleaning frequencies for all rooms. Previous table 3 and 4 were combined to form Table 4.
04	DEC 02 2020	1. Include instruction in steps 6.3.8.5 and 6.3.9.5 about confirming contact time in Cleaning, Use, and Maintenance Logbook.
05	MAR 09 2021	1. Include Step 6.1.7.5 and Note under it to include use of Facility Based Cleaning Flows for Cleanrooms. 2. Revise Notes under steps 6.3.8.3 and 6.3.9.3 to ensure cleaning personnel is aware of flow of cleaning, and also referring to the new approved cleaning flows which will further explain the proper flow.

SOP No.	Title	Revision No.
IGN-028	CLEANING OF PROCESSING AND NON-PROCESSING ROOMS	08

Revision No.	Effective Date	Description of Changes
06	AUG 23 2022	1. Include procedure for cleaning of a Passbox. 2. Update weekly cleaning procedure to reflect proper flow and include Passbox cleaning, when applicable.
07	SEP 08 2022	1. Included Step 6.1.7.4 for collection/use of WFI or Purified Water for cleaning. 2. Removed the mention of R&D Labs 406 and 407 following facility modifications. 3. Updated the wording of Visual Inspection Room to Inspection and Packaging Rooms.
08	JAN 2 7 2023	1. Note under Step 6.2.1 is extended to explain the cleaning activities for Clean Room Supporting areas.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	4/19/2021-4/30/2021* FEI NUMBER 3015156709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jugal K. Taneja, Managing Member

FIRM NAME	STREET ADDRESS
BPI Labs LLC	12393 Belcher Rd S Ste 450
CITY, STATE, ZIP CODE, COUNTRY Largo, FL 33773-3097	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer and 503B Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
Pre-Approval, NDA #205029 Supplement 10: Epinephrine, USP Pre-Filled Syringes 1mg/mL

OBSERVATION 1

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, during inspection, it was observed that the equipment "Groinger Plunger Rod and Labelling Machine type SMKE with de-nester" intended for labeling the pre-filled epinephrine syringes referenced in your NDA application has not been installed and qualified for use.

OBSERVATION 2

Potential suppliers were not evaluated and selected based on their ability to meet specified requirements.

Specifically, your firm was not evaluating suppliers based upon their ability to meet requirements established in your *Vendor Management System* procedure (SOP IGN-034) and *Purchasing System* procedure (SOP IPC-001). Your firm's initial qualification (signed 02/26/2019) of your supplier of sterile 1 mL syringes indicates that a "review of collected data shows that the company has a vigorous quality system and capable of meeting customer expectations," but the approved supplier did not provide the information required per your firm's procedures and the questionnaire provided. For example, the initial *Questionnaire for Customers* provided by your supplier as a self-audit indicated that their Site Master File, manufacturing equipment, site maps and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Saundrea A Munroe, Investigator Emma R Schaefer, Investigator Jessica L Pressley, Investigator	X Saundrea A Munroe Investigator Signed By: Saundrea A Munroe - S Date Signed: 04-30-2021 10:43:20 4/30/21	4/30/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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drawings, an explanation of how product is protected from the manufacturing environment, deviation handling procedures, previous deviations and OOS syringes, and an explanation of rejected batches of syringes within the last year were not provided. The supplier indicated that this information could be provided at the next on-site audit. There has not been an on-site audit conducted since this initial qualification nor is one scheduled by the firm. Additionally, this self-assessment indicated that the supplier has not been inspected by a regulating body and doesn't confirm the supplier's understanding of FDA's regulations, which is a requirement of the firm's *Purchasing System* procedure.

OBSERVATION 3

Risk analysis is inadequate.

Specifically, your firm's risk analysis conducted as part of the *Combination Product Compliance 21 CFR Part 4 Drug and Device Constituent Parts* document you identified as the design history file for your firm's 1 mL epinephrine syringe does not adequately identify the hazards, estimated risks, and mitigations associated with the use of your finished combination product.

For example, your firm identifies the glass syringe and rubber plunger components of your finished 1 mL epinephrine syringe as high risk for particulate matter, bacterial endotoxin, and lack of sterility in the *Product Development Report for Epinephrine Injection, USP 1 mG/mL* under section 2.1.3. In your firm's design history file your risk analysis conducted for the finished 1 mL epinephrine syringe device does not evaluate the risk levels for the eight risks identified by your firm. Additionally, one of the mitigations listed for risk of particulates is "incoming materials controls". Your firm's supplier control's do not adequately evaluate your supplier's capabilities of meeting the supplier requirements established by your firm, including technical and regulatory requirements. Your firm's supplier of syringes for this combination product was not subject to a quality

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	Saundrea A Munroe, Investigator Emma R Schaefer, Investigator Jessica L Pressley, Investigator	X	4/30/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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agreement and did not provide evidence to support their abilities to meet your firm's established supplier requirements during their initial self-audit approved on 02/26/2019.

OBSERVATION 4

Procedures for design transfer have not been adequately established.

Specifically, your firm's design history file for your 1 mL epinephrine syringe combination product did not contain a documented design transfer that supported the device's design was correctly translated into production specifications. Under design transfer your firm documented "there is no transfer involved."

OBSERVATION 5

The type and extent of control to be exercised over the product and suppliers was not clearly defined.

Specifically, your firm did not establish a quality agreement with your supplier that defined the type and extent of control to be exercised over the sterile 1 mL syringe that is a component of your firm's sterile 1 mL epinephrine syringe combination product until 04/22/2021. This is required per SOP IGN-034 Section 6.3.6 upon vendor approval. Your firm's supplier of sterile 1 mL syringes was approved on 02/26/2019.

*DATES OF INSPECTION

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	Saundrea A Munroe, Investigator Emma R Schaefer, Investigator Jessica L Pressley, Investigator	X	4/30/2021

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4/19/2021(Mon), 4/20/2021(Tue), 4/21/2021(Wed), 4/22/2021(Thu), 4/23/2021(Fri), 4/26/2021(Mon), 4/27/2021(Tue), 4/28/2021(Wed), 4/30/2021(Fri)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

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	Saundrea A Munroe, Investigator Emma R Schaefer, Investigator Jessica L Pressley, Investigator	X 4/30/21 Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 04-30-2021 10:43:20	4/30/2021

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

bpi Labs

12393 Belcher Road, Suite # 450
Largo, FL 33773
Phone: (727) 471-0850
Fax: (727) 544-3595

May 21, 2021

Monica R. Maxwell
Program Division Director
Office of Pharmaceutical Quality Operations (OPQO), Division II
Food and Drug Administration
ORAPharm2_responses@fda.hhs.gov

Subject: Response to FDA Inspectional Observations from 04/19/2021 to 04/30/2021

Dear Madam,

This correspondence is in response to the 04/19/2021 through 04/30/2021 pre-approval inspection of NDA # 205029 Supplement # 9: Epinephrine Injection, USP 10 mg / 10 mL (10 mL Vial) and NDA # 205029 Supplement # 10: Epinephrine Injection, USP 1 mg / mL (1 mL Syringe) to be manufactured commercially by BPI Labs, LLC, at 12393 Belcher Road, Suite # 450, Largo, FL 33773 (FEI Number 3015156709), upon FDA approval.

This communication is in response to the Form FDA 483 Inspectional Observations issued to BPI Labs, LLC ("BPI") specific to its NDA # 205029 Supplement # 10: Epinephrine Injection, USP 1 mg / mL (1 mL Syringe) by FDA Investigators Ms. Saundrea A Munroe and Ms. Emma R Schaefer (collectively, referred to as the "Investigators").

BPI would like to bring to your attention that no FDA 483 observations were issued to NDA # 205029 Supplement # 9: Epinephrine Injection, USP 10 mg / 10 mL (10 mL Vial) at the end of the inspection. Investigators mentioned during the close out meeting that this drug product was going to be recommended for approval. BPI respectfully requests FDA to facilitate the approval of the NDA # 205029 Supplement # 9: Epinephrine Injection, USP 10 mg / 10 mL (10 mL Vial) in order to commence the commercial manufacturing as soon as possible.

In addition, BPI would like to acknowledge that no FDA 483 observations were issued during the 503B outsourcing facility inspection that occurred simultaneously with the pre-approval inspection. The 503B outsourcing facility inspection was conducted by FDA Investigator Ms. Jessica L Pressley.

In regard to the Form FDA 483 Inspectional Observations issued to BPI specifically to its NDA # 205029 Supplement # 10: Epinephrine Injection, USP 1 mg / mL (1 mL Syringe), BPI accepts the Investigators' observations and commits to address the issue expeditiously. BPI believes it has taken and commits to continue to take any and all necessary measures to ensure its customers

bpi Labs

12393 Belcher Road, Suite # 450
Largo, FL 33773
Phone: (727) 471-0850
Fax: (727) 544-3595

well-being and safety. Enclosed please find an attachment that addresses BPI's responses to the FDA Investigators' observations on an individual and systemic basis.

Our corrective action plan will address all issues effectively and comply with Current Good Manufacturing Practices (cGMP) Regulations (Title 21, Code of Federal Regulations, Parts 210, 211, and 4).

BPI would like to inform the Agency that all corrective actions taken have been completed, as can be evidenced from our responses enclosed with this letter, except Observation 1.

BPI expects to complete the qualification of the intended equipment, TechLine Horizontal Roller Syringe Wrap Labeling System Machine, to be used in commercial labeling of NDA # 205029 Supplement # 10: Epinephrine Injection, USP 1 mg / mL (1 mL Syringe) and submit the executed qualification protocols and associated final report to FDA on or before 09/30/2021.

BPI's action plan for Observation 1 includes the specifics of its actions along with targeted timelines. We will closely monitor the implementation of the plan and will provide your Office with updates along with evidence of implementation. Should we change any of our commitments, we will provide you with our reasons and supporting documentation.

Henceforth, upon receipt of BPI's final response related to this FDA 483 observation, BPI respectively requests that the Agency accepts the submitted executed qualification documentation of the TechLine Horizontal Roller Syringe Wrap Labeling System Machine in lieu of a second separate visit to our facility to inspect the qualification exercise of the mentioned machine onsite. Instead, the Agency would be more than welcome to inspect such documentation at our facility at any convenient time, i.e., next BPI cGMP inspection or pre-approval inspection associated with BPI other filed NDAs or ANDAs.

Accordingly, we would like to request a review of our response and action plan at your earliest convenience.

Finally, as per Investigators' request during the close out meeting, BPI is also enclosing along with this response the information related to non-conformance NCR No. I-21004 associated to the sanitization of the Purified Water System.

Please feel free to contact me at (727) 471 0850 Extension 200 if you have any questions or concerns with our responses.

bpi Labs

12393 Belcher Road, Suite # 450
Largo, FL 33773
Phone: (727) 471-0850
Fax: (727) 544-3595

Cordially,

M. Salazar

Mauricio Salazar
Chief Quality & Compliance Officer
BPI Labs, LLC
12393 Belcher Road, Suite # 450, Largo, FL 33773
(727) 471-0850 Extension 200
mauricios@belcherpharma.com

PRE-APPROVAL, NDA # 205029 SUPPLEMENT 10: EPINEPHRINE, USP PRE-FILLED SYRINGES 1 MG/ML

OBSERVATION 1:

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, during inspection, it was observed that the equipment "Groinger Plunger Rod and Labelling Machine type SMKE with de-nester" intended for labeling the pre-filled epinephrine syringes referenced in your NDA application has not been installed and qualified for use.

BPI'S RESPONSE TO OBSERVATION 1:

BPI acknowledges and accepts the investigator's observation.

BPI's application NDA # 205029 Supplement 10 for Epinephrine, USP Pre-Filled Syringes 1 mg/mL submitted to FDA on 03/19/21 included the current installed and qualified labeling machine, i.e., Labeler (Model #: Q105 Stepper), referenced via SOP IPK-004 "Handling of the Labeler (Model # Q105 Stepper)", as part of the proposed intended commercial Labeling Master No.: PK-I117-0-10 "Master Batch Packaging Record – Labeling Instructions" document for this product (refer to Exhibit – 1.1).

In regards to the observation noted by the FDA, BPI would like to clarify the situation encountered with the Q105 Stepper labeling machine, included in the Supplement information given to FDA as part of the submission, and the "Groinger Plunger Rod and Labelling Machine type SMKE with de-nester" (hereinafter referred to as "Groninger labeling machine") as discussed with the FDA investigators during this inspection.

BPI's initial intention was to utilize the Q105 Stepper labeling machine for the labeling of the pre-filled epinephrine syringes as it was expected to be suitable for both vials and syringes configurations. However, further technical and operational assessment of the Q105 Stepper labeling machine along with discussion with the equipment manufacturer revealed that this equipment will not be the most ideal labeling machine to be used for the pre-filled syringes. This finding identified the need to re-evaluate the need to purchase and commission the Groninger labeling machine for the labeling operation of the pre-filled epinephrine syringes.

At this time, the available quotation received by BPI for this Groninger labeling machine was shown to the FDA investigators (refer to Exhibit – 1.2) and also the explanation of the technical constraints related to the current installed and qualified Q105 Stepper labeling machine for the

pre-filled syringes was presented during the inspection. BPI confirmed that the Groninger labeling machine had not been purchased, installed, and qualified for use.

After the FDA inspection, BPI contacted the manufacturer of the Groninger labeling machine to inquire about its availability based on the past quotation. Unfortunately, the manufacturer confirmed that due to the COVID-19 pandemic this equipment has very long lead time for delivery.

As a result, BPI searched for alternate suitable labeling machines for the labeling operation of pre-filled syringes. BPI identified the TechLine Horizontal Roller Syringe Wrap Labeling System machine, manufactured by Quadrel Labeling Systems, as adequate for the intended use based on the technical specifications and product design (refer to Exhibit – 1.3 for the quotation provided by this firm).

Quadrel Labeling Systems confirmed that the TechLine labeling machine is expected to be delivered to BPI on or before 08/31/21 (refer to Exhibit – 1.4 for copy of purchase order).

BPI commits to install and qualify the TechLine labeling machine and expects to complete this activity and submit the executed qualification protocols and associated final report to the FDA on or before 09/30/21.

OBSERVATION 2:

Potential suppliers were not evaluated and selected based on their ability to meet specified requirements.

Specifically, your firm was not evaluating suppliers based upon their ability to meet requirements established in your *Vendor Management System* procedure (SOP IGN-034) and *Purchasing System* procedure (SOP IPC-001). Your firm's initial qualification (signed 02/26/2019) of your supplier of sterile 1 mL syringes indicates that a "review of collected data shows that the company has a vigorous quality system and capable of meeting customer expectations," but the approved supplier did not provide the information required per your firm's procedures and the questionnaire provided. For example, the initial *Questionnaire for Customers* provided by your supplier as a self-audit indicated that their Site Master File, manufacturing equipment, site maps and drawings, an explanation of how product is protected from the manufacturing environment, deviation handling procedures, previous deviations and OOS syringes, and an explanation of rejected batches of syringes within the last year were not provided. The supplier indicated that this information could be provided at the next on-site audit. There has not been an on-site audit conducted since the initial qualification nor is one scheduled by the firm. Additionally, this self-assessment indicated that the supplier has not been inspected by a regulatory body and doesn't confirm the supplier's understanding of FDA's regulations, which is a requirement of the firm's *Purchasing System* procedure.

BPI'S RESPONSE TO OBSERVATION 2:

BPI acknowledges and accepts the investigator's observation. However, BPI would like to explain to the Agency all the available procedures that were in place at the time of the FDA inspection to evaluate and select potential vendors based on their ability to meet specified requirements.

New vendors are initially approved in the quality system following the requirements documented in SOPs IPC-001 "Purchasing System" and IGN-034 "Vendor Management System." Then, vendors are re-qualified in a periodic manner as per the guidelines written in both mentioned procedures. Both the initial and re-qualification exercises are well defined to assess the adequacy of the vendor performance at all times.

Refer to Exhibit – 5.1 for copy of mentioned SOPs IPC-001 Revision No. 04 and IGN-034 Revision No. 04 that were effective at the time the FDA inspection was conducted.

In regards to the observation noted by the FDA, specifically related to SCHOTT Schweiz AG which is the vendor supplying the syringes for the epinephrine pre-filled syringes 1 mg/mL, BPI would like to clarify the execution of all available procedures that were in place at the time of the

FDA inspection to evaluate and select potential vendors based on their ability to meet specified requirements, consistent with the quality system standards available in both above mentioned SOPs.

Firstly, SCHOTT Schweiz AG was initially approved in the quality system on 02/26/19 (refer to Exhibit – 5.2). SCHOTT Schweiz AG is one of the world's leading manufacturers of special glass and polymers including vials, cartridges, and syringes ready to use for the pharmaceutical industry; this company was established in year 1930.

During the initial qualification of this reputed vendor, BPI requested a variety of technical documentation for the components that were required as part of product development as well as an understanding of the quality principles of this firm. Based on their internal administrative process, SCHOTT Schweiz AG does not complete feedback questionnaires and rather they provide their own self-assessment explaining several information about the company. As part of this initial process, BPI identified few points that were not fully communicated and explained in SCHOTT Schweiz AG's self-assessment and despite making diligent efforts by BPI to clarify such information as further preliminary understanding of the vendor, SCHOTT Schweiz AG did not provide the clarifications requested due to some organizational reason, out of BPI's control. That being said, as stated below BPI has been able to get further clarifications on these points.

Further evaluation of this firm made at the time of initial qualification revealed that a US DMF (i.e., 18416) was filed for the components SCHOTT Schweiz AG intended to distribute to United States. In addition, the technical documentation related to the components BPI was interested to acquire was found highly accurate and complete (refer to Exhibit – 2.1 for an example of technical data). Moreover, SCHOTT Schweiz AG presented certifications from accredited organizations in regards to ISO 9001 and ISO 15378 (refer to Exhibit – 2.2) confirming vendor's understanding in quality (i.e., development, engineering, manufacturing and sales of primary packaging materials made of glass tubing and polymers) and vendor's experience in audits under a regulatory environment. Finally, the vendor reputation verified during initial approval confirmed that SCHOTT Schweiz AG adheres to good quality standards according to available public data.

BPI approved SCHOTT Schweiz AG on 02/26/19 to supply components for research and development use because all data indicated that the vendor had a robust quality system capable of meeting customer expectations, inline with technical data, certifications, vendor history, and DMF filing in United States.

BPI would like to clarify to the Agency that SCHOTT Schweiz AG is a quality focused and highly knowledgeable firm. This company has provided detailed technical documents from day one related to the design, manufacturing, and controls for its components, confirming that this mentioned vendor fully understands the GMP regulations / expectations in an FDA environment.

Secondly, this vendor was re-qualified in the quality system on 02/17/21 (refer to Exhibit – 5.3), based on two years re-qualification period. As part of this re-qualification process, SCHOTT Schweiz AG performance was scrutinized based on technical data, available certifications in ISO 13485, ISO 14001, and ISO 45001 (refer to Exhibit – 2.3), and vendor history with BPI since the initial approval, and found out that six shipments were received, inspected, tested, and released for use at BPI without any problem or unwanted trend, corroborating one more time that this vendor had proper systems in place capable of meeting customer expectations and that BPI had available procedures to evaluate the quality of the components received.

In accordance with above specifics, please be advised that BPI has carefully evaluated SCHOTT Schweiz AG and has selected it based on its ability to meet specified requirements, which has been further substantiated with SCHOTT Schweiz AG's performance since February 2019 to date (i.e., no rejections, no unwanted trends).

It is important to inform to the Agency that all these explanations and evidences were shown and discussed with the FDA investigator during the inspection.

Nonetheless as part of this observation, BPI performed a thorough evaluation of all vendors related to commercial materials and components, and confirmed that adequate initial vendor approval and vendor re-qualification exercises have been systematically conducted including the periodic evaluation of vendor's performance and materials / components quality, inline with the requirements of SOPs IPC-001 and IGN-034. This finding further validates that BPI has been following its internal controls at all times.

As a further assurance, BPI contacted SCHOTT Schweiz AG again to inquire one more time about some information that was not provided by this vendor at the time of initial qualification. As a result SCHOTT has agreed to have a remote audit discussion with BPI with the purpose of clarifying all the pending items, including the ones pointed out by the Agency. During this process conducted on 05/20/21, SCHOTT Schweiz AG explained the majority of the open questions and shared specifics about their controls in place, validating that SCHOTT Schweiz AG has a strong quality system tailored to meet customer needs (refer to Exhibit – 2.4 for the updated SCHOTT Schweiz AG report).

As a further assurance and as part of continuous improvement, BPI revisited the wording of its controls for initial and re-qualification of vendors and identified an opportunity for enhancement to present in a more explicit manner the current expectations and practices on this topic. Consequently, BPI has revised SOP IGN-034 "Vendor Management System" in the quality system to clarify the requirements of initial and re-qualification of vendors, including the addition of handling self-assessments provided by the firms in lieu of BPI's feedback questionnaire. The revised SOP was made effective on 05/18/21 as Revision No. 05; all users of this SOP were part of the review and approval process (refer to Exhibit – 5.7 for a copy of the revised SOP along with the respective change control). BPI believes that clearer instructions on

this SOP would contribute to avoid misinterpretations about the process of evaluating, selecting, and monitoring vendors.

As a final point, BPI would like to clarify to the Agency that SCHOTT Schweiz AG is a vendor classified for research and development use only at this specific time (i.e., no components is currently used in any commercial product) and for this reason on-site audit need as per SOP IGN-034 has not been undertaken yet. Once this vendor is transitioned from research and development to commercial, at that time the requirement of on-site audit will be assessed as per the frequency established in this mentioned SOP, and if selected, this vendor will be added to the "Vendor On-site Audit Tentative Schedule Plan" for on-site audit planning and execution.

In conclusion, BPI believes that procedures that defined the evaluation and selection of vendors based on their ability to meet specified requirements were established in the quality system from day one and were executed effectively, that initial and re-qualification processes for SCHOTT Schweiz AG has been done methodically, and that SCHOTT Schweiz AG is a vendor considered in respectable standards and capable of meeting customer needs, reaffirming that BPI has followed its SOPs and has operational systems to control and monitor vendors in a consistent manner.

OBSERVATION 3:

Risk analysis is inadequate.

Specifically, your firm's risk analysis conducted as part of the *Combination Product Compliance 21 CFR Part 4 Drug and Device Constituent Parts* document you identified as the design history file for your firm's 1 mL epinephrine syringe does not adequately identify the hazards, estimated risks, and mitigations associated with the use of your finished combination product.

For example, your firm identifies the glass syringe and rubber plunger components of your finished 1 mL epinephrine syringe as high risk for particulate matter, bacterial endotoxin, and lack of sterility in the *Product Development Report for Epinephrine Injection, USP 1 mg/mL* under section 2.1.3. In your firm's design history file your risk analysis conducted for the finished 1 mL epinephrine syringe device does not evaluate the risk levels for the eight risks identified by your firm. Additionally, one of the mitigations listed for risk of particulates is "incoming materials controls". Your firm's supplier control's do not adequately evaluate your supplier's capabilities of meeting the supplier requirements established by your firm, including technical and regulatory requirements. Your firm's supplier of syringes for this combination product was not subject to a quality agreement and did not provide evidence to support their abilities to meet your firm's established requirements during their initial self-audit approved on 02/26/2019.

BPI'S RESPONSE TO OBSERVATION 3:

BPI acknowledges and accepts the investigator's observation.

BPI would like to clarify to the Agency that the risk assessment using qualitative tool (high, medium, and low terminology) was performed for the glass syringe and rubber plunger as part of the Product Development Report No. IPT-R-I11 "Epinephrine Injection, USP 1 mg/mL" under Section 2.1.3 (refer to Exhibit – 3.1 for a copy of Section 2.1.3 – only pages 1, 25, 26, and 27 are included in this exhibit; refer to Exhibit 4.1 for a copy of the entire Product Development Report No. IPT-R-I11).

As part of product design for Epinephrine Injection, USP 1 mg/mL, it was determined that the particulate matter, bacterial endotoxin (BET), and sterility of the syringe and rubber plunger pose "high" risk level, hence necessary mitigation controls were established to monitor these risks in a consistent manner (refer to below Table 1 for details). Based on thorough evaluation of these critical quality attributes impacting directly the product quality, it was understood that this high risk could be mitigated by performing adequate internal testing of incoming syringes and rubber plungers prior to release and use for production. In addition, it was defined during product development that the final finished product also needed to be tested for particulate matter,

bacterial endotoxin (BET), and sterility as part of the release specifications to ensure patient safety during usage.

Table 1 – Incoming Materials and Finished Product Testing Controls

Item	Test	Specification	BPI Internal Acceptance Criteria	USP Acceptance Criteria
Syringe	Particulate Matter	SPC I3021 Particles ≥ 10µm	NMT 600 particles per container (10% of USP <788>)	NMT 6000
		Particles ≥ 25µm	NMT 60 particles per container (10% of USP <788>)	NMT 600
	Bacterial Endotoxins Test	SPC I3021	NMT 0.25 EU / mL	NMT 0.25 EU / mL, equal to Water For Injection
	Sterility Test	SPC I3021	No evidence of microbial growth	No evidence of microbial growth
Rubber Plunger	Particulate Matter	SPC I3020 Particles ≥ 10µm	NMT 600 particles per container (10% of USP <788>)	NMT 6000
		Particles ≥ 25µm	NMT 60 particles per container (10% of USP <788>)	NMT 600
	Bacterial Endotoxins Test	SPC I3020	NMT 0.25 EU / mL	NMT 0.25 EU / mL, equal to Water For Injection
	Sterility Test	SPC I3020	No evidence of microbial growth	No evidence of microbial growth
Finished Product	Particulate Matter	SPC I117 Particles ≥ 10µm	NMT 6000 per container	NMT 6000 per container
		Particles ≥ 25µm	NMT 600 per container	NMT 600 per container
	Bacterial Endotoxins Test	SPC I117	NMT 40 E.U. / mg of Epinephrine	NMT 357.0 EU/mg of Epinephrine, refer USP monograph
	Sterility Test	SPC I117	No evidence of microbial growth	No evidence of microbial growth

BPI performed risk analysis as per the FDA Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination Products FINAL GUIDANCE, January 2017, specified in iii. Risk Analysis page 44. BPI believes risk levels, either qualitative or quantitative, can be performed. Quantitative analysis is recommended in order to evaluate if mitigations are required or not, but BPI has implemented mitigations in this case nevertheless to ensure there is no negative impact to product quality.

BPI further reviewed the SOP IGN-035 "Handling of Combination Products" and improvements were made to provide additional instructions on risk analysis related to manufacturing as well as use-related. The revised SOP was made effective on 05/20/21 as Revision No. 03; all users of this SOP were part of the review and approval process (refer to Exhibit – 3.2 for a copy of the revised SOP along with the respective change control). BPI believes that clearer instructions on this SOP would help to assess better the risks associated as part of product design going forward.

Moreover, the combination product document associated with the design of epinephrine pre-filled syringes "Design Controls for Epinephrine Injection, USP 1 mg/mL (1 mL Syringe)", Section No. CP-I11-02, was revised to perform the risk analysis with quantitative risk levels for manufacturing related items of this mentioned product inline with the revised SOP IGN-035. Refer to Exhibit – 4.4 for copy of the revised section.

Additionally, a new section related to the combination product associated with the use-related risk analysis of epinephrine pre-filled syringes "Use-Related Risk Analysis for Epinephrine Injection, USP 1 mg / mL (1 mL Syringe)", Section CP-I11-08, was created to evaluate the use-related risk analysis linked with this mentioned product inline with the revised SOP IGN-035. Refer to Exhibit – **3.3** for copy of the revised section.

On the other hand, it is important to mention that BPI has diligently approved and re-qualified all vendors associated with the cGMP operations, including Schott Schweiz AG which is the supplier of the syringes, to ensure these are evaluated on a periodic basis to confirm their capabilities of meeting BPI requirements. Furthermore, BPI has worked systematically to generate the quality agreement between BPI and Schott Schweiz AG and to approve it in the quality system before the commercial manufacturing of the epinephrine pre-filled syringes product, in agreement with the internal company standards. The quality agreement was provided to the FDA investigators on 04/23/21 during the inspection. Refer to the responses for Observation 2 and Observation 5 to get a clearer and detailed understanding of the available controls at BPI for vendor evaluation and for quality agreements.

Finally, BPI would like to conclude that the hazards, risks, and mitigations associated with the use of the epinephrine pre-filled syringes combination product were further discussed and clarified, and it is believed that this document now reflects a more thorough risk analysis according to the product design and intended use.

OBSERVATION 4:

Procedures for design transfer have not been adequately established.

Specifically, your firm's design history file for your 1 mL epinephrine syringe combination product did not contain a documented design transfer that supported the device's design was correctly translated into product specifications. Under design transfer your firm documents "there is no transfer involved".

BPI'S RESPONSE TO OBSERVATION 4:

BPI acknowledges and accepts the investigator's observation. However, BPI would like to clarify to the Agency the design transfer activities to support the device's design and how BPI has performed this activity.

As a general policy, any product development activity is performed following Quality by Design (QbD) concepts as per US FDA guidance, which includes identification of raw materials and container closure system components, such as syringes and plungers, conducting of several compatibility studies, formulation developments, laboratory experimental batches manufacturing, risk assessments of the formulation variables, manufacturing process developments, initial risk assessments of the drug product manufacturing process, establishment of mitigation controls, and execution of exhibit batches (stability batch) manufacturing and testing activities.

As part of this process, various risk analyses are conducted, necessary specifications are established, test methods, batch manufacturing records, batch packaging records, and stability protocols are generated, among others, and finally technology transfer is executed to transition the product from research and development to production.

Specifically, for Epinephrine Injection, USP 1 mg/mL syringe product all these activities are performed and explicitly written in the Product Development Report (PDR) for this mentioned product (Document No. IPT-R-I11 – refer to Exhibit – 4.1). As the combination product requires Design Controls as per 21 CFR Part 4 Regulation of Combination Products, Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination Products FINAL GUIDANCE, January 2017, BPI used the activities performed as per above mentioned PDR as a reference and guidance to determine the combination product documentation.

As all design transfer activates were conducted as per the PDR and three batches of Epinephrine Injection, USP 1 mg / mL Pre-Filled Syringes (Batch Numbers I117R002, I117R003, and I117R004) were manufactured and tested for all critical quality attributes per approved

specifications, it was found that the combination product meets the pre-determined specifications. However, BPI accidentally missed to explicitly write the design transfer activity in the first version of the Design Controls document, Section No. CP-I11-02, Revision 01 (refer to Exhibit – 4.2 for copy of this section), and accepts that this unwanted situation created a gap in understanding the design transfer strategy utilized by BPI. From discussions with FDA investigator, BPI modified the Design Controls document, Section No. CP-I11-02, Revision 02, to incorporate the proper documentation associated with design transfer improvements according to the Product Development Report IPT-R-I11 (refer to Exhibit – 4.3 for a copy of the revised section). This revised section was provided to the FDA investigators during the inspection.

As a further assurance and as part of this observation, BPI proactively reviewed again the Design Controls document, Section No. CP-I11-02, Revision 02, specifically design transfer topic, and identified an extra enhancement in regards to making reference of internal SOPs associated with product development procedures, and to acknowledge the adequacy of the design transfer for the epinephrine pre-filled syringes combination product based on the acceptable results of three batches meeting pre-determined specifications and proving the overall design controls established and design transfer are effective. Refer to Exhibit – 4.4 for a copy of the revised Section No. CP-I11-02, Revision 03, Effective Date 05/20/21.

In conclusion, BPI acknowledges the inadvertent gap created in the Design Controls document, Section No. CP-I11-02, Revision 01, associated with the design transfer, even though the available standard SOP IGN-035 "Handling of Combination Products" was appropriate and included the expected discussion on this topic. Furthermore, BPI commits to be more attentive whenever creating any combination product section in the future for any new product to make sure information is accurate and precise reflecting the company's strategy from product development to the intended production environment.

OBSERVATION 5:

The type and extent of control to be exercised over the product and suppliers was not clearly defined.

Specifically, your firm did not establish a quality agreement with your supplier that defined the type and extent of control to be exercised over the sterile 1 mL syringe that is a component of your firm's sterile 1 mL epinephrine syringe combination product until 04/22/2021. This is required per SOP IGN-034 Section 6.3.6 upon vendor approval. Your firm's supplier of sterile 1 mL syringes was approved on 02/26/2019.

BPI'S RESPONSE TO OBSERVATION 5:

BPI acknowledges and accepts the investigator's observation. However, BPI would like to explain to the Agency all the available procedures that were in place at the time of the FDA inspection to define and execute the type and extent of control to be exercised over vendors and components were met.

New vendors are initially approved in the quality system following the requirements documented in SOPs IPC-001 "Purchasing System" and IGN-034 "Vendor Management System". Then, vendors are re-qualified in a periodic manner as per the guidelines written in both mentioned procedures. Both the initial and re-qualification exercises are well defined to assess the adequacy of the vendor performance at all times.

Similarly, new components are initially approved in the quality system following the requirements documented in SOP IGN-003 "Creation and Modification of Code Numbers and National Drug Code Numbers (NDC)"; the components are first introduced in the company for research and development purposes. Specification for each component is generated in the quality system describing all incoming controls to be exercised during physical, chemical, and microbiological testing as part of full testing, retesting, and reduced testing. Moreover, each component is introduced to the qualification program stipulated in SOP IQA-010 "Vendor Qualification Program" defining the type and extent of control to be exercised over the specific component during initial full testing and subsequent reduced testing.

Refer to Exhibit – 5.1 for copy of mentioned SOPs IPC-001 Revision No. 04, IGN-034 Revision No. 04, IGN-003 Revision No. 01, and IQA-010 Revision No. 03 that were effective at the time the FDA inspection was conducted.

In regards to the observation noted by the FDA, specifically related to the Clear Glass Syringes Ready to Use Packaging Component, BPI Code Number I3021, supplied by SCHOTT Schweiz AG, BPI would like to clarify the execution of all available procedures that were in place at the

time of the FDA inspection to define and execute the type and extent of control to be exercised for this vendor and this syringe, consistent with the quality system requirements explained above.

SCHOTT Schweiz AG was initially approved in the quality system on 02/26/19 (refer to Exhibit – 5.2). This vendor was re-qualified in the quality system on 02/17/21 (refer to Exhibit – 5.3), based on two years re-qualification period.

Clear Glass Syringes Ready to Use Packaging Component code number creation was approved in the quality system on 11/11/19 with material type as "Research and Development" and under Code Number I3021 (refer to Exhibit – 5.4).

Specification for Code Number I3021 was initially approved on 12/27/19 as Revision No. 01 (refer to Exhibit – 5.5). This specification clearly defined the full testing, reduced testing, and retesting requirements to be utilized for the type and extent of control of this component during release.

Based on SOP IQA-010, full testing needs to be executed per specification on three consecutive different vendor lots received by BPI; each lot tested needs to conform to established specifications in order to qualify this component for reduced testing. Precisely, BPI has received three shipments of component Code Number I3021 from SCHOTT Schweiz AG and performed successful full testing accordingly to the specification. As of now, this component is still classified as "Full Testing" since one extra consecutive different vendor lot is needed to be received and tested as part of the "Reduced Testing" certification (refer to Exhibit – 5.6 for the full testing data of the three shipments).

The above confirms that BPI has determined clear procedures to define the type and extent of control to be exercised on vendors and components, has executed the procedures in place with SCHOTT Schweiz AG and with the Clear Glass Syringes Ready to Use Packaging Component (Code Number I3021), and hence has full understanding and control about the quality of this component handled by the firm.

On the other hand, BPI has determined the need to generate quality agreements for some vendors depending on the type of component that is being supplied. These quality agreements are intended to provide an overall approach about the implementation of oversight and controls between parties involved with the purpose of establishing each party's key specific roles and manufacturing activities to comply with cGMP. Specifically, quality agreements for ready to use pre-sterile packaging components (i.e., syringes) are only required at BPI for commercial materials (refer to Exhibit – 5.1 for copy of SOPs IPC-001 and IGN-034).

As of today, all components supplied to BPI by SCHOTT Schweiz AG are still categorized under "Research and Development", including the Clear Glass Syringes Ready to Use Packaging

Component (Code Number I3021), and all shipments received so far from this mentioned vendor have only been used for the manufacturing of research and development lots. Accordingly, it is evident that the component pointed out by the Agency is not approved for commercial use until now and therefore the quality agreement was technically not needed yet based on internal BPI's standards stated in SOPs IPC-001 and IGN-034.

BPI started working with SCHOTT Schweiz AG in September 2020 in order to generate the quality agreement between both firms as part of completeness of tasks for potential and upcoming commercial use of this vendor and associated components. For some administrative reasons, SCHOTT Schweiz AG took longer time to finalize this quality agreement despite the frequent and diligent follow up made by BPI. Finally, the quality agreement was approved on 04/22/21 and confirmed to be adequate to initiate the further control of the upcoming commercial shipments. The same was also provided to the investigator during the inspection.

As explained in this response, the Clear Glass Syringes Ready to Use Packaging Component (Code Number I3021) has not been internally approved for commercial use although all incoming and in-process controls for the shipments received so far have been meticulously monitored during release and use and found them to be acceptable and appropriate ratifying the quality and performance of SCHOTT Schweiz AG. Based on all the facts mentioned as part of this answer, BPI believes that there is no negative impact on SCHOTT Schweiz AG and on the Clear Glass Syringes Ready to Use Packaging Component (Code Number I3021) by not having the quality agreement approved before 04/22/21 since the vendor and the component are still under research and development use and BPI has followed strictly its internal standards and controls.

It is important to inform to the Agency that all these explanations and evidences were shown and discussed with the FDA investigator during the inspection.

Nonetheless as part of this observation, BPI performed a thorough evaluation of all commercial materials and components and confirmed that adequate quality agreements are in place and approved prior to any commercial distribution of the associated products, inline with the requirements of SOPs IPC-001 and IGN-034. This finding further validates that BPI has been following its internal controls at all times.

As a further assurance, BPI revisited the wording of its controls for quality agreements and identified an opportunity for improvement to present in a more explicit manner the current expectations and practices on this topic. Consequently, BPI has revised SOP IGN-034 "Vendor Management System" in the quality system to clarify the requirements of quality agreements, including the ones that are required for materials and components transitioning from research and development to commercial use. The revised SOP was made effective on 05/18/21 as Revision No. 05; all users of this SOP were part of the review and approval process (refer to Exhibit – 5.7 for a copy of the revised SOP along with the respective change control). BPI

believes that clearer instructions on this SOP would contribute to avoid misinterpretations about the need and timeliness of the quality agreements, whenever applicable.

Finally, BPI believes that procedures that defined the type and extent of control to be exercised over vendors and components that were incorporated into the quality system from day one and executed effectively, did not require a quality agreement between BPI and SCHOTT Schweiz AG to be in place since 02/26/19, and that quality agreement between both mentioned firms was already approved on 04/22/21 prior to the release of the associated commercial product, reaffirming that BPI has followed its SOPs and has operational systems to control vendors and components intended for commercial purposes.

11B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☒ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☒ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: OurPharma LLC

Physical Address: 2512 S City Lake Road

City: Fayetteville State: AR Zip Code: 72701

Telephone: 479-313-8200 Fax: 479-249-8172

Toll Free Number: 1-833-290-2654 (Required per NAC 639.708)

E-mail: mstrickland@ourpharma.net Website: www.ourpharma.net

Supervising Pharmacist: Morgan Strickland ✓ Nevada License #: 23136 ✓

SERVICES PROVIDED

Yes/No

- ☐ ☒ Parenteral
- ☒ ☐ Sterile Compounding
- ☐ ☒ Non Sterile Compounding
- ☒ ☐ Mail Service Sterile Compounding
- ☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: 500.00 CK-1058809 ✓

11-7-22

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3014064135

Please provide the name of the facility as registered with the FDA and the registration number:
OurPharma LLC Registrant DUNS: 041422637

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Morgan Strickland Nevada License Number: 23136

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: _____

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY Page 5

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Arkansas

Parent Company if any: OurPharma Holdings LLC

Address: 2512 S City Lake Rd

City: Fayetteville State: AR Zip: 72701

Telephone: 479-313-8200 Fax: 479-249-8172

Contact Person: Peter O. Kohler

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Peter O. Kohler (Name) 3657 East Leawood Way, Fayetteville, AR, 72703 (Address)

b) Multi-Management Services, Inc. (Name) 9601 Baptist Health Drive, Little Rock, AR, 72205 (Address)

c) WELSCO, Inc. (Name) 9006 Crystal Hill Road, North Little Rock, AR, 72113 (Address)

d) Angela E. Harrison (Name) 24 Hickory Creek Drive, Little Rock, AR, 72212 (Address)

2) Provide the number of shares issued by the corporation. 25,000,000

3) What was the price paid per share? $1.00

4) What date did the corporation actually receive the cash assets? 12/20/2017

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☑

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Morgan Strickland
Print Name of Authorized Person

10/13/2022
Date

OurPharma Holdings, LLC
Investor List

Investor	Member	Total Units	% Equity
Peter O. Kohler		11,050,000	44.2%
Muti-Management Services, Inc.	Brent Beaulieu	3,500,000	14.0%
Welsco, Inc	Angela E.Harrison	1,500,000	6.0%
Angela E. Harrison		1,000,000	4.0%
AR Venture Capital Investment Trust	Mark Conine	1,000,000	4.0%
Carlos Lagomarsino Revocable Trust	Carlos Lagomarsino	1,000,000	4.0%
William Clark		700,000	2.8%
Scot Rogers		500,000	2.0%
Philip Grace		500,000	2.0%
Mike Mauldin		400,000	1.6%
OurPharma Family, LLC	Brooke K. Erwin	350,000	1.4%
OurPharma Family, LLC	Stephen E. Kohler	350,000	1.4%
OurPharma Family, LLC	Todd R. Kohler	350,000	1.4%
OurPharma Family, LLC	Adam S. Kohler	350,000	1.4%
John C Lindsey Revocable Trust	John C. Lindsey	250,000	1.0%
John Starling		250,000	1.0%
Mike Lamberth		250,000	1.0%
Charles Richard Lane		200,000	0.8%
Roger Smart		200,000	0.8%
Taylor and Julie Faught Living Trust	Taylor Faught	200,000	0.8%
IRA Innovations LLC f/b/o Michael W. Wallace	Mike Wallace	200,000	0.8%
Lewis Epley		175,000	0.7%
Benjamin Ellsworth		150,000	0.6%
Timothy B. Shmidl Revocable Trust	Timothy B. Shmidl	150,000	0.6%
Joe Hadden		125,000	0.5%
Ann Rosso		100,000	0.4%
Sharon D Tabor Revocable Trust	Scott E. Tabor	100,000	0.4%
Stobaugh Family Revocable Trust	John Stobaugh	100,000	0.4%
Total		$ 25,000,000	100.0%

Arkansas Secretary of State
John Thurston
State Capitol Building ♦ Little Rock, Arkansas 72201-1094 ♦ 501-682-3409

Certificate of Good Standing

I, John Thurston, Secretary of State of the State of Arkansas, and as such, keeper of the records of domestic and foreign corporations, do hereby certify that the records of this office show

OURPHARMA, LLC

authorized to transact business in the State of Arkansas as a Limited Liability Company, filed Articles of Organization in this office August 26, 2016.

Our records reflect that said entity, having complied with all statutory requirements in the State of Arkansas, is qualified to transact business in this State.

In Testimony Whereof, I have hereunto set my hand and affixed my official Seal. Done at my office in the City of Little Rock, this 29th day of July 2022.

John Thurston
Secretary of State

Online Certificate Authorization Code: d6a8744fe833501
To verify the Authorization Code, visit sos.arkansas.gov

OurPharma Executives

Name	Title	Address	Office Phone
Erwin, Brooke	VP & CFO	1345 S Spring Loop, Fayetteville, AR 72703	479-313-8222
Gerhardt, Patrick	VP of Operations	3740 Whitefish St, Bentonville, AR 72712	479-313-8234
Kohler, Adam	Executive VP	2616 N Grant St, Little Rock, AR 72207	479-313-8288
Kohler, Peter	President & CEO	3657 E Leawood Way, Fayetteville, AR 72703	479-313-8238

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: OurPharma LLC

Address: 2512 S City Lake Rd

City: Fayetteville State: AR Zip: 72701

I hereby authorize the Arkansas State Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant Morgan Stan

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
WD05150	Active / Good Standing	12/14/2018	12/31/2022

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☑ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☑ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☑ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☑ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☑ Yes ☐ No

Signature of State Official	Title	State	Date	State Seal
Nancy Sweet	Admin. Analyst	AR	10/13/2022	

ARKANSAS STATE BOARD OF PHARMACY ★ 1891 ★

3132

Arkansas State Board of Pharmacy

322 South Main Street, Suite 600, Little Rock, Arkansas 72201

2021 - 2022 WHOLESALE DISTRIBUTOR LICENSE

OurPharma, LLC

located at:

2512 South City Lake Road, Fayetteville, AR 72701

COPY

License #: WD05150 Original License Date: 12/14/2018

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Arkansas State Board of Pharmacy
322 South Main Street, Suite 600 Little Rock, AR 72201
P: 501.682.0190 F: 501.682.0195
asbp@arkansas.gov • www.pharmacyboard.arkansas.gov
John Clay Kirtley, Pharm.D., Executive Director

November 25, 2020

Morgan K. Strickland (PD11707)
C/O OurPharma LLC (WD05150;AR20903)
2512 South City Lake Road
Fayetteville, AR 72701

RE: Facility Inspection Conducted 11/16/2020 through 11/18/2020

Dr. Strickland:

The following requirements and/or recommendations are as a result of a scheduled inspection occurring on the date(s) stated above. It should be noted that this inspection occurred during a dynamic state of operation during product development. Regulations within 21 CFR Part 210 and 211 were utilized during the review of the firm's cGMP operations. I appreciate the assistance and cooperation provided by you and/or your staff during this review:

CFR 211.67(a) Equipment cleaning and maintenance
Specifically, a visible white residue left behind by cleaning agents was observed on windows and walls throughout the product production areas.

Specifically, damaged metal wall corner trim was observed to be scratched with exposed bare metal within the "negative storage room", caulk on ceiling tile seams was observed to not be smooth, and debris was observed on a cart's wheel located in the "west corridor".

CFR 211.46, 211.22(c) and 211.22(d) Ventilation, air filtration, air heating and cooling/Responsibilities of quality control unit
Specifically, the third-party certification reports dated 5/15/20 and 11/07/20 did not provide congruency with internal facility monitoring records and/or related SOPs (i.e., 11/07/20 suite 1 humidity; 5/15/20 and 11/07/20 suite 1 HD buffer room pressure gradient excessively negative), and there was lack of documentation by the quality control unit related to these discrepancies.

CFR 211.22(c) Responsibilities of quality control unit
Specifically, the validation of the sodium chloride (lot 172631/C), sodium metabisulfite (1904100064), and norepinephrine bitartrate (lot 20J12-BB01-PR00997) vendors did not address why the manufacturer/repackager provided COAs did not include all aspects of the respective USP monograph (i.e., NaCl: limit of potassium <852> and aluminum; Na2S2O5: residual solvents <467>; norepinephrine bitartrate: residual solvents <467>).

Specifically, the firm's pest control reports were of inadequate detail to determine completeness, actions taken, and recommendations provided. In addition, there is a lack of documented prospective review by the quality control unit of pest control processes.

CFR 211.25(a) Personnel qualifications
Specifically, upon review of the training records for three individuals (PT04115; PT91633; PD08384) I was unable to determine the degree of compliance with established firm training requirements.

Your response to each finding should be forwarded to this office within thirty (30) days. These responses to the above findings must include an itemized list of each finding with the corrective/proposed corrective action, responsible individual, and completion/projected completion date. Once completed, you must forward supporting documentation (i.e., pictures, invoices, SOP, documentation, etc) to my attention at ASBP@arkansas.gov.

If we may be of assistance at any time, do not hesitate to contact our office.

Respectfully,

Kevin Robertson, Pharm.D.
Inspector/Investigator

OurPharma
2512 S. City Lake Road | Fayetteville, AR 72701
479-313-8200 | ourpharma.net

December 28, 2020

VIA ELECTRONIC MAIL

Kevin Robertson, Pharm.D.; Inspector/Investigator
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201
Kevin.Robertson@arkansas.gov

RE: Response to Facility Inspection Conducted 16-18 November 2020

Dr. Robertson,

OurPharma would like to take this opportunity to respond to the requirements and/or recommendations listed in the Inspection Report issued on November 25, 2020 *("Report")*.

OurPharma would like to provide the Arkansas State Board of Pharmacy *("Board")* with assurance that it is committed to providing the highest quality compounded medications and to express appreciation for the collaborative spirit with which this inspection was conducted. OurPharma respects Dr. Robertson's expertise and takes the Board's remarks and concerns seriously.

OurPharma believes that the corrective actions set forth below will demonstrate its sincere intent to work cooperatively with the Board and meet all expectations for compliance. OurPharma hopes to continue constructive dialogue so that the facilities it serves can access high-quality compounded medications. As such, OurPharma provides the following responses to the concerns noted in the Report.

Concern 1: CFR 211.67(a) Equipment cleaning and maintenance

Specifically, a visible white residue left behind by cleaning agents was observed on windows and walls throughout the product production areas.

Specifically, damaged metal wall corner trim was observed to be scratched with exposed bare metal within the "negative storage room", caulk on ceiling tile seams was observed to not be smooth, and debris was observed on a cart's wheel located in the "west corridar".

OurPharma Response to Concern 1

OurPharma understands that visible residue left behind by cleaning agents is not ideal and is committed to identifying a method to remove or reduce this residue without compromising the disinfectant efficacy or environmental control of the production areas. Specifically, trial methods for residue removal were conducted utilizing both sterile water for injection and sterile isopropyl alcohol with sterile mops and rubber blades. The most promising methods will be formally evaluated through execution of STY-20-023 *Residue Reduction Study Protocol* (Exhibit 1). The objective of this study is to outline the procedure for the

determination and establishment of an effective and valid process for reduction of cleaning agent residues within the clean room environment while maintaining environmental control.

A qualified contact laboratory will perform microbiological identification testing as applicable and OurPharma will perform associated environmental monitoring. Results obtained from this study will be used in the determination of an effective residue reduction process and frequency. OurPharma anticipates the execution and analysis to be completed in January 2021 and will provide the Board a copy of the protocol summary report when it is available.

Additionally, the caulk that was not smooth was removed and reapplied the week of December 5, 2020. The exposed metal in negative storage (Room 2, ISO 8) was also repaired and cart wheels were cleaned. This work was completed under work order WO-189 (Exhibit 2) and was followed by a triple clean per SOP-GMP-0022 *Cleanroom Sanitization Procedure*. Photos of the reapplied caulk are included as Exhibit 3.

Concern 2: CFR 211.46, 211.22(c) and 211.22(d) Ventilation, air filtration, air heating and cooling/Responsibilities of quality control unit

Specifically, the third-party certification reports dated 5/15/20 and 11/07/20 did not provide congruency with internal facility monitoring records and/or related SOPs (i.e., 11/07/20 suite 1 humidity; 5/15/20 and 11/07/20 suite 1 HD buffer room pressure gradient excessively negative), and there was lack of documentation by the quality control unit related to these discrepancies.

OurPharma Response to Concern 2

OurPharma is committed to ensuring the facility certification contractor and report generated are appropriate for the facility, appropriately documented, and adequately reviewed. OurPharma provided the certification contractor (Advanced 797) with improvement requests for the next certification report, specifically:

- Identification of room names per approved facility drawings to ensure consistency
- Clear acceptance criteria for critical parameters such as temperature, humidity, and differential pressures
- Minimal ISO classifications for each area of the facility to be classified
- A facility map

These enhancements were used to amend the most recent facility certification report (Exhibit 4). OurPharma Quality then reevaluated the room certifications and pass/fail criteria. Additionally, OurPharma requested details regarding the sampling method and for the sampling locations to be indicated on the map in future reports. The clean room environment at OurPharma is scheduled for routine recertification under dynamic operating conditions in January 2021. Upon request, OurPharma will provide a copy of the January 2021 recertification to the Board when it is available.

Concern 3: CFR 211.22(c) Responsibilities of quality control unit

Specifically, the validation of the sodium chloride (lot 172631/C), sodium metabisulfite (1904100064), and norepinephrine bitartrate (lot 20J12-BB01-PR00997) vendors did not address why the manufacturer/repackager provided COAs did not include all aspects of the respective USP monograph (i.e., NaCl: limit of potassium <852> and aluminum; Na2S2O5: residual solvents <467>; norepinephrine bitartrate: residual solvents <467>).

Specifically, the firm's pest control reports were of inadequate detail to determine completeness, actions taken, and recommendations provided. In addition, there is a lack of documented prospective review by the quality control unit of pest control processes.

OurPharma Response to Concern 3

OurPharma understands the importance of assessing quality of raw materials and has reviewed FDA's current Guidance for Industry[1] (*"503B Guidance"*) to ensure its procedures comply with the current compliance expectations. The 503B Guidance requires that component specifications "address the attributes necessary to ensure the quality of the finished drug product" and "minimally include those tests described in ICH Q6A's section 3.2 'Universal Tests/Criteria.'" OurPharma notes that these 'Universal Tests/Criteria' include description, identification, and assay; OurPharma is currently performing a comprehensive assessment of all drug components to compare the manufacturer/repackager Certificate of Analysis (*"COA"*) to the respective monograph.

All components for which the COA does not identify full monograph compliance will be identified and any missing attributes assessed for criticality, including collaboration with the supplier to see if the missing elements can be added to the COA. If the supplier cannot or will not revise the COA it provides to OurPharma, a written risk assessment shall be performed to assess potential impact to compliance with the 503B Guidance. As applicable, OurPharma will revise component specifications and written procedures. This comprehensive assessment is expected to be completed in first quarter 2021. Upon request, OurPharma will provide the Board with an update upon completion.

OurPharma contacted its pest control contractor, Ridapest, to request increased robustness of their reports. Specifically, they have updated the facility map to include locations of recently added traps and will ensure that each of these traps are checked each time they service OurPharma's facility (biweekly). The reports will also include a specific breakdown of what pests are found in each of the traps, in what quantities, as well as any feedback they may have for improvement. SOP-GMP-0055 *Pest Control* was revised to add these requirements and to include additional detail on the pesticide application and report review process.

Concern 4: CFR 211.25(a) Personnel qualifications

Specifically, upon review of the training records for three individuals (PT04115; PT91633; PD08384) [the inspector] was unable to determine the degree of compliance with established firm training requirements.

OurPharma Response to Concern 4

Before responding, OurPharma would like to provide additional detail regarding this concern. Dr. Robertson reviewed training files for documentation related to material sanitization, cleaning, and aseptic technique; this training documentation was complete and present for all personnel files reviewed.

OurPharma acknowledges that the organization of personnel training files can be improved to more efficiently demonstrate both what training is required and what training has been completed. As a continuous improvement effort, Quality will be uniformly restructuring all training folders to organize the contents by date and separate didactic training from qualification activities. After this restructuring of the physical training files, Quality will then conduct an audit against current training matrices to ensure

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[1] Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; Draft Guidance for Industry. https://www.fda.gov/media/88905/download.

compliance with GMP-SOP-0020 *Employee Training Program*. Finally, each training file will receive a quick-reference cover sheet for those operational activities that require requalification, indicating the last date completed and the next due date. OurPharma anticipates these improvements will be completed in first quarter 2021. Upon request, an update will be provided to the Board.

In closing, OurPharma believes it has fully addressed the Board's Concerns and outlined appropriate corrective actions within respectable timelines. OurPharma welcomes any discussion the Board deems necessary to continue the collaborative and constructive dialogue that was present during the inspection.

Respectfully,

/s/ Morgan K. Strickland

Morgan K. Strickland, Pharm.D.

QA / RA Manager, OurPharma

Enclosures

OurPharma
2512 S. City Lake Road | Fayetteville, AR 72701
479-313-8200 | ourpharma.net | FEI 3014064135

October 15, 2021

Department of Health and Human Services
Food and Drug Administration
1201 Main Street, Suite 7200
Dallas, TX 75202
ORAPHARM2_RESPONSES@fda.hhs.gov

RE: FEI 3014064135; Response to Facility Inspection Conducted 20-30 September 2021

OurPharma LLC ("OurPharma") would like to take this opportunity to respond to the requirements listed in the Form FDA 483 observations issued to OurPharma LLC on September 30, 2021. OurPharma respects and appreciates the role of the FDA in ensuring regulatory compliance to promote patient safety and takes all FDA findings very seriously. OurPharma would like to provide the FDA with assurance that it is committed to providing the highest quality compounded medications and will be diligent in responding to the Form FDA 483 observations.

OurPharma is committed to continuous quality improvement and believes that the corrective actions set forth below will demonstrate its sincere intent to work cooperatively with the FDA to meet all expectations for regulatory compliance.

FDA Observation 1

Aseptic Processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm has no documented justification for the orientation of the non-viable particle monitoring probes located in the ISO 5 biological safety cabinets (BSC). The placement of the isokinetic probe is not fixed and is bumped and moved during cleaning of BSCs. Your firm cannot demonstrate that the orientation and placement of the probes provides o meaningful sample.

In addition, your firm has not qualified under actual conditions of use the non-viable particulate probes and the active air samplers within the ISO 5 BSCs. The system was initially qualified in December 2018 and the BSCs were not installed until sometime in January/February 2019.

OurPharma Response to Observation 1

In response to Observation 1, OurPharma would like to acknowledge the importance of having a robust environmental monitoring program. For that reason, the OurPharma facility utilizes continuous non-viable particle monitoring units that are placed inside both the facility's ISO 5 Biological Safety Cabinets (BSCs) and within each of the facility's ISO 7 buffer rooms. OurPharma recognizes and appreciates the FDA's

OurPharma
2512 S. City Lake Road | Fayetteville, AR 72701
479-313-8200 | ourpharma.net | FEI 3014064135

observation that the sampler probes within the ISO 5 BSCs should be positioned in a fully upright fashion, toward the direction of the airflow, to provide the most meaningful data. The sampling probes were reoriented into a fully upright position, prior to the end of the FDA inspection. As stated in the Form FDA 483 observation, the sampling probes can lose their orientation as they are moved for cleanroom sanitization activities, and OurPharma acknowledges that no "correct" position was previously defined in written procedures. OurPharma updated GMP-SOP-0131, Apex Remote Particle Counter SOP to depict the proper orientation of the non-viable sampler probe on 10/07/2021 (Attachment 1). All members of the Production, Quality, and Facilities departments at OurPharma were trained on the requirements of this procedure on 10/08/2021 (Attachment 2). In addition, prompts requiring employees to confirm correct probe orientation prior to initiating production activities were also placed within each master production batch record (example, Attachment 3).

Before responding to the second part of Observation 1, OurPharma would like to clarify that the continuous environmental monitoring system was initially installed and qualified in December 2018. The qualification included assessment of the adherence of the non-viable samplers to the Functional Design Specifications prescribed by Lighthouse Worldwide Solutions (LWS) and codified in LWS-S111978-FDS-001 within the ISO7 buffer room spaces. The BSCs were installed and then initially qualified on 02/10/2019. During initial qualification of the BSCs, the continuous particle monitoring units were present and operational within the BSCs. Additionally, the BSCs have been certified 5 times (every six months) since initial commissioning for use in accordance with established OurPharma procedures.

OurPharma acknowledges that the validated state of the non-viable particle monitoring units within the BSCs should have been confirmed in addition to or as part of initial commissioning of the BSCs and classified suite for use. To address this concern, OurPharma drafted validation protocol STY-21-009 (Attachment 4) to evaluate the non-viable samplers with placement inside the BSCs and has scheduled qualification to be completed no later than 11/30/2021. All original acceptance criteria will be assessed during the repeat execution of these protocols to confirm that the continuous non-viable monitoring system is and has been operating in a validated state.

FDA Observation 2:

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting to produce aseptic conditions.

Specifically, your firm did not include the material used for the arm rests on the ISO5 Biological Safety Cabinets (BSCs) in your disinfectant efficacy study. Your firm has no documentation to show that disinfectants used are effective on this material.

In addition, your firm has not evaluated the suitability of the material used for the arm rests for use in on ISO5/ISO7 cleanroom environment or for use in sterile production.

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2512 S. City Lake Road | Fayetteville, AR 72701
479-313-8200 | ourpharma.net | FEI 3014064135

OurPharma Response to Observation 2

OurPharma understands the importance of assessing disinfectant efficacy in the ISO classified spaces and is committed to evaluating the armrest material for appropriateness in the cleanroom environment. While OurPharma did perform a disinfectant efficacy study for materials present within the cleanroom environment, the firm acknowledges that the armrest material, which is factory-installed on the units by the BSC manufacturer, was inadvertently omitted from this study. To address this concern, OurPharma has procured the required coupons for the armrest material used on each of the BSCs and has scheduled a disinfectant efficacy study using this material to begin no later than 11/30/2021. The protocol (Attachment 5) will evaluate the efficacy of each disinfectant used in the ISO classified environment. OurPharma will also conduct an internal audit of the ISO classified environment to ensure that no additional materials were inadvertently omitted for inclusion in the disinfectant efficacy studies. If additional gaps are identified, a subsequent disinfectant efficacy study will be executed as outlined above.

Additionally, an evaluation of the materials of construction was completed. The armrest material for the BSC is composed of stainless steel coated in ethylene propylene diene monomer rubber (EPDM). EPDM is a common component in many cleanroom applications, including molding, gaskets, and seals. Due to the nature of the stainless steel and closed cell EPDM, the particle emission behavior and cleanability make them suitable for cleanroom applications. The BSC manufacturer's brochure (Attachment 6) confirms that the BSCs utilized at OurPharma are designed for application within the ISO5/ISO7 aseptic processing environment and also come with additional cGMP optional features.

OurPharma would like to clarify that the armrest materials are located at the edge of the ISO5 BSC, both behind and above the direct compounding area. Personnel have been trained to only place elbows on these armrests and always work at least 6 inches within the BSC. In addition, routine personnel monitoring samples are collected both during and after routine compounding activities and include both fingertip and forearm samples. An assessment of OurPharma's current processes and environmental control, in the absence of a formal study, was completed to determine whether or not the arm rests should be removed in the interim. Environmental monitoring data for August 2020 through August 2021 (Attachment 7) was evaluated for each suite in which production activities occurred with no adverse trends noted. Trending demonstrated that out of over 8000 viable samples, 99.44% of all viable air, surface, and personnel monitoring samples collected within the ISO 7 Buffer Rooms and the ISO 5 BSCs recovered zero (0) Colony Forming Units (CFUs). Only one (1) sample exceeded CFU action limits. Based on this analysis of historical environmental trending, the classified environment is operating with a high level of environmental control.

Because of the way the BSCs are designed, in order to temporarily remove the armrest, the front portion of the hood itself would have to be removed, which would be a critical change to the design and invalidate the units' current qualifications for use. Given the historically demonstrated high level of environmental control, OurPharma believes attempting to temporarily remove the armrests would present a significantly higher risk than their continued use during execution of the disinfectant efficacy study. OurPharma expects the disinfectant efficacy study to be completed in Q4 2021 and will provide FDA with a copy of the completed summary report when it is available.

OurPharma
2512 S. City Lake Road | Fayetteville, AR 72701
479-313-8200 | ourpharma.net | FEI 3014064135

In closing, OurPharma wants to express its appreciation for the collaborative and professional discussions with FDA during this inspection. The firm believes the responses described herein fully resolve the 483 observations outlined by the inspector.

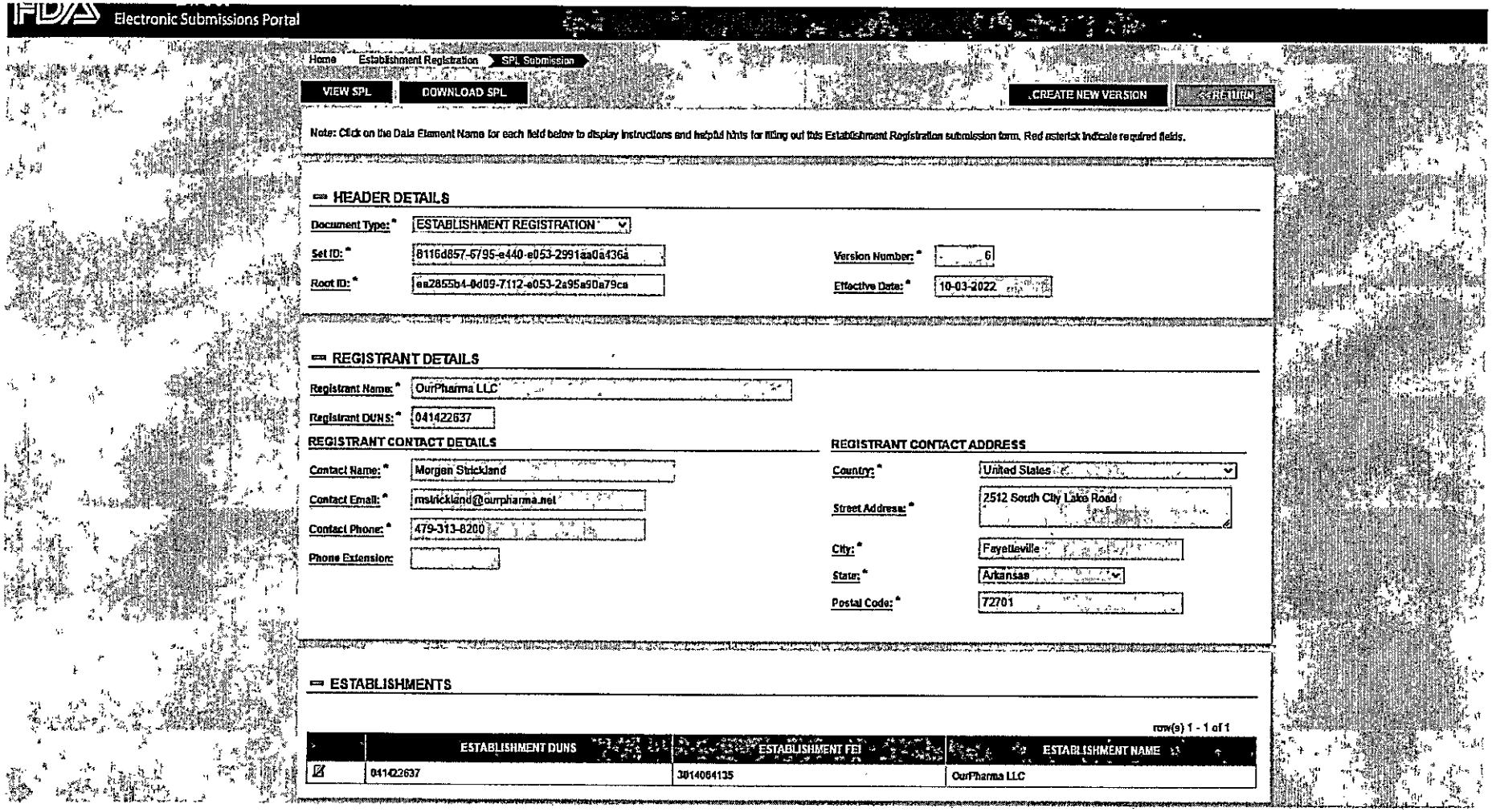
Respectfully,

Morgan K. Strickland, Pharm.D.

QA/RA Manager, OurPharma

cc Kevin Robertson, Pharm.D.; Arkansas State Board of Pharmacy

Peter O. Kohler, MD; OurPharma President & CEO



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REGISTRANT DETAILS

Registrant Name: * OurPharma LLC

Registrant DUNS: * 041422637

REGISTRANT CONTACT DETAILS

Contact Name: * Morgan Strickland

Contact Email: * mstrickland@ourpharma.net

Contact Phone: * 479-313-8200

Phone Extension:

REGISTRANT CONTACT ADDRESS

Country: * United States

Street Address: * 2512 South City Lake Road

City: * Fayetteville

State: * Arkansas

Postal Code: * 72701

ESTABLISHMENTS

row(s) 1 - 1 of 1

	ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
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Issue Date:	12/14/2018
Expiration Date:	12/31/2024
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Current Standing:	Good Standing
Disciplinary Action:	No
Address:	2512 South City Lake Road Fayetteville, AR 72701
Phone:	(479)313-8200
Fax:	(479)713-8181

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322 South Main Street, Suite 600
Little Rock, AR 72201
Phone: 501-682-0190 | Fax: 501-682-0195
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Hikma Pharmaceuticals USA Inc., Cherry Hill, NJ	J. Barton Kalis 856-489-2247	9/15/2021	12/5/2022	7/7/2022	No	Open
Hybrid Pharma, LLC, Deerfield Beach, FL	Ponswamy Rajalingam 954-708-2771	1/14/2015	11/7/2022	9/3/2021	Yes (https://www.fda.gov/media/158758/download)	Warning Letter Issued 6/7/2022 (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hybrid-pharma-llc-629021-06072022)
Imprimis NJOF, LLC, Ledgewood, NJ	Jeffrey Palmer +1-973-804-1635	11/12/2016	11/19/2022	1/29/2021	Yes (https://www.fda.gov/media/151431/download)	Regulatory Meeting Held 8/29/22
IntegraDose Compounding Services, LLC, Minneapolis, MN	Craig Else 612-672-5216	5/8/2018	11/2/2022	8/2/2021	Yes (/about-fda/fda-commissioner/integradose-compounding-services-llc-minneapolis-mn-483-issued-08022021)	Recall Initiated 9/2021 (/safety/recalls-market-withdrawals-safety-alerts/integradose-compounding-services-llc-issues-voluntary-nationwide-recall-cefazolin-injection-products)
KRS Global Biotechnology, Inc., Boca Raton, FL	Charles Richardson 888-502-2050	12/15/2013	12/6/2022	8/14/2019	Yes (https://www.fda.gov/media/134261/download)	Regulatory Meeting Held 7/30/2021
Leesar Inc., Fort Myers, FL	Maria Gautier 239-939-8925	4/30/2014	11/15/2022	10/29/2021	Yes (https://www.fda.gov/media/156685/download)	Untitled Letter Issued 6/17/2022 (https://www.fda.gov/media/163365/download)
Mark Cuban Cost Plus Drug Company, PBC, Dallas, TX	Alexander Oshmyansky 303-907-8003	11/2/2022	11/2/2022	Not yet inspected	N/A	N/A
McGuff Outsourcing Solutions, Inc. Santa Ana, CA	Si Pham 1-800-603-4795; ext=314	1/11/2023	1/11/2023	Not yet inspected	N/A	Yes
Medi-Fare Drug, Blacksburg, SC	Anne-Marie Davis 864-839-6500	12/17/2013	12/27/2022	4/6/2017	No	Remote Regulatory Assessment Assignment Issued 1/25/2021[8]
MedisourceRx, Los Alamitos, CA	Amy Summers 714-455-1300	2/14/2017	11/15/2022	11/10/2022	Yes	Open[7]
Molecular PharmaGroup, New Providence, NJ	Amanda Lanze 908-588-3440	5/8/2018	12/19/2022	Not yet inspected	N/A	N/A
Nephron Sterile Compounding Center, LLC (NSCC), West Columbia, SC	Lou Kennedy 803-569-3110	7/15/2014	11/9/2022	2/10/2023	Yes	Open[7]
New England Life Care, Inc. dba Advanced Compounding Solutions, Woburn, MA	Roula Samhoun 781-832-5758	3/2/2017	12/20/2022	4/28/2022	Yes (https://www.fda.gov/media/162647/download)	Open[7]
Nubratori, Inc., Torrance, CA	Gulshakar Khwaja 310-218-4153	2/24/2017	10/28/2022	12/20/2021	No	FMD-145 Letter Issued 5/6/2022
Olympia Compounding Pharmacy, Orlando, FL	Marco Loleit 407-673-2222	3/10/2014	11/1/2022	3/2/2022	Yes (https://www.fda.gov/media/160667/download)	Open[7]
OurPharma LLC, Fayetteville, AR	Morgan Strickland 479-313-8200	3/15/2019	11/8/2022	9/30/2021	Yes (https://www.fda.gov/media/154264/download)	FMD-145 Letter Issued 3/14/2022

Registered Outsourcing Facilities

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 4/24/2023

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility[1]	Date of Most Recent Registration as an Outsourcing Facility[1]	End Date of Last FDA Inspection Related to Compounding[2]	Was a Form FDA-483 issued?[3]	Other Action, if Any, Based on Last Inspection[4,5]
AnazaoHealth Corporation, Las Vegas, NV	Jaclyn Wong 800-995-4363 Ext=3120	9/23/2014	11/29/2022	7/29/2022	Yes (https://www.fda.gov/media/163365/download)	Open[7]
ANNOVEX PHARMA, INC, Lorton, VA	Kenneth Erickson 540-642-5104	10/14/2021	10/30/2022	Not yet inspected	N/A	N/A
Apollo Care, Columbia, MO	Jarred Dudding 573-441-8900	9/14/2017	1/3/2023	9/8/2021	Yes (https://www.fda.gov/media/158299/download)	Open[7]
Athenex Pharma Solutions, LLC, Clarence, NY	Lori Giles Aleshin 716-815-6478	4/10/2017	11/10/2022	8/28/2019	Yes (https://www.fda.gov/media/132333/download)	FMD-145 Letter Issued 8/10/2021
Atlas Pharmaceuticals, Phoenix, AZ	Nickolaus Banda 480-208-1855	11/8/2017	12/21/2022	5/21/2021	Yes (/about-fda/fda-commissioner/atlas-pharmaceuticals-llc-phoenix-az-483-issued-05212021)	FMD-145 Letter Issued 5/3/2022
BayCare Integrated Service Center, LLC dba BayCare Central Pharmacy, Temple Terrace, FL	Kenneth Jozefczyk 813-901-6339	6/4/2019	11/10/2022	12/10/2019	Yes (https://www.fda.gov/media/152762/download)	FMD-145 Letter Issued 4/4/2022
Belcher Pharmaceuticals, LLC, Largo, FL	Shyam Busireddy 727-471-0850	05/18/2021	11/9/2022	Not yet inspected	N/A	N/A
Bennett Pharmaceuticals of America LLC, Hudson, WI	James Mulvahill 952-381-9027	4/19/2022	1/16/2023	Not yet inspected	N/A	N/A
BPI Labs LLC, Largo, FL	Chandra Kasireddy 727-471-0850	3/4/2019	11/10/2022	4/30/2021	Yes (https://www.fda.gov/media/158757/download)	FMD-145 Letter Issued 9/10/2021
Brookfield Medical/Surgical Supply, Inc., Brookfield, CT	James Cangelosi 203-775-0862	1/12/2015	12/20/2022	4/4/2022	Yes (https://www.fda.gov/media/161532/download)	Open
BSO LLC, Lakewood, CO	Anne Szilagyi 877-267-3410	11/24/2015	11/2/2022	3/11/2021	Yes (https://www.fda.gov/media/149780/download)	FMD-145 Letter Issued 9/10/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	9/20/2021-9/30/2021* FEI NUMBER 3014064135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Peter O. Kohler, President & CEO

FIRM NAME	STREET ADDRESS
OurPharma LLC	2512 S City Lake Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, AR 72701-5013	Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm has no documented justification for the orientation of the non-viable particle monitoring probes located in the ISO 5 biological safety cabinets (BSC). The placement of the isokinetic probe is not fixed and is bumped and moved during cleaning of the BSCs. Your firm cannot demonstrate that the orientation and placement of the probes provides a meaningful sample.

In addition, your firm has not qualified under actual conditions of use the non-viable particulate probes and the active air samplers within the ISO 5 BSCs. The system was initially qualified in December 2018 and the BSCs were not installed until sometime in January/February 2019.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the to produce aseptic conditions.

Specifically, your firm did not include the material used for the arm rests on the ISO 5 Biological Safety Cabinets (BSC) in your disinfectant efficacy study. Your firm has no documentation to show that the disinfectants used are effective on this material.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO	X	9/30/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	9/20/2021-9/30/2021* FEI NUMBER 3014064135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Peter O. Kohler, President & CEO

FIRM NAME	STREET ADDRESS
OurPharma LLC	2512 S City Lake Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, AR 72701-5013	Outsourcing Facility

In addition, your firm has not evaluated the suitability of the material used for the arm rests for use in an ISO5/ISO 7 cleanroom environment or for use in sterile production.

***DATES OF INSPECTION**
9/20/2021(Mon), 9/21/2021(Tue), 9/22/2021(Wed), 9/23/2021(Thu), 9/24/2021(Fri), 9/27/2021(Mon), 9/28/2021(Tue), 9/29/2021(Wed), 9/30/2021(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO	X	9/30/2021

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: OurPharma LLC

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 2512 S City Lake Rd

City: Fayetteville State: AR Zip: 72701

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 479-313-8200 Website: www.ourpharma.net

Licensing Company Email:

Section 2: Personal Information

First: Peter Middle: Ogden Last: Kohler

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] E Leawood Way

City: Fayetteville State: AR Zip: 72703

Telephone: [redacted] Email: pKohler@ourpharma.net

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Blacksburg High School		09/51-05/55	
Address	**City**	**State**	**Zip**
3401 Bruin Lane	Blacksburg	VA	24060
Diploma/Degree obtained, if any			
Certificate			
School Name		**From - To (MM/YY – MM/YY)**	
University of Virginia		8/55 - 6/59	
Address	**City**	**State**	**Zip**
UREG P.O. Box 400203	Charlottesville	VA	22903
Diploma/Degree obtained, if any			
B.A.			
School Name		**From - To (MM/YY – MM/YY)**	
Duke Medical School		8/59 - 5/63	
Address	**City**	**State**	**Zip**
124 Davison Bldg.	Durham	NC	27710
Diploma/Degree obtained, if any			
MD			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/06-08/23	[redacted] E Leawood Way	Fayetteville	AR	72703
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: OurPharma LLC				From - To (MM/YY – MM/YY): 08/16 to 08/23
Business Address: 2512 City Lake Road	City: Fayetteville	State: AR	Zip: 72701	
Phone: 479-313-8200	Title: CEO			
Description of Duties: overall responsibility for activities and operations				

Business Name: University of Arkansas for Medical Sciences (UAMS)				From - To (MM/YY – MM/YY): 03/09 – 06/16
Business Address: 1125 N. College Ave	City: Fayetteville	State: AR	Zip: 72703	
Phone: 479-713-8000	Title: Vice Chancellor			
Description of Duties: Overall responsible for academic activities of branches of pharmacy, medical and nursing schools on regional campus				

Business Name				From - To (MM/YY – MM/YY)
Business Address	City	State	Zip	
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address	City	State	Zip	
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address	City	State	Zip	
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	X	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
		AR	Fayetteville	Washington
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
OurPharma LLC				
Name of Business/Industry/Entity				
Cromwell Construction				

Provide explanation below:

In 2019, there were issues that arose with the original design and construction of our facility. Since the parties were unable to come to an acceptable resolution on our own, the contract called for those issues to be addressed through mediation first, then arbitration through the AAA, if necessary. OurPharma participated as the Claimant in that process which was fully resolved in July, 2022.

Original Signature (electronic, copies or stamps not accepted)

8/21/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Kohler

Print Name (First, Last)

Peter Kohler

Original Signature (electronic, copies or stamps not accepted)

8/22/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Arkansas, ss. County of Washington

I, Peter Kohler, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Peter Kohler

Original Signature

8/22/2023

Date

Subscribed and Sworn to before me this 22nd day of August 2023.

Notary Public Signature

JACOB L SKLAR COMM. # 12717040 NOTARY PUBLIC MY COMM. EXP. NOV 22, 2031 WASHINGTON COUNTY, ARKANSAS

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

4

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler OurPharma, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 2512 S City Lake Road

City Fayetteville State AR Zip 72701

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (479) 313-8200 Website www.ourpharma.net

Licensing Company Email mstrickland@ourpharma.net

Section 2: Personal Information

First Angela Middle Eve Last Harrison

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Hickory Creek Drive

City Little Rock State AR Zip 72212

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Arkansas		09/85 - 05/89	
Address	**City**	**State**	**Zip**
1125 West Maple Street	Fayetteville	AR	72701
Diploma/Degree obtained, if any			
Bachelor of Arts - Psychology			

School Name		From - To (MM/YY – MM/YY)	
Pulaski Academy		09/82 - 05/85	
Address	**City**	**State**	**Zip**
12701 Hinson Road	Little Rock	AR	72212
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/08 - Current	[redacted]Hickory Creek Drive	Little Rock	AR	72212
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
WELSCO, Inc.			03/91 - Current	
Business Address		**City**	**State**	**Zip**
9006 Crystal Hill Road		North Little Rock	AR	72113
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
11/22/2004	07/29/009	AR	Hamburg	Ashley
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CV-04-299-3		Ashley County Circuit Court		
Reason/Charge				
Welding Fume Lawsuit				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Defendant			Lawsuit	
Name of Business/Industry/Entity				
WELSCO, Inc.				

Provide explanation below:

Around 2004, an Arkansas attorney began filing a number of welding fume/welding rod lawsuits in various circuit courts throughout the state attempting to recover monetary damages from the welding rod manufacturers for the plaintiff's exposure to welding fumes. Plaintiffs' attorney admitted to Ms. Harrison that he only named WELSCO, Inc (domiciled in Arkansas and a distributor of the products) as a defendant in addition to the manufacturer in order to keep the suits in the Arkansas Circuit Courts. The lawsuits involving WELSCO, Inc. as a named defendant were dismissed without prejudice.

Original Signature (electronic, copies or stamps not accepted)

March 29, 2023
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
11/22/2004	08/05/2009	AR	Hamburg	Ashley
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CV-04-300-3		Ashley County Circuit Court		
Reason/Charge				
Welding Fume Lawsuit				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Defendant		Lawsuit		
Name of Business/Industry/Entity				
WELSCO, Inc.				

Provide explanation below:

Around 2004, an Arkansas attorney began filing a number of welding fume/welding rod lawsuits in various circuit courts throughout the state attempting to recover monetary damages from the welding rod manufacturers for the plaintiff's exposure to welding fumes. Plaintiffs' attorney admitted to Ms. Harrison that he only named WELSCO, Inc (domiciled in Arkansas and a distributor of the products) as a defendant in addition to the manufacturer in order to keep the suits in the Arkansas Circuit Courts. The lawsuits involving WELSCO, Inc. as a named defendant were dismissed without prejudice.

Original Signature (electronic, copies or stamps not accepted)

March 29, 2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angela Harrison

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

April 5, 2023

Date

Please have this section completed in the presence of a Notary Public.

State of Arkansas, ss. County of Pulaski

I, Aline Daniels, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Aline Daniels

Original Signature

April 19, 2023

Date

Subscribed and Sworn to before me this 19th day of April, 2023

Aline Daniels

Notary Public Signature

ALINE DANIELS
Comm. No. 12389197
NOTARY PUBLIC
My Comm. Exp. Feb. 1, 2029
PULASKI CO., ARKANSAS

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler OurPharma, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 2512 S City Lake Road

City Fayetteville State AR Zip 72701

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 479/313-8200 Website www.ourpharma.net

Licensing Company Email mstrickland@ourpharma.net

Section 2: Personal Information

First William Middle Edward Last Clark

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]Cameronwood Road

City Little Rock State AR Zip 72223

Telephone [redacted] Email wclark@clarkcontractors.net

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Arkansas		08/87 - 05/91	
Address	**City**	**State**	**Zip**
1 University of Arkansas	Fayetteville	AR	72701
Diploma/Degree obtained, if any			
Bachelor of Science Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Little Rock Central High		01/86 - 05/87	
Address	**City**	**State**	**Zip**
1500 S. Park St.	Little Rock	AR	72202
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Catholic High School for Boys		08/83 - 12/85	
Address	**City**	**State**	**Zip**
6300 Father Tribou St.	Little Rock	AR	72205
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/13 - 03/23	[redacted] Cameronwood Road	Little Rock	AR	72223
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Clark Contractors, LLC			01/09 - 03/23
Business Address	**City**	**State**	**Zip**
15825 Cantrell Road	Little Rock	AR	72223
Phone	**Title**		
501/868-3133	CEO		
Description of Duties			
Strategic planning, business development			

Business Name			From - To (MM/YY – MM/YY)
Simmons Bank			01/08 - 03/23
Business Address	**City**	**State**	**Zip**
501 S. Main St.	Pine Bluff	AR	71601
Phone	**Title**		
870/541-1300	Corporate Director		
Description of Duties			
Strategic oversight			

Business Name			From - To (MM/YY – MM/YY)
D1 Little Rock			10/14 - 03/23
Business Address	**City**	**State**	**Zip**
10 Viewpointe Cove	Little Rock	AR	72223
Phone	**Title**		
501/289-5609	Investor		
Description of Duties			
None			

Business Name			From - To (MM/YY – MM/YY)
NewCrest Image Real Estate Fund II, LP			02/21 - 03/23
Business Address	**City**	**State**	**Zip**
15825 Cantrell Road	Little Rock	AR	72223
Phone	**Title**		
501/868-3133	Partner		
Description of Duties			
Review bank statements and investment updates, forward communications to other partners			

Business Name			From - To (MM/YY – MM/YY)
Crossroads, LLC			08/06 - 03/23
Business Address	**City**	**State**	**Zip**
3111 JFK Blvd.	NoAh Little Rock	AR	72116
Phone	**Title**		
501 912-1000	Investor		
Description of Duties			
None			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
CR Retail, LLC			03/07 - 03/23	
Business Address		City	State	Zip
3111 JFK Blvd.		North Little Rock	AR	72116
Phone	Title			
501 912-1000	Investor			
Description of Duties				
None				

Business Name			From - To (MM/YY – MM/YY)	
Purple Bear, LLC			05/07 - 03/23	
Business Address		City	State	Zip
3111 JFK Blvd.		North Little Rock	AR	72116
Phone	Title			
501 912-1000	Investor			
Description of Duties				
None				

Business Name			From - To (MM/YY – MM/YY)	
Tempus Grand Rapids			07/21 - 03/23	
Business Address		City	State	Zip
One Allied Drive, Suite 2410		Little Rock	AR	72202
Phone	Title			
501/340-0457	Investor			
Description of Duties				
None				

Business Name			From - To (MM/YY – MM/YY)	
CapRoq Core I			12/12 - 03/23	
Business Address		City	State	Zip
One Allied Drive, Suite 2410		Little Rock	AR	72202
Phone	Title			
501/340-0457	Investor			
Description of Duties				
None				

Business Name			From - To (MM/YY – MM/YY)	
1201 Baucum, LLC			05/19 - 03/23	
Business Address		City	State	Zip
One Allied Drive, Suite 2410		Little Rock	AR	72202
Phone	Title			
501/340-0457	Investor			
Description of Duties				
None				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Business Interests cont'd.

11300 CW Building 03/21 – 03/23
One Allied Drive, Suite 2410 Little Rock, AR 72202 501/340-0457
Investor – no duties

Tempus Crosspoint 09/19 – 03/23
One Allied Drive, Suite 2410 Little Rock, AR 72202 501/340-0457
Investor – no duties

Boise Tempus Kimball, LLC 04/17 – 04/21
One Allied Drive, Suite 2410 Little Rock, AR 72202 501/340-0457
Investor – no duties

Tempus Oshkosh, LLC 09/20 – 12/21
One Allied Drive, Suite 2410 Little Rock, AR 72202 501/340-0457
Investor – no duties

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Clark

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-13-23

Date

Please have this section completed in the presence of a Notary Public.

State of Arkansas, ss. County of Pulaski

I, Carrie M Dailey, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Carrie M Dailey

Original Signature

3-13-2023

Date

Subscribed and Sworn to before me this 13th day of March, 2023

Notary Public Signature

SHARON K. ISHAM
COMM. EXP.
12-06-2030
No. 12379976
FAULKNER
COUNTY
(Seal)
NOTARY PUBLIC - ARKANSAS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler OurPharma, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 2512 S City Lake Road

City Fayetteville State AR Zip 72701

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (479) 313-8200 Website www.ourpharma.net

Licensing Company Email mstrickland@ourpharma.net

Section 2: Personal Information

First Carlos Middle _____ Last Lagomarsino

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] E. Las Olas Blvd. Unit [redacted]

City Fort Lauderdale State FL Zip 33301

Telephone [redacted] Email Cllago@bellsouth.net

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of NC at Chapel Hill		1982 - 1985	
Address	**City**	**State**	**Zip**
	Chapel Hill	NC	
Diploma/Degree obtained, if any			
B.A. Economics			
School Name		**From - To (MM/YY – MM/YY)**	
Apex High School		1978-1982	
Address	**City**	**State**	**Zip**
	Apex	NC	
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/21 - present	[redacted] E. Las Olas Blvd. unit [redacted]	Fort Lauderdale	FL	33301
02/20 - 05/21	[redacted] Mercato Way	Naples	FL	34108
07/17 - 02/20	[redacted] Highway A1A	Vero Beach	FL	32963
01/12 - 07/17	[redacted] Mola Ave.	Fort Lauderdale	FL	33301
1/05 - 01/12	[redacted] Bala Lane	Wilmington	NC	28409

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Cloudhesive			07/14 - present
Business Address	**City**	**State**	**Zip**
	Fort Lauderdale	FL	
Phone	**Title**		
	Shareholder/seed capital		
Description of Duties			
Provided Startup Capital and Board Observer			

Business Name			From - To (MM/YY – MM/YY)
HomeInsurance.com			10/07 - 5/12
Business Address	**City**	**State**	**Zip**
	Wilmington	NC	
Phone	**Title**		
	Owner		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Allstate			06/92 - 10/07
Business Address	**City**	**State**	**Zip**
	Wilmington	NC	
Phone	**Title**		
	Owner		
Description of Duties			
Owner of Allstate Agency			

Business Name			From - To (MM/YY – MM/YY)
Procter and Gamble			09/85-06/92
Business Address	**City**	**State**	**Zip**
	Cincinnati	OH	
Phone	**Title**		
	International District Manager		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Martin Self Storage			2007 - present
Business Address	**City**	**State**	**Zip**
	Wilmington	NC	
Phone	**Title**		
	Owner		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Ourpharma			2019 - present
Business Address	City	State	Zip
	Fayetteville	AR	72701
Phone	Title		
	Shareholder		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date 3/11/23

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lagomarsino, Carlos

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 3/11/23

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, Carlos Lagomarsino, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date 3/11/23

Subscribed and Sworn to before me this 11 day of March 2023

Vershaum Smith

Notary Public Signature

Vershaum Smith
Comm.: HH 164116
Expires: Aug. 11, 2025
Notary Public - State of Florida

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: OurPharma LLC

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 2512 South City Lake Road

City: Fayetteville State: AR Zip: 72701

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 4793138200 Toll Free # (NAC 639.708, NRS 639.23286): N/A

Fax: N/A Contact Email: mstrickland@ourpharma.net

Website: https://ourpharma.net/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Morgan Strickland

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23136

Name of Person with direct knowledge of compounding procedures: Morgan Strickland

Email of Person with direct knowledge of compounding procedures: mstrickland@ourpharma.net

Telephone of Person with direct knowledge of compounding procedures: 4793138223

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ■ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
SEE ATTACHED (Sterile Compounded Products Spreadsheet)

4. Will you be utilizing beyond use dates in excess of USP-797? ■ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
All products are assessed for expiration dating through stability testing via a third party laboratory. These practices follow guidelines set forth in the Code of Federal Regulations Title 21.
SEE ATTACHED (Stability Program SOP)

6. What laboratory performs this additional testing?
Name: ARL BioPharma (Analytical Research Laboratories)
Address: 840 Research Parkway, Ste. 546
City: Oklahoma City State: OK Zip: 73104
Telephone: 4052711144

7. What is your procedure for visual inspection of compounded sterile products?
SEE ATTACHED (Visual Inspection Process of Finished Product)

8. How often do you perform glove fingertip and medial fill testing?

Fingertips: SEE ATTACHED (Environmental and Personnel Monitoring SOP)
Media Fills: SEE ATTACHED x2 (Aseptic Process Validation) (Aseptic Personnel Qualification)

9. What is your policy if an employee fails a glove fingertip or media-fill test?

SEE ATTACHED (Aseptic Personnel Qualification)
SEE ATTACHED (Cleanroom Gowning Qualification)
SEE ATTACHED (Environmental and Personnel Monitoring SOP)
SEE ATTACHED (Incidents, Deviations, and Non-Conformances)

10. Describe your initial and annual training program for all personnel performing sterile compounding:

SEE ATTACHED (Employee Training Program)
SEE ATTACHED (Aseptic Personnel Qualification)
SEE ATTACHED (Cleanroom Gowning Qualification)

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

SEE ATTACHED (Cleanroom Sanitization Procedure)

12. Who performs the sterile compounding process at your facility?

Sterile compounding processes are performed by personnel who have completed training, been tested for competency, and qualified through our Aseptic Personnel Qualification process (see attached). The only personnel eligible for sterile compounding qualification are pharmacists and pharmacy technicians holding the title of Aseptic Specialist, Senior Aseptic Specialist, or Operations Trainer.

13. Who is responsible and accountable for the sterile compounding process at your facility?

Primary Compounding Supervisors: Operations Manager Daniel Hubbard, Operations Pharmacists Allen Snider, David Freeman, and Lacy Archer, Director of Quality & Regulatory Affairs Morgan Strickland, and VP of Operations Patrick Gerhardt. All personnel are responsible and accountable for all actions performed.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

SEE ATTACHED (Packaging and Shipping)

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

All of our products are considered high risk due to the number of manipulations and large potential batch sizes.
SEE ATTACHED (Sterile Compounded Products Spreadsheet)

2. What sterilization methods are utilized at your facility?

Aseptic, sterilizing filtration is performed after formulation for products compounded from API.

3. Does your facility utilize biological indicators? ☐ Yes ☒ No

4. If yes, describe how they are utilized:

N/A

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jacob L Sklar

Name of Person who Completed the Form

Compliance Coordinator

Title

Signature (copies or stamps not accepted)

08/23/2023

Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

OurPharma LLC - Sterile Compounded Products to Potentially be Sold to Nevada Customers (as of August 2023)				
NDC	API	Strength/Volume	Container	Notes
73013- 1001-01	Fentanyl Citrate	2.5mg/50mL	50mL Cassette	Repackaged from vials
73013- 1004-01	Fentanyl Citrate & Bupivacaine HCl	100mcg/50mL & 0.125%	60mL Syringe	
73013- 1007-01	Fentanyl Citrate	2.5mg/50mL	60mL Syringe	
73013- 1010-01	Morphine Sulfate	30mg/30mL	30mL PCA Vial	
73013- 1013-01	Fentanyl Citrate	1mg/100mL	100mL Bag	Filled by addition to NaCl bag
73013- 1014-01	Fentanyl Citrate & Bupivacaine HCl	500mcg/250mL & 0.125%	250mL Bag	Filled by addition to NaCl bag
73013- 1016-01	Fentanyl Citrate	2.5mg/250mL	250mL Bag	Filled by addition to NaCl bag
73013- 1019-01	Fentanyl Citrate & Bupivacaine HCl	200mcg/100mL &0.125%	100mL Bag	Filled by addition to NaCl bag
73013- 1020-01	Morphine Sulfate	30mg/30mL	30mL BD Syringe	
73013- 1021-01	Morphine Sulfate	30mg/30mL	35mL Monoject Syringe	
73013- 1022-01	Morphine Sulfate	30mg/30mL	35mL Plungerless Syringe	
73013- 1023-01	Fentanyl Citrate & Bupivacaine HCl	500mcg/250mL & 0.1%	250mL Bag	Filled by addition to NaCl bag
73013- 1025-01	Fentanyl Citrate & Bupivacaine HCl	200mcg/100mL & 0.0625%	100mL Bag	Filled by addition to NaCl bag
73013- 1027-01	Fentanyl Citrate & Bupivacaine HCl	200mcg/100mL & 0.0625%	100mL Cassette	
73013- 1028-01	Fentanyl Citrate & Bupivacaine HCl	200mcg/100mL & 0.125%	100mL Cassette	
73013- 1030-01	Hydromorphone HCl	10mg/50mL	50mL Cassette	
73013- 1031-01	Hydromorphone HCl	20mg/100mL	100mL Cassette	
73013- 1032-01	Hydromorphone HCl	6mg/30mL	30mL BD Syringe	
73013- 1033-01	Hydromorphone HCl	6mg/30mL	35mL Monoject Syringe	
73013- 1034-01	Hydromorphone HCl	6mg/30mL	35mL Plungerless Syringe	
73013- 1035-01	Hydromorphone HCl	6mg/30mL	30mL PCA Vial	
73013- 1040-01	Hydromorphone HCl	50mg/50mL	50mL Cassette	
73013- 1041-01	Hydromorphone HCl	100mg/100mL	100mL Cassette	
73013- 1042-01	Hydromorphone HCl	30mg/30mL	30mL BD Syringe	
73013- 1043-01	Hydromorphone HCl	30mg/30mL	35mL Monoject Syringe	
73013- 1044-01	Hydromorphone HCl	30mg/30mL	35mL Plungerless Syringe	
73013- 1045-01	Hydromorphone HCl	30mg/30mL	30mL PCA Vial	
73013- 1050-01	Fentanyl Citrate & Ropivacaine HCl	200mcg/100mL & 0.1%	100mL Bag	Filled by addition to NaCl bag
73013- 1052-01	Fentanyl Citrate & Ropivacaine HCl	300mcg/150mL & 0.2%	150mL Bag	Filled by addition to NaCl bag
73013- 1053-01	Fentanyl Citrate & Ropivacaine HCl	500mcg/250mL & 0.2%	250mL Bag	Filled by addition to NaCl bag
73013- 2000-01	Ketamine HCl	50mg/1mL	3mL Syringe	Repackaged from vials
73013- 2000-02	Ketamine HCl	25mg/0.5mL	3mL Syringe	Repackaged from vials
73013- 2001-01	Ketamine HCl	500mg/10mL	12mL Syringe	
73013- 2001-02	Ketamine HCl	250mg/5mL	6mL Syringe	
73013- 2001-03	Ketamine HCl	50mg/1mL	3mL Syringe	
73013- 2002-01	Ketamine HCl	10mg/1mL	3mL Syringe	
73013- 2002-02	Ketamine HCl	50mg/5mL	6mL Syringe	
73013- 2002-03	Ketamine HCl	100mg/10mL	12mL Syringe	
73013- 2004-01	Ketamine HCl	15mg/50mL	50mL Bag	Filled by addition to NaCl bag
73013- 2012-01	Ketamine HCl	200mg/100mL	100mL Bag	Filled by addition to NaCl bag
73013- 2016-01	Ketamine HCl	1.25g/250mL	250mL Bag	Filled by addition to NaCl bag
73013- 2018-01	Ketamine HCl	25mg/1mL	3mL Syringe	
73013- 4001-01	Ropivacaine HCl	0.1%	250mL Bag	Filled by addition to NaCl bag
73013- 4001-02	Ropivacaine HCl	0.1%	500mL Bag	Filled by addition to NaCl bag
73013- 4002-01	Ropivacaine HCl	0.2%	250mL Bag	Filled by addition to NaCl bag
73013- 4002-02	Ropivacaine HCl	0.2%	500mL Bag	Filled by addition to NaCl bag
73013- 4004-01	Bupivacaine HCl	0.1%	100mL Bag	Filled by addition to NaCl bag
73013- 4004-02	Bupivacaine HCl	0.1%	250mL Bag	Filled by addition to NaCl bag
73013- 4005-01	Bupivacaine HCl	0.125%	100mL Bag	Filled by addition to NaCl bag
73013- 4005-02	Bupivacaine HCl	0.125%	250mL Bag	Filled by addition to NaCl bag
73013- 4006-01	Bupivacaine HCl	0.2%	100mL Bag	Filled by addition to NaCl bag
73013- 4006-02	Bupivacaine HCl	0.2%	250mL Bag	Filled by addition to NaCl bag

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STABILITY PROGRAM SOP

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Table of Contents

1.0 PURPOSE 3
2.0 SCOPE 3
3.0 DEFINITIONS 3
4.0 RESPONSIBILITIES 4
5.0 PROCEDURE 4
6.0 APPLICABLE REFERENCES 10
7.0 QUALITY DOCUMENTS 10

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1. PURPOSE

1.1. This procedure describes the process by which stability studies are managed and executed. Data from the stability life cycle of chemical, physical, and microbiological changes will provide evidence to support product expiry when stored under labeled conditions.

2. SCOPE

2.1. This procedure applies to all drug products manufactured or repackaged by OurPharma, LLC which are intended for commercial distribution.

3. DEFINITIONS

3.1. Antimicrobial Effectiveness Testing – Testing that ensures that multiple dose products demonstrate effective antimicrobial effectiveness.

3.2. BUD – Beyond Use Dating – The date or time after which a CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded.

3.3. Out of Trend (OOT) - OOT any result which falls out of trend from a previously obtained data for the same product, usually greater than ±5% of the expected or previous result.

3.4. Out of Specification (OOS) – any result which fails to meet an established specification.

3.5. Container Closure System – the sum of packaging components that together contain and protect the drug product. This includes the primary packaging components which come in contact with the drug product.

3.6. Long-Term Testing – Stability studies under the defined storage condition for the retest period or shelf-life proposed.

3.7. Production Batch – a batch of material manufactured at production scale by using production equipment within the actual production facility

3.8. Release Specification – the combination of physical, chemical, biological, and microbiological tests and acceptance criteria that determine the suitability of a material at the time of its release.

3.9. Stability – The extent to which a product retains with in specified limits and throughout its period of storage and use.

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4. RESPONSIBILITIES

4.1. Quality Management

4.1.1. Approval of all studies prior to execution

4.1.2. Approval of study summary reports following execution

4.2. Quality Unit

4.2.1. Issuance and logging of study numbers

4.2.2. Maintenance of study logs

4.2.3. Initiating and developing studies as required

4.2.4. Execution of approved study in accordance with approved protocols

4.2.5. Development of summary reports follow result

4.2.6. Coordinate with contract laboratory to manage stability samples and results

4.3. Production Unit

4.3.1. Produce material needed to support stability studies

4.3.2. Perform production activities in accordance with applicable batch records and protocols

4.3.2.1. Production personnel should coordinate and action the packaging and shipping of samples for the contract testing laboratory.

4.3.3. Ensure samples for stability purposes are taken and handled in accordance with approved records and protocols.

5. PROCEDURE

5.1. General

5.1.1. All stability studies shall be performed under a protocol approved by Quality Management prior to execution per **GMP-SOP-0109**, *Study and Protocol Development.*

5.1.2. All stability studies shall have a summary report developed following execution which outlines the results and data obtained.

5.1.3. All stability samples shall be visually inspected per **GMP-SOP-0063** *Visual Inspection Process of Drug Product,* labeled per **GMP-SOP-0033** *Compounded Sterile Product Label Procedure* and packaged per **GMP-SOP-0083** *Packaging and Shipping.*

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5.1.4. Expiration dates shall be established via reliable, meaningful, and specific test methods. For products that are infused over a period of time, the in-use time should not exceed the expiration date.

5.1.5. Physical stability of the compounded or repackaged product shall signify that the preparation has retained physical properties in accordance with established specifications for the drug product, such as appearance and uniformity.

5.1.6. Chemical stability of the compounded or repackaged product shall signify that each active ingredient has retained its chemical integrity and labeled potency within the specified limits.

5.1.7. All products being studied shall be in the final proposed packaging container/closure and packaging configuration with a representative product label.

5.2. Stability Study Development

5.2.1. Study identification numbers are requested from and assigned by the Quality Unit per **GMP-SOP-0109**, *Study and Protocol Development*.

5.2.2. Studies shall include all pertinent information needed to properly identify the drug product and drug product formulation as well as the container, closure, labeling, and packaging.

5.2.3. Quality Management shall review and approve all studies prior to execution.

5.2.4. Following execution and results, a summary report shall be written following the completion of the study.

5.2.4.1. Interim summary reports may be drafted as needed to support the extension of product dating over time and as data becomes available. Such report shall be reviewed and approved by Quality prior to the extension of product dating.

5.3. Contract Laboratory Study Management

5.3.1. Contract analytical and microbiological testing laboratories (CTLs) utilized to provide testing which supports product stability shall be an approved and qualified vendor and must utilize quantitative stability-indicating methods as appropriate.

5.3.2. The CTL should be notified of the required testing parameters, storage conditions, and intended BUD through the stability protocol developed internally.

5.3.3. If the contract laboratory develops an internal protocol to manage the storage and testing of stability samples, such protocol shall be reviewed and approved by Quality Management and subsequently attached to the approved OurPharma stability protocol.

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5.3.4. All data generated by the contract testing laboratory shall be attached to the original stability protocol and such results summarized in the summary report.

5.3.4.1. All raw data or COAs generated by the contract laboratory shall be reviewed and approved by Quality Management prior to inclusion in the applicable study.

5.4. Selection of Products Requiring Stability

5.4.1. New Compounded Drug Products

5.4.1.1. Prior to commercialization, all new compounded drug products shall have completed a stability study which meets the requirements of this stability program.

5.4.1.2. At least three (3) separate lots shall be evaluated under the approved study in long-term storage conditions as defined within.

5.4.1.3. A stability study under long-term storage conditions shall be evaluated at a minimum of four (4) time points across the full range of the intended product dating.

5.4.1.4. All products shall be studied in the final container closure which is intended for commercial distribution.

5.4.2. Established Drug Products

5.4.2.1. For established drug products, a single lot shall be re-evaluated under an approved stability study which meets the requirements of this stability program annually.

5.4.2.1.1. An annual stability study under long-term storage conditions shall be evaluated at a minimum of three (3) time points across the full range of the intended product dating.

5.4.2.2. Following initial product stability studies, all significant changes to the drug product formulation, manufacturing process, or container and closure system shall be evaluated by Quality for potential impact to product stability. Significant changes may include, but are not limited to:

5.4.2.2.1. Major process or facility changes

5.4.2.2.2. Ingredient manufacturer or specifications

5.4.2.2.3. Container/closure change, including manufacturer, type (e.g., cassette to syringe), or secondary packaging

5.4.2.3. If a change has been determined to be significant, a single lot of product may be placed on stability for evaluation.

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5.4.2.4. If the single lot on stability exhibits out of trend results compared to the original study, then a full three-lot stability study may be warranted to confirm product dating and release specifications.

5.5. Collection of Samples

5.5.1. Products which are produced for the purposes of supporting an approved stability study shall be segregated and properly identified. All production personnel should be made aware that the Lot, or a portion of the Lot, is to be allocated for stability purposes.

5.5.2. All samples taken should be documented in the associated production record and incorporated into production reconciliation as appropriate.

5.5.3. Samples taken shall be a composite of the beginning, middle, and end of the batch in the order that the primary containers are filled to ensure that results are representative of the entire process.

5.5.4. If selected product is unable to be inducted the same day of manufacturing, product must be stored in segregated and properly labeled containers. Containers shall be stored at controlled room temperature conditions until they can be transferred into the appropriate stability condition.

5.5.5. Samples submitted to the contract testing laboratories should be sent for next day delivery, and care should be taken to ensure that samples are not exposed to excessive excursions from the intended storage conditions during transit.

5.6. Storage Conditions.

5.6.1. Long-Term Stability Testing Conditions

5.6.1.1. Generally defined as 25°C ± 2°C / 60% RH ± 5% RH

5.6.1.2. For semi-permeable containers, long-term conditions are defined as:

5.6.1.2.1. 25°C ± 2°C / 40% RH ± 5% RH; OR

5.6.1.2.2. 30°C ± 2°C / 35% RH ± 5% RH

5.6.1.3. All required testing shall be performed first and last time-point or at any time point in which product dating will be extended.

5.6.2. Orientation of Samples

5.6.2.1. Samples selected for stability shall be inducted and stored in the same orientation intended for commercial distribution and storage.

5.7. Testing Requirements, as applicable

5.7.1. Physical Attributes

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5.7.1.1. Physical Description, Color, Clarity, etc.

5.7.1.2. Identification

5.7.2. Chemical Attributes

5.7.2.1. Assay of active ingredients; to include anti-microbial preservatives for containers labeled as multi-dose

5.7.2.2. pH

5.7.2.3. Osmolarity

5.7.3. Microbiological Attributes

5.7.3.1. Sterility (USP <71>)

5.7.3.2. Sub-visible particulate (USP <788>; <789>)

5.7.3.3. Bacterial Endotoxin (BET; USP <85>)

5.7.3.4. Antimicrobial Effectiveness Test (AET; USP <51>) for containers labeled as multi-dose

5.7.3.5. Container Closure Integrity Test (CCIT)

5.8. Evaluation of Testing

5.8.1. All results of testing shall be reviewed and approved by the Quality Management and included in a summary report at the conclusion of the study.

5.8.1.1. An interim summary report may be drafted and approved by Quality to establish product dating prior to the complete conclusion of the study.

5.8.2. Deviations shall be investigated per **GMP-SOP-0202** *Incidents, Deviations, and Non-Conformances* and the results of any such investigation shall be included in the associated summary report.

5.8.3. Out of Specification (OOS) results shall be investigated per **GMP-SOP-0047**, *Out of Specification SOP* and the results of any such investigation shall be included in the associated summary report.

5.9. Determining and Establishing Expiration Date and Release Specifications

5.9.1. Data obtained from the execution of stability studies will be used to establish product expiration date and release specifications.

5.9.1.1. A determination of finished product dating should be made in the associated summary report which contains the data used to establish the product specific dating. Release specifications are set such that, given the

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established stability profile at the defined storage conditions, the drug product will be within its established product specifications at the time of expiry.

5.10. Bracketing Approach

5.10.1. Use of bracketing in stability studies allows for more streamlined evaluation of drug products for which there are multiple strengths or volume presentations produced. Bracketing assumes that the stability of intermediate strengths (or intermediate fill volumes) is adequately represented by the extremes tested.

5.10.2. For multiple drug products to be eligible for bracketing stability studies, the candidate formulations should vary only in strength (or concentration) or fill volume. Although individual excipient amounts may vary, all excipients (in worst-case amounts) should be in all bracketed formulations. Proportional formulations are not required. The same container closure system must be used.

5.10.3. If three or more strengths, concentrations, or volume presentations exist, intermediate cases for stability studies as follows may reflect an appropriate use of bracketing:

5.10.3.1. If 3 or 4 drug product strengths, concentrations, or volume presentations are produced, test the high and low extremes (e.g., if available strengths include 2.0 mg/mL, 3.5 mg/mL, 5.0 mg/mL, and 10.0 mg/mL, test 2.0 mg/mL and 10.0 mg/mL).

5.10.3.2. If 5-10 drug product strengths, concentrations, or volume presentations are produced, test the high and low extremes and 1 intermediate case.

5.10.3.3. If more than 10 drug product strengths, concentrations, or volume presentations are produced, test the high and low extremes and 2 intermediate cases.

5.10.4. It is critical that determination of the extremes be done with care. For example, with respect to volume fill, the appropriate extremes are not necessarily always the highest and lowest fluid volume fills. Rather, the head space-to-fluid volume ratio may better represent the appropriate extreme depending on the container volume used in the various presentations.

5.10.5. Bracketing does not apply to microbial testing of sterility, endotoxins, or bioburden. Bracketing may be appropriate for water activity testing and antimicrobial effectiveness testing when used in conjunction with a preservative content testing strategy.

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6. APPLICABLE REFERENCES

6.1. 21 CFR 210 & 211: cGMP in Manufacturing, Processing, Packing, or Holding of Drugs and Finished Pharmaceuticals

6.2. ICH Guidance for Industry Q1A – Q1F

6.3. FDA Guidance for Industry – Q1D Bracketing and Matrixing Designed for Stability Testing of New Drug Substances and Products

6.4. Revised Draft Guidance for Industry: Current Good Manufacturing Practices for Outsourcing Facilities Registered Under Section 503B of the FD&C Act

6.5. USP <1150>, "Pharmaceutical Stability"

6.6. USP <1191>, "Stability Considerations in Dispensing Practice"

6.7. USP <1225>, "Validation of Compendial Procedures"

7. QUALITY DOCUMENTS

7.1.* GMP-SOP-0047, *OUT OF SPECIFICATION SOP

***7.2.* GMP-SOP-0202 INCIDENTS, DEVIATIONS, AND NON-CONFORMANCES**

7.3. GMP-SOP-0109, STUDY AND PROTOCOL DEVELOPMENT

7.4. GMP-SOP-0063 VISUAL INSPECTION PROCESS OF DRUG PRODUCT

7.5. GMP-SOP-0033 COMPOUNDED STERILE PRODUCT LABEL PROCEDURE

7.6. GMP-SOP-0083 PACKAGING AND SHIPPING

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VISUAL INSPECTION PROCESS OF FINISHED PRODUCT

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Table of Contents

1.0 PURPOSE 3
2.0 SCOPE 3
3.0 RESPONSIBILITIES 3
4.0 DEFINITIONS 3
5.0 EQUIPMENT AND MATERIALS 5
6.0 GENERAL INFORMATION 6
7.0 PROCEDURE 6
8.0 QUALITY DOCUMENTS 12
9.0 REFERENCES 12

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1.0 PURPOSE

1.1 To provide a process in which finished product is 100% visually inspected for defects.

2.0 SCOPE

2.1 This procedure is applicable to all qualified personnel performing visual inspection of finished drug products compounded or repackaged by OurPharma, LLC.

3.0 RESPONSIBILITIES

3.1 It is the responsibility of all personnel involved in the visual inspection process to follow the procedure as outlined at all times.

3.1.1 All equipment and materials should be monitored for functionality and any damage to equipment or changes to functionality should be reported to management promptly.

3.2 It is the responsibility of supervisors/managers to ensure all personnel in their departments are properly trained and to ensure compliance to this SOP as outlined at all times.

3.3 It is the responsibility of the Quality Assurance department to ensure compliance to this SOP as outlined at all times.

4.0 DEFINITIONS

4.1 **Acceptable Quality Limit (AQL)** – an inspection standard that determines the acceptable number of defective components that can be found during random sampling based on statistical analysis.

4.2 **Container/Closure Integrity (CCI)** – the ability of a package to prevent product loss, to block microorganism ingress, and to limit entry of detrimental gases or other substances, thus ensuring that the product meets all necessary safety and quality standards. A defect that risks the integrity of the container closure system at unacceptable risk is a critical defect.

4.3 **Critical** – defects which may cause serious adverse patient reaction, or death, if the product is used. This classification includes any non-conformity that compromises the integrity of the container and thereby risks microbiological contamination of the sterile product.

4.4 **CSP** – Compounded Sterile Preparation

4.5 **Defect** – any abnormality that impacts or has the potential to impact the safety, identity, strength, quality, or purity of the product and/or cause injury to the patient. These nonconforming drug products can be grouped into categories based on patient and compliance risk. Defects shall be categorized as critical, major, or minor.

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4.6 **Defect Library** – the body of records documenting the established product defects with images, description, category, and disposition. This document shall be used to train and set standard acceptance criteria for visual inspection personnel.

4.7 **Eye Break** – time away from the inspection booth, i.e., standard break, lunch break, etc.

4.8 **IPA** – isopropyl alcohol

4.9 **Lux** – a unit of illuminance and luminous emittance, measuring luminous power (perceived power of light) per unit area.

4.10 **Major** – defects that carry risks of temporary impairment, medically reversible reactions, or involve probability of a serious adverse reaction. This classification is also assigned to any defect which causes impairment to the use of the product (may result in a malfunction that makes the product unusable).

4.11 **Manual Visual Inspection** – the process of manually handling and presentation of filled containers under controlled conditions of lighting and background provided by qualified equipment to allow for human visual inspection.

4.12 **Minor** – defects which do not impact product performance or compliance; they are often cosmetic in nature, affecting only product appearance and pharmaceutical elegance.

4.13 **Particulate Matter** - consists of mobile, undissolved particles, other than gas bubbles, unintentionally present in the solutions.

4.14 **Visible Contaminant** – a particle that is more than 100 micrometers in size and can be seen with the naked eye.

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5.0 EQUIPMENT AND MATERIALS

5.1 Lighted, Non-Glare White/Matte Black Inspection Booth

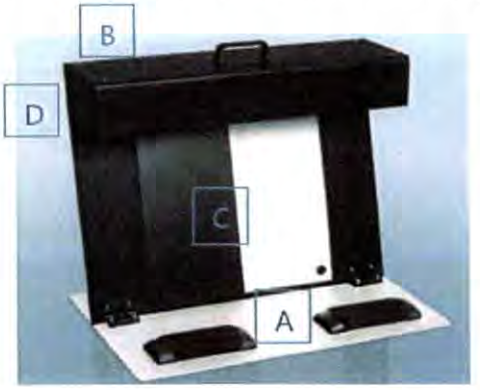


Figure 1: Inspection booth diagram;
[A] Arm rests,
[B] light switch (back of unit),
[C] black and white background,
[D] Adjustable light intensity dial

5.1.1 The Bosch Portable Material Inspection Hoods can be powered on using the rocker switch on the back of the unit.

5.1.2 Light Intensity Adjustments

5.1.2.1 For Inspection Hoods with LED light fixtures, light intensity can be adjusted after powering on using a three-position selector. The selector is located on the light fixture and allows for OFF "0" (one bulb high and one bulb off), LOW "I" (one bulb high and one bulb low), and HIGH "II" (both bulbs high).

5.1.2.2 For Inspection Hoods with optional adjustable intensity LED lighting, light intensity can be adjusted using the 10-turn adjustment knob on the side of the Inspection Hood. Rotate the knob clockwise to increase light intensity and counterclockwise to decrease intensity.

5.2 Calibrated Light Meter

5.2.1 To operate the traceable dual-range light meter, turn the meter on by sliding the power off/range switch (left switch) to the 2000-19990(x10) Lux position. Place the light sensor at the inspection point. Multiply the display reading by 9.1. If this number is outside of the approved lux range, adjustments are to be made until reading is within range. If unable to reach required lux range, notify quality and production management prior to proceeding with inspection.

5.3 Metronome

5.3.1 The metronome should be used during visual inspection to assist in maintaining the appropriate inspection rate per unit.

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6.0 GENERAL INFORMATION

6.1 Inspection shall occur on 100% of units from each manufactured lot before labeling to maximize container clarity.

6.2 Inspection of product shall take place utilizing a lighted non-glare white/matte black inspection booth.

6.3 The inspection environment should be free from distractions (e.g., use of personal electronics, excessive conversation, music, etc.) and extraneous light.

6.4 Inspectors shall be required to take a minimum 5-minute eye break per hour of inspection.

6.4.1 Breaks through rotation of non-inspection functions (e.g., material handling, labeling, completing documentation, etc.) shall be deemed an adequate break as long as it meets the minimum 5-minute duration.

6.5 The inspection process may occur over multiple time points with multiple inspectors. The visual inspection section(s) within the batch record should be filled out each time inspection occurs.

6.6 Only one lot of each presentation type is allowed at each visual inspection booth at any one time.

6.6.1 If multiple lots of each presentation type are present in the visual inspection area, each lot must be clearly segregated by utilizing a physical stanchion/divider between inspection booths.

6.7 A competency check is required for each presentation type prior to performing visual inspection independently. Requalification is required annually.

7.0 PROCEDURE

7.1 Preparation for Inspection

7.1.1 Personnel shall don a hairnet, mask, and gloves prior to inspecting.

7.1.2 The visual inspection area must be cleared for use to ensure no remnants from prior batches are present.

7.1.3 Inspection booth(s) will be wiped down with 70% IPA prior to use and as needed.

7.1.4 Turn on the inspection booth light.

7.1.5 Using the calibrated/traceable light meter, verify that the booth will meet the required light intensity range of 5000-10,000 lux at the viewing point.

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7.1.5.1 Verification must occur for each lot, at minimum, at the beginning of visual inspection activities. The results of this verification will be recorded on the corresponding batch record.

7.1.5.2 Additional verifications may be necessary, and subsequent performances will be done if inspection of the lot is performed in multiple sessions or if the light source is switched off for any reason during the process.

7.2 Delivery of Product to Inspector(s)

7.2.1 Pharmacist or designee delivers product to the inspector.

7.2.1.1 This and any subsequent handoffs are to be recorded in the Finished Product Chain of Custody section of the batch record.

7.3 Container Handling

7.3.1 Any unit demonstrating evidence of exterior drug residue (ex: liquid, stickiness, powder residue, streaking) shall be wiped using a SIPA-saturated sterile wipe to ensure accurate 100% visual inspection and to prevent unwanted drug exposure.

7.3.2 Visual inspectors shall inspect one unit at a time in a manner that limits distraction from any non-inspection activities.

7.3.3 Containers shall be handled in a manner that does not compromise the container/closure integrity (e.g., manipulation of the plunger, cap, or any physical barrier of the product container).

7.3.4 Family B & D container-specific handling: Inspectors shall pick up the container and **carefully swirl and invert** by slowly turning the container upside down and back upright inside the visual inspection booth while visually inspecting the product.

7.3.4.1 The gentle swirling and inversion of the container will displace particles, if any, from the inner surfaces of the container/closure and puts them in motion.

7.3.4.2 Inspectors should take care not to introduce air bubbles that could potentially mask a particle or be mistaken for a particle.

7.3.4.2.1 In the event that air bubbles are inadvertently introduced, set aside that unit and reinspect once air bubbles have settled.

7.3.5 Family A & C container-specific handling: Inspectors shall pick up the container and **carefully invert** by slowly turning the container upside down and back upright inside the visual inspection booth while visually inspecting the product.

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7.3.5.1 The gentle inversion of the container will displace particles, if any, from the inner surfaces of the container/closure and puts them in motion.

7.3.5.1.1 Swirling of these container types is not necessary, as the large amount of air within the container will displace the particles during inversion without introducing excessive air.

7.3.5.1.2 Swirling of these container types would regularly create excessive air bubbles that could potentially mask a particle or be mistaken for a particle, which could potentially impact qualified personnel's ability to properly visually inspect the finished product.

7.3.5.2 Inspectors should take care not to introduce air bubbles that could potentially mask a particle or be mistaken for a particle.

7.3.5.2.1 In the event that air bubbles are inadvertently introduced, set aside that unit and reinspect once air bubbles have settled.

7.3.6 Any mishandled units shall be documented and deducted from accepted units after visual inspection.

7.3.6.1 Mishandled units (e.g., dropped on the floor) should not be included in the total rejected units from visual inspection unless actual defects were identified prior to mishandling. However, they should be documented within the visual inspection section for reconciliation purposes.

7.4 Inspection Categories

7.4.1 The following inspection categories shall be performed on each container.

7.4.1.1 **Container/Closure Integrity** – inspect for signs of deterioration, broken seals, leaks, and cracks.

7.4.1.1.1 Extra consideration should be given to bags when examining for leaks during all post-production activities. If there is an active or suspected leak, that unit shall be segregated and rejected as a defective unit.

7.4.1.2 **Container/Closure Type** – inspect for correct type (e.g., syringe, dropper, cap, etc.) according to the batch record.

7.4.1.3 **Container/Closure Size** – inspect for correct size (e.g., 50mL, 100mL, 250mL, etc.) according to the batch record.

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7.4.1.4 **Product/Container Fill Volume –** inspect for correct fill volume of product within the container (e.g., 1mL in a 3mL syringe) according to the batch record.

7.4.1.5 **Product Appearance** – inspect for correct product appearance (e.g., solution, suspension, etc.) according to the batch record.

7.4.1.6 **Product Color/Clarity** – inspect for correct product color and clarity (e.g., clear, colorless) based on established criteria located under Drug Product Information on the batch record.

7.4.1.7 **Product Viscosity/Turbidity –** inspect for increased/decreased viscosity and/or turbidity against the product's established appearance.

7.4.1.8 **Visible Particulates –** inspect for visible particulates (particulate matter). Examples include but are not limited to:

7.4.1.8.1 **Extrinsic –** environmental contaminants from outside the process (e.g., insect parts, hair, fibers, paint, rust)

7.4.1.8.2 **Intrinsic –** qualified product contact materials (stainless steel, glass, rubber, silicone oil) that comes from within the process (processing equipment or primary packaging).

7.4.1.8.3 **Inherent** – part of the formulation (e.g., protein agglomerates in biologics).

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7.5 Inspection Criteria – Defect Classification

7.5.1 Defects shall be classified into 3 categories: critical, major, and minor.

Defect Category	Examples
Critical	- Evidence of microbial growth - Turbidity or change in solution color/clarity - Broken, cracked, and/or leaking container - Seal on container broken, missing, or jagged - Cap broken, missing, or lifted - Stopper on container missing, misaligned, or otherwise compromised
Major	- Particle/spot/smudge inside container, adhered to container or stopper - Particle or fiber in solution (can be black, white, colored, translucent, etc.) - Incorrect fill volume (overfill or underfill) - Uneven or missing graduations - Large air bubble - Deformed plunger - Cap over-crimped or under-crimped
Minor	- Cosmetic defect on outside of the primary container, or appearance defect, such as excessive scratches or smudges, container and/or cap discoloration, or crimped tubing.

7.6 Inspection Rate

7.6.1 Each container shall be inspected for defects for a minimum of 10 seconds – 5 seconds against the white background and 5 seconds against the black background.

7.6.2 Once inspection of the container is complete, the inspector shall place the container in the correct designated bin.

7.6.2.1 If the Visual Inspector encounters a defect, the defect will be recorded under the appropriate defect classification and defect description within the visual inspection section of the product batch record.

7.6.2.1.1 The container will be placed in the appropriate section in the designated defect (rejected) bin based on defect classification (critical, major, minor).

7.6.2.2 If a new or unlisted defect description is encountered, the defect description will be recorded as "other" in the batch record, and the Inspector will provide a description in the associated "comments" section.

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7.6.2.2.1 The container will be placed in the appropriate section in the designated defect (rejected) bin based on defect classification (critical, major, minor).

7.6.2.2.2 If a new particulate matter defect is identified during the visual inspection process of finished drug product, initiate GMP-Form-0212 *Visual Inspection Defect Library Record* to document the defect and submit it to Operations and Quality management for review. Once reviewed, this new defect will be added to GMP-WI-0027, *Visual Inspection Defect Library.*

7.6.2.3 If the container passed, then the container will be placed in the designated accepted bin.

7.6.2.4 During inspection, product waiting to be inspected, accepted units, and rejected units shall remain segregated throughout the inspection process.

7.6.3 Once inspection is complete, rejects shall be placed in a Ziploc bag and labeled as REJECTED by writing on the bag or using a REJECTED sticker.

7.6.3.1 The product description, Lot #, NDC, and quantity of rejected units shall be recorded on the bag.

7.6.3.2 Any product that fails visual inspection should be given to a pharmacist or designee for reconciliation then to be logged for destruction.

7.6.4 Once inspection is complete, the Inspector shall notify Quality to complete the post VI AQL inspection.

7.7 AQL Inspection

7.7.1 AQL Inspection

7.7.1.1 Once the initial 100% visual inspection is complete, before products can be processed for labeling and packaging, Quality shall perform a secondary visual inspection AQL inspection of accepted units.

7.7.1.2 Post-Visual Inspection AQL Inspection shall be performed to achieve a general inspection level II at an AQL of 0.01 for critical defects, 0.65 for major defects and 4.0 for minor defects (See **Appendix 1, pg 12**). In the event that the above allowable AQL limits are exceeded, an incident shall be initiated per GMP-SOP-0202 *Incidents, Deviations, and Non-Conformances.*

7.7.1.3 A second 100% visual inspection and subsequent AQL inspection will then be performed to achieve a general inspection level II at an AQL of 0.01 for critical defects, 0.25 for major defects and 4.0 for minor defects.

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7.7.1.4 In the event that the AQL limits are exceeded a second time, the batch will be rejected and a deviation investigation initiated to determine the root cause and assess potential impact.

7.8 Product Status/Storage Location

7.8.1 Inspected product is stored in a quality hold status until the finished product can be released per GMP-SOP-0013 *Batch Review and Disposition.*

7.8.1.1 When product is released, it is moved from quality hold to finished goods status, where the finished product will be moved to the finished goods inventory and prepared for shipment.

7.9 Trending

7.9.1 Data obtained from the in-process 100% inspection should be analyzed for adverse trends on a periodic basis, at least annually.

8.0 QUALITY DOCUMENTS

8.1 GMP-SOP-0013 *Batch Review and Disposition*

8.2 GMP-SOP-0210 *Visual Inspection Qualification Program*

8.3 GMP-WI-0027 *Visual Inspection Defect Library*

8.4 GMP-Form-0212 *Visual Inspection Defect Library Record*

8.5 GMP-Training-0013 *Visual Inspection of Cassettes-Training*

8.6 GMP-Training-0006 *Visual Inspection of Syringes-Training*

8.7 GMP-Training-0007 *Visual Inspection of Bags-Training*

8.8 GMP-Training-0017 *Visual Inspection of PCA Vials-Training*

9.0 REFERENCES

9.1 21 CFR 211, Current Good Manufacturing Practice for Finished Pharmaceuticals

9.2 Inspection of Injectable Products for Visible Particulates Guidance for Industry, Draft Guidance, December 2021

9.3 USP <1> Injections and Implanted Drug Products (Parenterals) – Product Quality Tests

9.4 USP <788> Particulate Matter in Injections

9.5 USP <790> Visible Particulates in Injections

9.6 USP <1790> Visual Inspection of Injections

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APPENDIX 1:

Lot or batch size	Special inspection levels				General inspection levels		
	S-1	S-2	S-3	S-4	I	II	III
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	E	F
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1 200	C	C	E	F	G	J	K
1 201 to 3 200	C	D	E	G	H	K	L
3 201 to 10 000	C	D	F	G	J	L	M
10 001 to 35 000	C	D	F	H	K	M	N
35 001 to 150 000	D	E	G	J	L	N	P
150 001 to 500 000	D	E	G	J	M	P	Q
500 001 and over	D	E	H	K	N	Q	R

Sample size code letter	Sample size	Acceptable quality levels (normal inspection)																										
		0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31
B	3	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45
C	5	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧
D	8	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧		
E	13	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧			
F	20	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧		
G	32	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧			
H	50	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧				
J	80	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧				
K	125	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧					
L	200	⇩	⇩	⇩	⇩	⇩	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧						
M	315	⇩	⇩	⇩	⇩	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧							
N	500	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧								
P	800	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧									
Q	1 250	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧										
R	2 000	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧

⇩ = Use first sampling plan below arrow. If sample size equals, or exceeds, lot or batch size, carry out 100 % inspection.

⇧ = Use first sampling plan above arrow.

Ac = Acceptance number

Re = Rejection number

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ENVIRONMENTAL AND PERSONNEL MONITORING SOP

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Table of Contents

1. PURPOSE 3
2. SCOPE 3
3. DEFINITIONS 3
4. RESPONSIBILITIES 4
5. PROCEDURE 5
6. APPLICABLE REFERENCES 13

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1. PURPOSE

1.1. This SOP defines the program, procedures, and requirements for environmental monitoring and personnel monitoring in the controlled classified cleanrooms at OurPharma, LLC.

1.2. This document defines the environmental monitoring and personnel monitoring alert and action limits per ISO classification, sample type, and sample location.

2. SCOPE

2.1. This procedure applies to all environmental monitoring and personnel monitoring activities at OurPharma, including: Active Viable Air Monitoring, Surface Monitoring, Personnel Monitoring, Non-Viable Particulate Monitoring.

3. DEFINITIONS

3.1. Aseptic Specialist - Qualified personnel performing critical aseptic processes in the ISO5 environment. Aseptic specialists have been qualified on all appropriate tasks in regard to maintaining the integrity of the ISO5-classified hoods during aseptic fill operations.

3.2. At Rest (Static) - A state/status of the cleanroom facility in which all environmental engineering services are functioning, with necessary equipment installed and operable as specified, but without operating personnel in the room and no aseptic operations in process.

3.3. Controlled Environment - Any area in an aseptic processing facility for which non-viable airborne particulate levels and microorganism levels are controlled in accordance with ISO Cleanroom Classification and appropriate to the activities conducted within the environment.

3.4. Environmental Monitoring (EM) - A sampling process performed on a routine basis to demonstrate that the manufacturing environment is in a state of control in regard to bioburden, microorganisms, and non-viable particulates per ISO Standards of Room Classifications. Environmental Monitoring can also verify the effectiveness of the prescribed cleaning procedures for the control of microbiological contaminants in the cleanrooms. Additionally, personnel performing aseptic operations are monitored to ensure proper gowning/garbing and aseptic technique(s) employed during compounding processes do not adversely impact product integrity.

3.5. Critical Aseptic Processes - A process where aseptic technique is critical to maintaining sterility of the product; examples include filling, capping, and any other process whereby the sterilized drug product is not in a closed system.

3.6. Replicate Organism Detection and Counting (RODAC) - Industry standard contact media plate used for environmental monitoring to sample and measure microorganisms present on a flat surface.

3.7. Trypticase Soy Agar (TSA) - A general purpose, industry standard, non-selective media used for microbial growth.

3.8. Alert Level - A defined level of microbiological data designed to give an early warning of potential drift from normal environmental operating conditions.

3.9. Action Level - A defined level of microbiological data established in accordance with written regulatory guidelines.

3.10. Excursion – Environmental Monitoring events that exceed a pre-defined action limit, often resulting in an Incident or a Deviation.

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3.11. Consecutive Recoveries: The occurrence of ≥ 3 chronologically sequential alert level events from the same sample location, which may indicate a shift in environmental quality and should be investigated for potential impact to the cleanroom environment and/or compounded sterile product(s).

3.12. Personnel Monitoring (PM) - Monitoring that takes place each time the aseptic specialist leaves the cleanroom during production as well as immediately after the critical aseptic process is complete.

3.13. Aseptic Environmental Monitoring - Surface and air sampling for evaluation of potential microbial contamination in the environment during the aseptic fill process.

3.14. Dynamic Sampling - Environmental monitoring sampling conducted under conditions of normal production with personnel present, equipment in place, and active aseptic operations are ongoing.

3.15. Media Plate - Petri plates containing growth media used for EM are used in two size formats, a 90-100mm diameter plate, called a TSA plate herein, and a 55mm diameter RODAC plate, called a RODAC plate herein.

3.16. Physical Defects - Any non-normal attribute of agar sampling plates that may skew the integrity of the sample. Examples: desiccation, cracks, bubbles, surface irregularities, excessive condensation, convexity (contact plates only), color, etc.

3.17. Microbial Enumeration - Quantification of microbial growth on a media plate.

3.18. Air Monitoring - The use of a device or equipment to sample a measured amount of air in a specified time period to quantify the total airborne particulate or microbiological status of a controlled space.

3.19. Colony Forming Unit (CFU) : a common unit in microbiology used to estimate the number of viable microbiological cells in a given sample

3.20. NMT: Not more than

4. RESPONSIBILITIES

4.1. Quality Control is responsible for training and assuring competency of personnel performing this procedure, including—but not limited to—the following:

4.1.1. A competency check is required prior to performing environmental plating independently. Requalification is required annually.

4.1.2. Conducting and/or coordinating EM sampling during aseptic operations.

4.1.3. Completing appropriate environmental monitoring documentation each time sampling is performed, and reviewing the EM form(s) to ensure all applicable locations have been sampled.

4.1.4. Ensuring the EM samples/plates are incubated at the prescribed temperature(s) for the appropriate time(s). See Sec. 5, below.

4.1.5. Documenting the incubation start time(s), end time(s), and incubator transfer time(s) per the parameters defined in Sec. 5, below.

4.1.6. Ensuring the timely reading of all EM samples. This includes proper microbial enumeration, documentation, and archiving of all EM data.

4.1.7. Reviewing all environmental sampling data and corresponding EM forms.

4.1.8. For deviations and/or investigations related to Environmental Monitoring excursions, QC personnel are generally responsible for drafting the investigation(s), and QA Management is ultimately responsible for the approval of the investigation(s).

4.2. Quality Personnel are responsible for:

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4.2.1. Ensuring that all personnel performing environmental and personnel monitoring have been appropriately trained in:
  4.2.1.1. Processes and technique(s) used to maintain aseptic conditions.
  4.2.1.2. Clean room gowning technique(s) and gowning qualification
  4.2.1.3. Appropriate clean room behavior
  4.2.1.4. Any/all procedures and/or work instructions directly related to the operation of Active Air samplers (viable and non-viable)
4.2.2. Reporting and trending environmental monitoring data and personnel monitoring data.
4.2.3. Establishing Alert and Action limits and sampling frequencies for EM sampling locations.
4.2.4. Documenting Alert and/or Action Levels and notifying appropriate management of ISO5 excursions.

5. PROCEDURE

5.1. Sampling Locations: All active viable and non-viable air and surface sampling locations are listed and diagrammed according to the following attachments:

Attachment 1: Suite 4 and surrounding corridors

Attachment 2: Suite 3 and surrounding corridors

Attachment 3: Suite 2 and surrounding corridors

Attachment 4: Suite 1 and surrounding corridors

5.2. Applicable Environmental Monitoring Sampling Form are used to document raw EM data.

5.3. Active viable air monitoring in the ISO7 and ISO8 areas is to be completed per GMP-WI-0003, ActiveCount 100H Microbial Viable Air Sampler LMS Work Instruction for Operation. Prior to use, current instrument calibration must be verified. Quality and Facility management should be notified if calibration is due within the next 30 days. Agar plates should be labeled with the viable sampler ID, site location, date, start time, and sampler's initials.

5.3.1. Active Viable Sampling in the ISO5 BSC is performed during production using the SV1040 air sampling systems per GMP-SOP-0148, Flow Meter SOP. Agar plates should be labeled with the site location, date, start time, and sampler's initial set. Frequency of EM sampling is outlined below:

Table 1

Sampling Area	Frequency of Sampling
ISO5	Each Aseptic Fill Process
ISO7	Daily if suite is used for production, bi-weekly* if not
ISO8	Bi-Weekly*

*14 days +/- 4 days

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5.3.2. All agar plates used during the EM sampling process are inspected for physical defects—desiccation, cracks, excessive moisture—and any/all anomalies should be documented on the appropriate Environmental Monitoring Sampling Form(s).

5.3.3. Prior to use, the active viable air sampler(s), sampling grid(s), and sampling plate(s) are to be visually inspected for general cleanliness and sanitized per GMP-WI-0003, Active Count 100H Microbial Viable Air Sampler LMS Work Instruction for Operation.

5.3.4. All active viable air sample plates are to be incubated at 20-25°C for not less than 72 hours and at 30-35°C for not less than 72 hours. Total incubation time should be NMT 10 days.

5.3.5. At the end of the incubation period, the colony-forming units (CFUs) on each TSA plate will be counted according to SOP-SOP-0054, Microbial Enumeration and Verification.

5.3.6. All CFU counts and physical defects shall be documented/recorded on the appropriate Environmental Monitoring Sampling Form(s). CFU counts and documentation are then verified and reviewed by a second Quality representative.

5.3.7. Acceptance Criteria*:

Table 2

Sampling Area	CFU/plate	
	Alert	Action
ISO5	N/A	≥1
ISO7	≥6	≥10
ISO8	≥25	≥100

*See Table 8 for the requirements for EM investigations and/or species-level identifications

5.4. Non-Viable Particulate Monitoring

5.4.1. Minimum frequency of testing is outlined below:

Table 3

Sampling Area	Frequency of Sampling
ISO5	Each Aseptic Fill Process

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ISO7	Daily if suite is used for production, bi-weekly* if not
ISO8	Bi-weekly*

*14 days +/- 4 days

5.4.2. Non-Viable Particle Monitoring is to be completed per GMP-WI-0004, Solair 3350 Airborne Particle Counter LWS Work Instruction, GMP-SOP-0131, Apex Remote SOP, and GMP-SOP-0151, Remote 5104P Airborne Particle Counter. Note, the Apex R5 Remote and 5104P Remote units are continuous non-viable sampling systems controlled via Lighthouse (LWS) software and are not involved in manual EM sampling processes per the frequencies defined in Table 3.

5.4.3. Prior to use, current instrument calibration must be verified for the portable Solair 3350 Airborne Particle Counter(s). Quality and Facility management should be notified if calibration is due within the next 30 days. Non-viable data collected from the portable Solair 3350 Airborne Particle Counters should be printed and initialed by the sampler. Once outside the cleanroom, printouts are to be attached to paper using tape, being careful to not cover any of the data. These attachments are photocopied for data integrity purposes. The original printout(s) and copies are to be initialed, dated, and attached to the appropriate EM form(s).

5.4.4. Continuous Non-viable particulate (NVP) monitoring data is collected by the Apex Remote 5104p and Apex R5 I Particle Counters and is maintained in the LMS Software. Applicable non-viable particulate data is printed and attached to production batch records as needed for batch disposition.

5.4.5. Acceptance Criteria*:

Table 4

Sampling Area	**Particles ≥ 0.5µm**	
	Alert (N/1 m^3)	**Action(N/1 m^3)**
ISO5	2,642	3,520
ISO7	264,169	352,000
ISO8	400,000	3,520,000
	Particles ≥ 5µm	
	Alert (N/1 m^3)	**Action(N/1 m^3)**
ISO7	2,190	2,930
ISO8	5,000	29,300

5.4.5.1. The particle count results will be compared against the acceptance criteria. Total airborne particle results that meet or exceed the action limits per 1000 L (1 m3) of air sampled require investigation per GMP-SOP-0202 Incidents, Deviations, and Non-Conformances.

5.4.5.2. The Lighthouse (LMS) non-viable particulate (NVP) monitoring system collects air samples continuously at the rate of 1 CFM (cubic foot per minute), with a full cubic meter (m^3) of air

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collected in 35.3 minutes. The number of particles collected in 1 CFM is extrapolated by the LMS System Software to particles/m^3, and the LMS alarm settings and notifications are based on this extrapolated value in order to allow for real-time responses to potentially changing particulate conditions in the Buffer Room(s) and/or Compounding Hood(s).

5.4.5.3. Real-time audible NVP alarms require compounding personnel working in the Buffer Rooms and BSCs to immediately halt aseptic manipulations and communicate to quality personnel, who will assess the number (#) of particulates captured in the 1 CFM air sample causing the alarm, and determine whether or not compounding can resume per real-time monitoring of the particulate levels in the affected ISO5 space.

5.4.5.4. In the event of a transient NVP alarm (<5 minutes at action level) recorded during production activities, an incident shall be initiated per GMP-SOP-0202. In order to determine whether or not the total NVP count exceeds the max allowable particles per m^3 per ISO 14644-1:2015, the total NVP count for the 35.3 minutes prior to and including the LMS alarm will be evaluated by running a real-time LMS Trend Report showing the non-viable particulate data for the affected channel (5.0 µm or 0.5 µm) for NLT 35.3 minutes prior to and including the NVP event causing the alarm.

5.4.5.4.1. In the event that the total NVP count does not exceed the max allowable particles per m^3 per ISO 14644-1:2015, the LMS report will be attached to the incident report, and the report will then be routed for closure. In the event that, the total NVP count does exceed the max allowable particles per m^3 per ISO 14644-1:2015, an investigation per GMP-SOP-0202 is required.

5.5. Viable Surface Monitoring (ISO5/ISO7/ISO8)

5.5.1. Frequency of testing:

Table 5

Sampling Area	Frequency of Sampling
ISO5	Each Aseptic Fill Process
ISO7	Daily if suite is used for production, bi-weekly* if not
ISO8	Bi-weekly*

*14 days +/- 4 days

5.5.2. RODAC surface samples are collected for each area as listed in Attachments 1-4 Sample Map (with key).

5.5.3. The sampling date, location, time, and sampler initial sets should be recorded on the bottom side of each contact plate. Prior to sampling, all RODAC surface contact plates shall be visually inspected for physical defects.

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5.5.4. To sample surfaces using a contact plate, firmly touch the sample area with the agar surface and gently roll the plate across the surface to be sampled.

5.5.5. Immediately after sampling, thoroughly spray and/or wipe all sampled areas using sterile 70% IPA and sterile wipes (or sterile pre-saturated 70% IPA wipes) before resuming aseptic operations and/or environmental monitoring duties.

5.5.6. EM plates will be incubated at 20-25°C for not less than 72 hours and at 30-35°C for not less than 72 hours. Total incubation time should be NMT 10 days.

5.5.7. At the end of the incubation period, the colony-forming units (CFUs) on each EM plate will be counted according to SOP-SOP-0054, Microbial Enumeration and Verification.

5.5.8. All CFU counts and physical defects will be documented/recorded on the appropriate Environmental Monitoring Sampling Form(s). CFU counts and documentation will then be verified and reviewed by a second Quality representative.

5.5.9. Acceptance Criteria*:

Table 6

Sampling Area	Contact Plate CFU	
	Alert	Action
ISO5	N/A	≥1
ISO7	≥3	≥5
ISO8	≥5	≥10

*See Table 8 for the requirements for EM investigations and/or species-level identifications

5.6. Personnel Monitoring (PM)

5.6.1. Personnel Monitoring will be performed for operators performing critical aseptic manipulations for each Lot of product(s) intended for distribution. Plates must be visually inspected for physical defects prior to sampling; persons performing PM sampling should verify that the plates have visible lot #'s and are within expiry; and plates are to be labeled with PM location (for example RH, LH, RFA, LFA), date, time, person sampled, and person performing the sampling.

5.6.2. Perform personnel monitoring by sampling the aseptic operators' gloved hands immediately after the operator completes critical aseptic processing and before exiting the ISO 5 (Class 100) hood. PERSONNEL MUST NOT USE STERILE 70% IPA SPRAY OR ANY

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OTHER CLEANING SOLUTION ON THE HANDS IMMEDIATELY PRIOR TO TAKING FINGERTIP SAMPLES.

5.6.3. Sample the left and right gloved hands with 90 mm TSA plates by firmly pressing and rolling each of the operators' fingertips to the TSA plate.

5.6.4. Sample the left and right forearms with TSA-RODAC plates by gently rolling the plate across the inner forearm, sampling where the outer glove cuff meets the sleeve of the coverall.

5.6.5. Sampling should be performed prior to operator removing hands from the ISO5 area, whenever possible. In the event of suspected contamination, sampling may be performed in the ISO7 buffer room in lieu of the ISO5 area. ISO7 buffer room sampling should be noted on the sampling plate(s) and within the batch record. Sampling shall be performed prior to glove changes, prior to taking breaks, and upon completing compounding. If a glove change was performed due to concern for contamination risk, this should be noted on the plate(s), EM form, and/or within the batch record.

Note: Extenuating circumstances (for example: fire alarms, needle sticks, exposure to hazardous drugs/dangerous chemicals, acute onset of illness, etc.) may necessitate emergency exits that prevent PM samples from being collected. In these cases, appropriate documentation should be recorded in the batch record(s) and/or the applicable EM form(s).

5.6.6. The aseptic specialist is to change the outer pair of sterile gloves and wipe the sampled gowning sites with saturated sterile 70% IPA wipes prior to participating in end of shift cleanroom sanitization activities.

5.6.7. Acceptance Criteria*:

Table 7

CFU/Contact Plate			
Gloved Fingertip		**Forearms**	
Alert	**Action**	**Alert**	**Action**
≥1	≥1	≥1	≥3

*See Table 8 for the requirements for EM investigations and/or species-level identifications

5.7. Sample Handling, Reporting and Analysis

5.7.1. All samples and defective plates must be transferred out of the sterile suite for incubation.

5.7.2. Document environmental monitoring data on the appropriate Environmental Monitoring Sampling Form(s).

5.7.3. EM sampled plates are incubated at as follows:

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5.7.3.1. EM plates will be incubated at 20-25°C for not less than 72 hours and at 30-35°C for not less than 72 hours. Total incubation time should be NMT 10 days.

5.7.3.2. At the end of the incubation period, the colony-forming units (CFUs) on each EM plate will be counted according to SOP-SOP-0054, Microbial Enumeration and Verification.

5.7.4. All CFU counts and physical defects will be documented/recorded on the appropriate Environmental Monitoring Sampling Form(s). CFU counts and documentation will then be verified and reviewed by a second Quality representative. The appropriate Environmental Monitoring Sampling Form(s) shall be filled out with the following information:

5.7.4.1. Suite and Batch Number, if applicable

5.7.4.2. Operator performing the sampling

5.7.4.3. Sample locations, dates, times

5.7.4.4. Sampler IDs

5.7.4.5. Plate lot number(s) and expiration date(s)

5.7.4.6. Incubation information:

5.7.4.6.1. Start Time and Date (per temperature)
5.7.4.6.2. Initial set of personnel incubating the samples
5.7.4.6.3. Final read and verification
5.7.4.6.4. Quality Review
5.7.4.6.5. CFU results
5.7.4.6.6. Acceptance criteria (pass or fail)

5.7.5. If Applicable: Document whether the sample meets or exceeds alert or action levels.

5.7.6. Quality personnel will review the environmental monitoring paperwork for any results that meet or exceed Alert and/or Action level criteria.

5.7.7. If any plates show evidence of physical defects post-incubation that could potentially invalidate the sample(s), it must be documented on the appropriate Environmental Monitoring Sampling Form(s). An investigation may be initiated per GMP-SOP-0202, Incidents, Deviations, and Nonconformances, if it is determined that the plates were compromised and/or the viability of the sample is questionable.

5.7.8. If Environmental Monitoring results meet or exceed prescribed Action Levels, an investigation will be initiated per GMP-SOP-0202, Incidents, Deviations, and Nonconformances, in order to assess potential product impact and to identify potential root cause(s). The requirements for EM investigations and/or species-level identifications are based on sample type, action limit(s), ISO classifications, and/or microbial morphology, and are summarized in Table 8, below:

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TABLE 8		
Type of EM Sample	**Action Limit**	**INC / INV / MicroID Required?**
ISO5 PM - Glove	≥ 1 CFU	INC/INV & MicroID required
ISO5 PM - Forearm	≥ 3 CFU	INC/INV & Micro ID required for action limit exceedance. INC and MicroID required for alert limit (≥ 1 CFU)
ISO5 Air Sample	≥ 1 CFU	INC/INV & MicroID required
ISO5 Surface Sample	≥ 1 CFU	INC/INV & MicroID required
ISO7 Air – Buffer Room	≥ 10 CFU	MicroID required for Buffer Room Recoveries (trending) INC/INV required for Action Limit excursions, CRO Fungal, and/or objectionable* MicroID results, if applicable
ISO7 Surface - Buffer Room, Ante Room	≥ 5 CFU	MicroID required for Buffer Room Recoveries (trending) INC/INV required for Action Limit excursions, CRO Fungal, and/or objectionable* MicroID results, if applicable
ISO7 Air Sample- Degown Room	≥ 10 CFU	Action Limit excursions require INC/INV & MicroID^
ISO7 Surface Sample- Degown Room	≥ 5 CFU	Action Limit excursions require INC/INV & MicroID^
ISO8 Air Sample**	≥ 100 CFU	Action Limit excursions require INC/INV & MicroID^
ISO8 Surface Sample**	≥ 10 CFU	Action Limit excursions require INC/INV & MicroID^

*Objectionable Organisms are defined as organisms likely to cause infection, allergic response, and/or toxaemia in patients receiving the product(s), and include Yeasts/Molds, *S. aureus, E. coli, Salmonella spp., Bacillus cereus, Burkolderia cepacia,* and *Pseudomonas aeruginosa.* For microorganisms that are less characterized but may present a potential health risk, applicable scientific and peer-reviewed literature will be used as necessary in risk assessments for actionable incidents/investigations with potential product impact

**Note: For ISO8 Material Transfer (MT) Rooms, ≥ 3 CFUs on surface/air sample plates requires microbial identification for trending and investigational purposes, if applicable.

^Recoveries from Ante, Buffer, MT, and Degown rooms during Aseptic Process Validations will be identified

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5.8 Environmental Monitoring Quarterly Trending

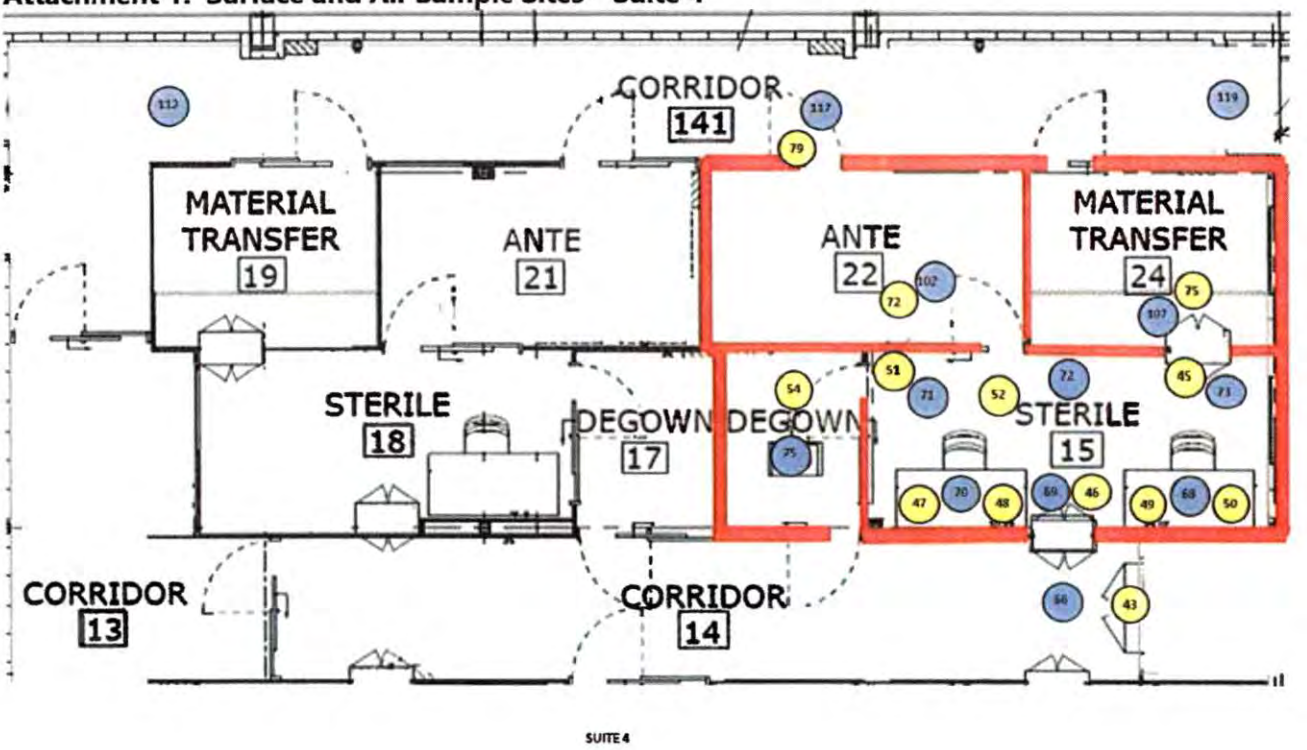
5.8.1 A member of Quality shall prepare a summary of environmental monitoring data on a quarterly basis. This report should include general trending data—including, but not limited to—overall excursion rates for EM sample types (viable surface, viable air, personnel, non-viable particulates), microbial recovery rates, and any remarkable trends that could potentially indicate a shift in the overall environmental quality of the classified cleanroom area(s).

6. APPLICABLE REFERENCES

6.1. GMP-SOP-0016, Cleanroom Gowning Procedure.
6.2. GMP-SOP-0202, Incidents, Deviations, and Nonconformances
6.3. GMP-SOP-0022 Cleanroom Sanitization Procedure
6.4. GMP-Form-0020 Environmental Monitoring Sampling Form
6.5. GMP-Form-0167 Negative Storage Sampling Form
6.6. GMP-Form-0202 Suite 1 Buffer Room Sampling Form
6.7. GMP-Form-0203 Suite 2 Buffer Room Sampling Form
6.8. GMP-Form-0204 Suite 3 Buffer Room Sampling Form
6.9. GMP-Form-0205 Suite 4 Buffer Room Sampling Form
6.10. GMP-WI-0003 ActiveCount 100H Microbial Viable Air Sampler
6.11. GMP-WI-0004 Solair 3350 Airborne Particle Counter
6.12. GMP-Form-0035 Environmental Plating Qualification Checklist
6.13. GMP-SOP-0148, Flow Meter SOP
6.14. GMP-SOP-0131 APEX Remote SOP
6.15. GMP-SOP-0151 Remote 5104P Airborne Particle Counter

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Attachment 1. Surface and Air Sample Sites – Suite 4

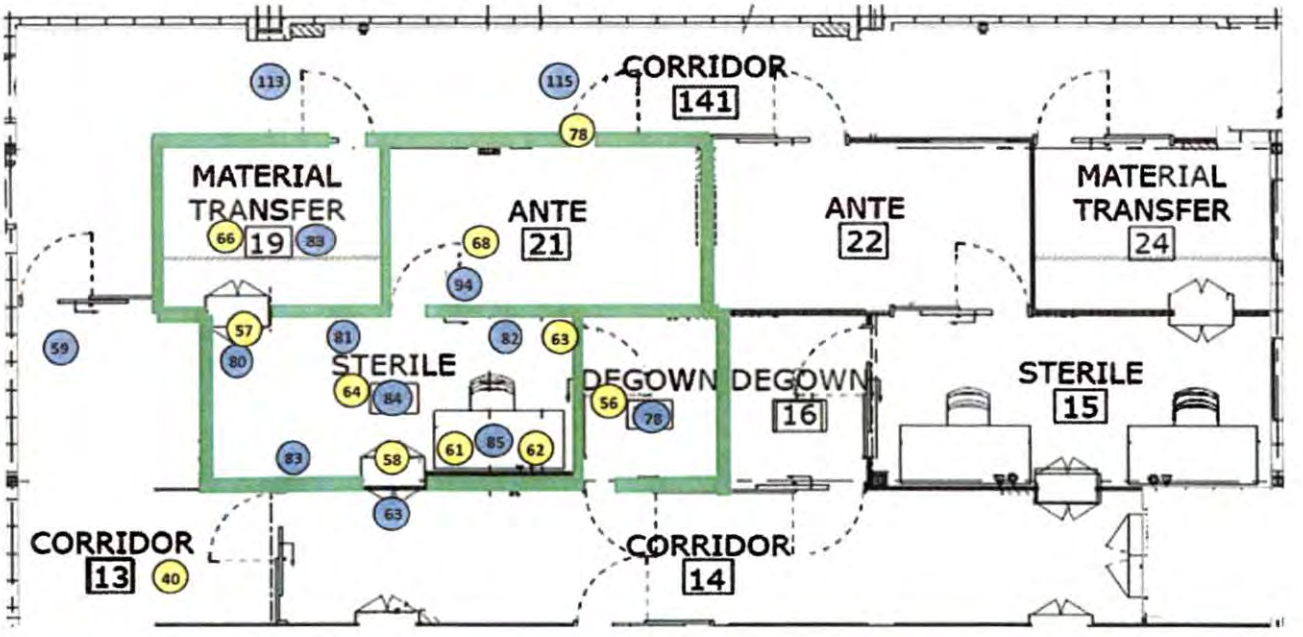


Viable and Non-Viable Air Samples		Surface/Contact Samples	
Sample ID	*Sampling Location/Description*	*Sample ID*	*Sampling Location/Description*
AV-66	Corridor 14, outside Buffer 4 PT	PT-43	Interior of PT, Corridor 14
AV-68*	Buffer 4, BSC 7	PT-45	Interior of PT from MT, inside Buffer 4
AV-69*	Buffer 4, in front of PT to Corridor 14	PT-46	Interior of PT to Corridor 14, inside Buffer 4
AV-70*	Buffer 4, BSC 8	HD-47	BSC 8 – Right Side
AV-71*	Buffer 4, near exit to Degown	HD-48	BSC 8 – Left Side
AV-72*	Buffer 4, middle of room on North wall	HD-49	BSC 7 – Right Side
AV-73*	Buffer 4, in front of PT from MT, near East wall	HD-50	BSC 7 – Left Side
AV-75	Degown, center of room	WA-51	Wall Sample: NW Corner of Buffer Room
AV-102	Anteroom, near entrance to Buffer 4	FL-52	Floor Sample: Buffer Room, inside door from Anteroom
AV-107	Material Transfer, South wall near PT to Buffer 4	FL-54	Floor Sample: Degown Room, near exit from Buffer 4
AV-112	Corridor 141, Northwest corner near fire exit	GB-72	Gowning Bench closest to Buffer Room entrance
AV-117	Corridor 141, outside the entrance to S4 Anteroom	FL-75	Floor Sample: Near PT in Material Transfer
AV-119	Corridor 141, Northeast corner near exit	DR-79	Door Sample: Corridor entrance to Anteroom

*Non-viable sampling is not required at these sites as the buffer room is continuously monitored via Apex Remote 5104p and Apex R5 Serial Particle Counters

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Attachment 2. Surface and Air Sample Sites – Suite 3

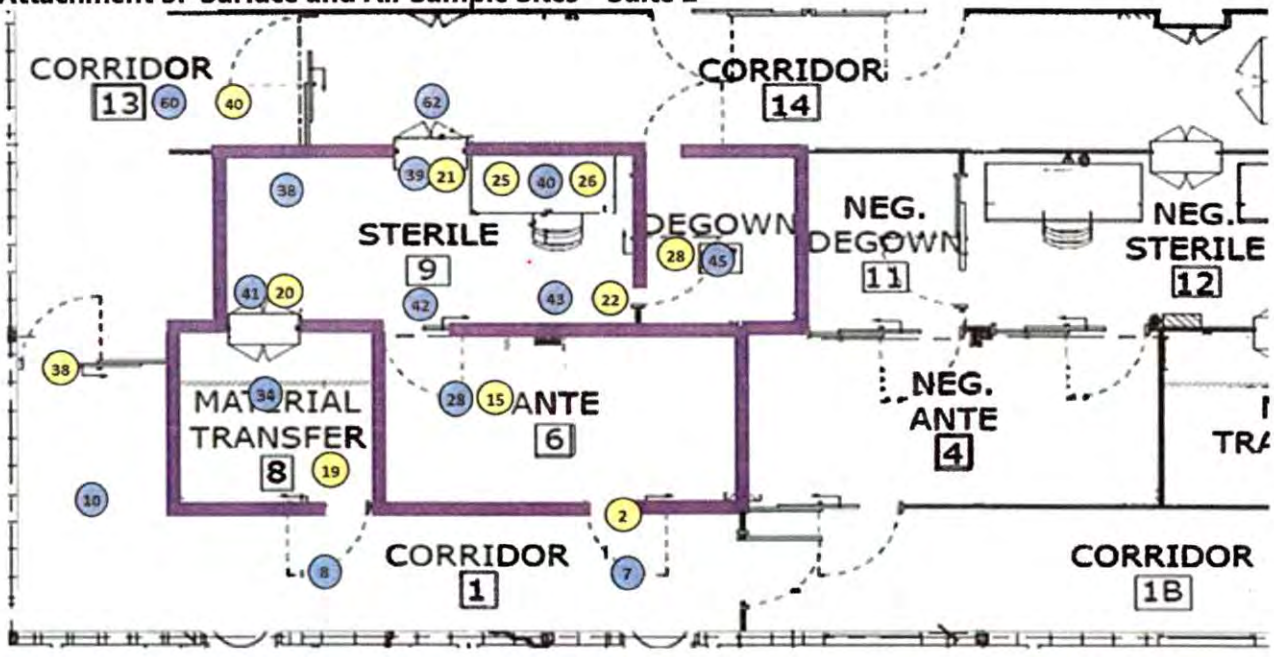


Viable and Non-Viable Air Samples		Surface/Contact Samples	
Sample ID	*Sampling Location/Description*	*Sample ID*	*Sampling Location/Description*
AV-59	Corridor 13, outside the door to Corridor 141	FL-40	Floor Sample: Corridor 13, near entrance to Corr. 14
AV-63	Corridor 14, outside Buffer 3 PT	FL-56	Floor Sample: Degown Room, near exit from Buffer 3
AV-78	Degown, center of room	PT-57	Interior of PT from Material Transfer, inside Buffer 3
AV-80*	Buffer 3, in front of PT from MT, near West wall	PT-58	Interior of PT to Corridor 14, inside Buffer 3
AV-81*	Buffer 3, North Wall; West of entrance from Ante	HD-61	BSC 5– Right Side
AV-82*	Buffer 3, North Wall; East of entrance from Ante	HD-62	BSC 5 – Left Side
AV-83*	Buffer 3, South Wall; West of PT	WA-63	Wall Sample: NE Corner of Buffer Room 3
AV-84*	Buffer 3, Center of Room, near BSC	FL-64	Floor Sample: Near center of Buffer Room 3
AV-85*	Buffer 3 BSC 5	FL-66	Floor Sample: Near PT in Material Transfer
AV-88	Material Transfer, near PT to Buffer 4	GB-68	Gowning Bench closest to Buffer Room entrance
AV-94	Anteroom, near entrance to Buffer 3	DR-78	Door Sample: Corridor entrance to Anteroom
AV-113	Corridor 141, near entrance to S3 Material Transfer		
AV-115	Corridor 141, near entrance to S3 Anteroom		

*Non-viable sampling is not required at these sites as the buffer room is continuously monitored via Apex Remote 5104p and Apex R5 Serial Particle Counters

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Attachment 3. Surface and Air Sample Sites – Suite 2

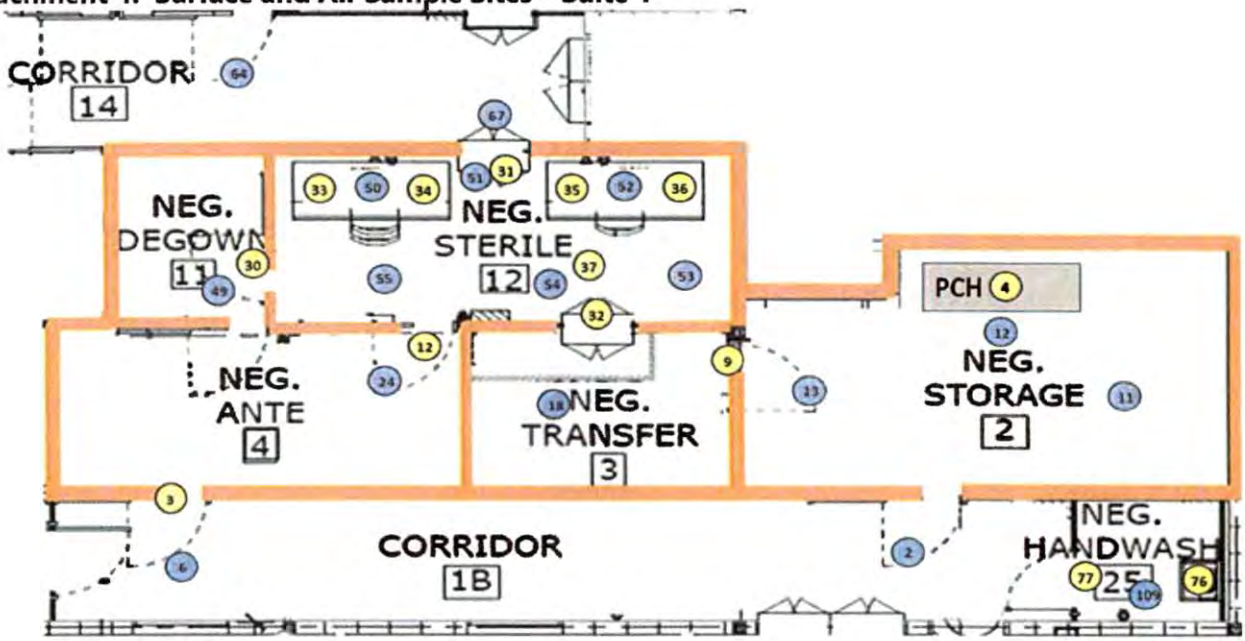


Viable and Non-Viable Air Samples		Surface/Contact Samples	
Sample ID	*Sampling Location/Description*	*Sample ID*	*Sampling Location/Description*
AV-7	Corridor 1, outside the entrance to S2 Anteroom	DR-2	Door Sample: Corridor 1 entrance to S2 Anteroom
AV-8	Corridor 1, outside the entrance to S2 MT	GB-15	Gowning Bench closest to Buffer Room entrance
AV-10	Corridor 1, High Personnel Traffic Area	FL-19	Floor Sample: MT, near entrance from Corridor 1
AV-28	Anteroom, near entrance to Buffer 2	PT-20	Interior of PT from MT, from inside Buffer 2
AV-34	Material Transfer, near PT to Buffer 2	PT-21	Interior of PT to Corridor 14, from inside Buffer 2
AV-38*	Buffer 2, NW Corner of Room	WA-22	Wall Sample: Near exit to DeGown
AV-39*	Buffer 2, in front of PT to Corridor 14	HD-25	BSC 4– Left Side
AV-40*	Buffer 2, BSC 4	HD-26	BSC 4 – Right Side
AV-41*	Buffer 2, in front of PT from MT, near West wall	FL-28	Floor Sample: Degown Room, near exit from Buffer 2
AV-42*	Buffer 2 middle of room near South wall	DR-38	Door Sample: Entrance to Corridor 13
AV-43*	Buffer 2, in front of door to DG, near East wall	FL-40	Floor sample, just West of door to Corridor 14
AV-45	Degown, center of room		
AV-60	Corridor 13, near door to/from Corridor 14,		
AV-62	Corridor 14, outside Buffer 2 PT		

*Non-viable sampling is not required at these sites as the buffer room is continuously monitored via Apex Remote 5104p and Apex R5 Serial Particle Counters

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Attachment 4. Surface and Air Sample Sites – Suite 1



Viable and Non-Viable Air Samples		Surface/Contact Samples	
Sample ID	*Sampling Location/Description*	*Sample ID*	*Sampling Location/Description*
AV-2	Corridor 1B, near entrance to Neg. Storage	DR-03	Door Sample: Corridor 1B entrance to Neg. Anteroom
AV-6	Corridor 1B, near entrance to Neg. Ante	DR-09	Door Sample: Entrance to Neg Transfer from Neg Storage
AV-11	Negative Storage, Near Floor Scale	GB-12	Gowning Bench closest to Buffer Room entrance
AV-12	Negative Storage, in front of PCH	DR-30	Door Sample: Degown Room; door from Neg Buffer
AV-13	Neg Storage, near entrance to Neg. MT	PT-31	Interior of PT to Corridor 14, from inside Neg Buffer
AV-18	Neg. Material Transfer, near center of room	PT-32	Interior of PT from Neg Transfer, from inside Neg Buffer
AV-24	Neg. Anteroom, near doom to Neg. Buffer	HD-33	BSC 1 – Left Side
AV-49	Neg. Degown, towards SE corner of room	HD-34	BSC 1 – Right Side
AV-50*	Negative Buffer, BSC 1*	HD-35	BSC 2 – Left Side
AV-51*	Negative Buffer, in front of PT to Corridor 14*	HD-36	BSC 2 – Right Side
AV-52*	Negative Buffer, BSC 2*	FL-37	Floor Sample: Neg Buffer, between H2 and PT
AV-53*	Negative Buffer, near SE corner*	SK-76	Negative Handwash Sink
AV-54*	Negative Buffer, south wall near middle of room*	FL-77	Negative Handwash Floor, near entrance from Corridor 1B
AV-55*	Negative Buffer, near SW corner*	PCH-04	Surface Sample; Center of PCH
AV-64	Corridor 14, near exits from DG3 and DG4		
AV-67	Corridor 14, outside Negative Buffer PT		
AV-109	Negative Handwash Room		

*Non-viable sampling is not required at these sites as the buffer room is continuously monitored via Apex Remote 5104p and Apex R5 Serial Particle Counters

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OurPharma

ASEPTIC PROCESS VALIDATION

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Table of Contents

1. PURPOSE 3
2. SCOPE 3
3. DEFINITIONS 3
4. RESPONSIBILITIES 3
5. FREQUENCY 3
6. APPROACH 4
7. METHODOLOGY 4
8. RATIONALE 5
9. INSTRUCTIONS 7
10. APPLICABLE REFERENCES 12
11. ATTACHMENTS 13

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1. PURPOSE

1.1. This procedure outlines the methodology, approach, and rationale utilized by OurPharma for aseptic process validation and revalidation.

2. SCOPE

2.1. This procedure applies to all sterile compounded or repackaged drug products produced through aseptic processing at OurPharma, LLC, 2512 S. City Lake Rd., Fayetteville, AR 72701.

2.2. This procedure does not apply to Aseptic Personnel Qualification. Refer to GMP-SOP-00114 Aseptic Personnel Qualification.

3. DEFINITIONS

3.1. QC – Quality Control

3.2. COA – Certificate of Analysis

3.3. COC – Certificate of Conformance

4. RESPONSIBILITIES

4.1. Quality Management

- **4.1.1.** Review and approval of media fill protocols prior to execution
- **4.1.2.** Review and approval of media fill protocol summary reports serving as final dispositioning
- **4.1.3.** Issuance of media fill batch records

4.2. Production Unit

- **4.2.1.** Preparing media fill protocols and summary reports
- **4.2.2.** Execution of media fill batch records and protocols

4.3. Quality Unit

- **4.3.1.** Issuing and maintaining media fill protocol numbers based on **GMP-FORM-0103 Media Fill Log**
- **4.3.2.** Execution of incubation and reading of results associated with media fill protocol execution

5. FREQUENCY

5.1. Initial Aseptic Process Validation

- **5.1.1.** Initial aseptic process validation shall consist of three (3) consecutively successful media fills executed prior to release of any represented drug product(s).

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5.2. Aseptic Process Revalidation

5.2.1. Aseptic process revalidation shall consist of a single successful media fill performed biannually or not more than every six (6) months per family of products.

6. APPROACH

6.1. The approach for aseptic process validation utilized by OurPharma will employ a family approach intended to qualify products grouped together based on similarities with respect to the following:

6.1.1. Pooling Process: the process in which bulk drug product is produced in a bulk container prior to filling.

6.1.2. Filling Process: the process in which bulk drug product is transferred from the bulk container into final container/closures.

6.1.3. Final Container/Closure: the type of container/closure system in which drug product is commercially available.

6.1.3.1. Refer to ATTACHMENTS for family-specific details.

7. METHODOLOGY

7.1. All drug products represented by the defined family shall be used to establish the aseptic process validation process through the execution of media fills.

7.2. Family specific media fills shall be designed to challenge the aseptic processing associated with drug product grouping using the defined worst-case scenario for the following:

7.2.1.1. Maximum number of pooled units

7.2.1.2. Maximum number of manipulations per pooled unit

7.2.1.3. Maximum number of final units produced

7.2.1.4. Maximum number of manipulations per final unit

7.2.1.5. Maximum required production time

7.2.1.6. Maximum number of manipulations during setup for pooling and filling

7.2.1.7. Routine interventions

7.2.1.7.1. Refer to ATTACHMENTS for family specific routine interventions.

7.2.1.8. Non-Routine interventions

7.2.1.8.1. Refer to ATTACHMENTS for family specific non-routine interventions.

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8. RATIONALE

8.1. Pooling Process

8.1.1. The pooling process utilized during aseptic process validation or revalidation shall be a direct simulation to produce sterile 3% tryptic soy broth solution used to challenge the aseptic processing required to produce a bulk drug product container for filling.

8.1.2. All pooling processes begin with sterile finished pharmaceutical drug products, therefore media fills will directly simulate this practice.

8.2. Theoretical Number of Final Units

8.2.1. The total number of final units produced during aseptic process validation or revalidation shall represent minimally the largest theoretical number of units defined per family.

8.2.2. The aseptic process validation or revalidation for each family will be designed to challenge the maximum theoretical number of units produced as a worst-case scenario.

8.3. Production Times

8.3.1. The duration of the aseptic process validation will be designed to minimally reflect the longest duration of hold or production time within the ISO5 classified environment.

8.3.2. When necessary, hold times will be incorporated into the aseptic process validation protocol design to meet and/or exceed the family required production time limits.

8.3.2.1.If under normal production conditions pooled drug product may be held in the sterile pool bag, such maximum hold time shall be incorporated into the study design.

8.4. Number of Manipulations During Setup

8.4.1. The number of manipulations during setup is specific to the tasks required to prepare the bulk drug product container, equipment, and production components in preparation for pooling or filling.

8.4.2. Each family will be assessed based on the number of manipulations required during setup for each drug product represented by the family being aseptically qualified.

8.4.2.1.The maximum number of manipulations during setup shall be utilized within the design of the aseptic process validation or revalidation.

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8.5. Number of Manipulations per Pooled or Filled Unit

8.5.1. The number of manipulations per unit pooled or filled shall reflect the worst-case scenario for the family represented by the aseptic process validation or revalidation.

8.5.2. Each family shall be assessed based on the drug products represented with respect to the total number of manipulations required to pool or fill each unit.

8.5.3. The aseptic process validation shall be designed to directly simulate the filling process with the maximum number of manipulations per unit pooled or filled utilized to challenge the family specific filling process.

8.6. Routine Interventions

8.6.1. Routine interventions shall be incorporated into the design of the aseptic process validation or revalidation based on the family specific routine interventions identified within **ATTACHMENTS.**

8.6.2. Routine interventions shall be used to address the typical tasks associated with the production of each drug product within the family being aseptically qualified.

8.7. Non-Routine Interventions

8.7.1. Non-routine interventions shall be incorporated into the design of the aseptic process validation or revalidation based on the family specific routine interventions identified within **ATTACHMENTS**.

8.7.2. The identified non-routine interventions shall be used to add additional stressful conditions and represent conditions or events which may occur during a production batch.

8.7.2.1.Examples of non-routine interventions include, but are not limited to:

8.7.2.1.1.Spill simulations

8.7.2.1.2.Extra shift changes

8.7.2.1.3.Extra glove changes

8.7.2.1.4.Skipping normal interval hood cleaning

8.7.2.1.5.Power failure simulation

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9. INSTRUCTIONS

9.1. 3% tryptic soy broth (TSB) will be utilized in place of drug products during aseptic process validation or revalidation as a growth media for challenging the sterile nature of drug products produced through aseptic processing.

9.1.1. TSB purchased as ready-to-use solution shall be released by the Quality Unit following inspection and verification of growth promotion testing performed by the manufacturer as indicated on the accompanying COA or COC.

9.2. Aseptic process validation consists of test cases designed to challenge the pooling and filling processes defined for each family.

9.3. Each media fill is governed by a media fill protocol, which is issued a unique number in the format of MFP-YY-XXX whereas:

9.3.1. MFP designates a media fill protocol

9.3.2. YY identified the two (2) digit year

9.3.3. XXX is a sequential number issued and maintained by QC based on **GMP-Form-0103 Media Fill Log**.

9.4. All media fill protocols shall include the following sections:

9.4.1. Approvals

9.4.1.1. Approvals are required from the following departments prior to execution:

9.4.1.1.1. Production Unit

9.4.1.1.2. Quality Unit

9.4.1.1.3. Quality Management

9.4.1.2. All approvals are maintained and controlled in the MasterControl™ electronic system.

9.4.2. Purpose

9.4.2.1. Purpose section is used to define the intent of the aseptic process validation and identify any personnel revalidation being included.

9.4.3. Scope

9.4.3.1. Scope section is used to define the family of products for which the aseptic process validation is applicable.

9.4.3.1.1. If qualification of personnel is going to be performed as participation of the process qualification, it should be addressed in the scope of the protocol.

9.4.4. Family Process Description

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9.4.4.1. The family process description is used to provide a brief description of the product process associated with the family of products being qualified or requalified.

9.4.5. Methodology

9.4.5.1. Methodology section is used to provide a detailed description of the challenges utilized to assess the family of products represented within the aseptic process validation or revalidation.

9.4.6. Instructions

9.4.6.1. Instruction section is used to provide specific steps required during the execution and provide clarity of the requirements contained and documented within the associated media fill protocol.

9.4.7. Acceptance Criteria

9.4.7.1. Acceptance criteria is defined to provide the Quality Unit with the specifications needed to disposition the media fill and/or aseptic process validation based on the content within the media fill protocol summary report.

9.4.8. Attachments

9.4.8.1. Signature Log

9.4.8.1.1. Signature identification log is used to document all personnel participating in the execution of the media fill protocol.

9.4.8.2. Deviation Log

9.4.8.2.1. Deviation log is used to document all observed deviations during the execution of the media fill protocol.

9.4.8.3. Deviation Record

9.4.8.3.1. Deviation record is required for all deviations listed within the Deviation Log and is used to summarize the deviations occurring during media fill protocol execution, as applicable.

9.4.8.4. Executed Media Fill Batch Record

9.4.8.4.1. A copy of the executed media fill batch record is used to document the execution of the media fill.

9.4.8.5. Incubation and Reading of Results

9.4.8.5.1. Incubation and reading of results are used to document the incubation parameters and results of the media filled units following defined incubation parameters.

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9.4.8.6.Growth Promotion

9.4.8.6.1.Growth promotion is used to document the growth promotion of the 3% tryptic soy broth following the completion of incubation and reading/interpretation of the results.

9.4.8.7.Environmental and Personnel Monitoring Results

9.4.8.7.1.Environmental and Personnel Monitoring is used to document the parameters and results of the Room and Technicians involved in the aseptic processing of the media filled units.

9.4.8.7.2.NOTE: Any positive recovery obtained during execution of a media fill shall be identified to the species level.

9.5. Following the execution of the media fill protocol, a media fill protocol summary report shall be drafted, reviewed, and approved inclusive of the following sections:

9.5.1. Approvals

9.5.1.1.Approvals are required from the following departments:

9.5.1.1.1.Production Unit

9.5.1.1.2.Quality Control

9.5.1.1.3.Quality Unit

9.5.1.1.4.All approvals are maintained and controlled in the MasterControl™ electronic system.

9.5.1.1.4.1.Approval by the Quality Unit serves as dispositioning and closure of the media fill based on the data generated and the provided validation statement within the media fill protocol summary report.

9.5.2. Summary of Execution

9.5.2.1.Summary of execution provides details to ensure that the media fill was executed per the approved protocol.

9.5.3. Summary of Deviations

9.5.3.1.Summary of deviations provides details to all observed deviations during the execution of the media fill protocol.

9.5.4. Discussion of Results

9.5.4.1.Discussion of results provides a summary of the results generated from the execution of the media fill protocol.

9.5.5. Validation Statement

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9.5.5.1.A statement provided by the Production Unit during media fill summary report development establishing the status of the scope of the media fill protocol as recommended for one of the following dispositions:

9.5.5.1.1.Approved meaning all acceptance criteria was successfully met and, if applicable, all deviations were assessed to have no impact and have been successfully closed.

9.5.5.1.2.Rejected meaning one or more of the acceptance criteria was not successfully met and/or one or more deviations were assessed to have a direct impact on the media fill or results generated.

9.5.5.2.If aseptic personnel are being qualified through the execution of a process validation media fill, activities, associated personnel, and personnel-specific results shall be discussed within the aseptic process validation protocol and associated summary report.

9.5.5.2.1.Refer to GMP-SOP-0114 Aseptic Personnel Qualification for more information on personnel qualification requirements.

9.6. Media Fill Execution

9.6.1. Media fills are performed as a direct simulation of the production process of the family of drug products represented.

9.6.2. Media fills are designed to challenge the production process through the use of 3% tryptic soy broth growth media at a minimum number of units to reflect the largest quantity of units produced by a single drug product within the family of drug products being qualified.

9.6.3. Rejects identified during the media fill execution shall be segregated and identified as a reject.

9.6.3.1.Rejects can be a result of, however is not limited to, the following rejection rationale:

9.6.3.1.1.Questionable aseptic technique

9.6.3.1.2.Damaged container/closure

9.6.3.1.3.Dropped filled unit

9.6.3.1.4.Leaking filled unit

9.6.3.1.5.A unit reject for any circumstance as would be rejected during routine operation

9.6.3.2.All units rejected during the media fill shall be incubated and interpreted.

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9.6.3.2.1. Rejected units shall not be used for determining the outcome of the media fill or aseptic process validation, and no failure investigation is required if the reject is not associated with a process design flaw.

9.6.3.2.2. All rejected units will be documented within the media fill protocol and detailed within the media fill protocol summary report.

9.7. Acceptance Criteria

9.7.1. Media Fill

9.7.1.1. There shall be zero (0) accepted units observed with microbiological growth through the incubation and reading of results per GMP-SOP-0116 Incubation and Evaluation of Media Filled Units.

9.7.1.2. The minimum quantity of accepted units produced shall reflect the largest quantity of units defined per family of drug products.

9.7.1.3. All routine and non-routine interventions shall be conducted per the approved media fill batch record and protocol.

9.7.1.4. Growth promotion shall be conducted on a representative sample of filled, accepted units following incubation with passing results.

9.7.1.5. Any deviations shall be closed by the Quality Unit and impact on the validated state determined.

9.7.1.6. All required supporting documentation shall be present.

9.7.2. Initial Aseptic Process Validation

9.7.2.1. Three (3) consecutive successfully completed media fill process simulations representative of a single family of drug products.

9.7.3. Aseptic Process Revalidation

9.7.3.1. One (1) successfully completed media fill process simulation representative of a single family of drug products.

9.8. Failure Investigation

9.8.1. All media fills for aseptic process validation or revalidation that fail to meet the defined acceptance criteria shall be accompanied by an investigation per **GMP-SOP-0202 Incidents, Deviations, and Non-Conformances**.

9.8.2. All acceptable units identified as positive for growth during the reading of results shall be identified for the observed organism.

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10. APPLICABLE REFERENCES

10.1.GMP-Form-0103 Media Fill Identification Log

10.2.GMP-SOP-0014 Aseptic Personnel Qualification

10.3.GMP-SOP-0116 Incubation and Evaluation of Media Filled Units

10.4.GMP-SOP-0202 Incidents, Deviations, and Non-Conformances

10.5.GMP-PDTMethods-0013 Family A- Aseptic Process Validation

10.6.GMP-PDTMethods-0023 Family B- Aseptic Process Validation

10.7.GMP-PDTMethods-0024 Family C-Aseptic Process Validation

10.8.GMP-PDTMethods-0065 Family D- Aseptic Process Validation

11. ATTACHEMENTS

11.1.ATTACHMENT-1: Family A

11.2.ATTACHMENT-2: Family B

11.3.ATTACHMENT-3: Family C

11.4.ATTACHMENT-4 Family D

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ATTACHMENT-1: Family A

Pooling Process

Sterile finished pharmaceuticals are pooled into a sterile IV bag through aseptic processing utilizing a repeater pump to pool vials, a repeater pump to pool IV bags, and manual injection utilizing a syringe, all occurring within the ISO5 classified environment.

Filling Process

Sterile, bulk drug product is filled into a final container/closure in the form of a cassette utilizing a repeater pump and tube set within the ISO5 classified environment.

Family A – Drug Products

Drug Product	FID	Final Container / Closure	Fill Volume (mL)	Pooling Manipulations		# of Pooled Units	Filling Manipulations		Theoretical # of Final Units
				Setup	Pooling		Setup	Filling	
HYDROmorphone HCl 0.2 mg/mL	1003-01	50 mL Cassette	50	9	8	13	9	4	320
HYDROmorphone HCl 0.2 mg/mL	1003-02	100 mL Cassette	100	9	8	24	9	4	220
fentaNYL Citrate 50 mcg/mL	1001	50 mL Cassette	50	3	2	320	9	4	320

Family A – Routine Interventions

Pooling Process - Repack	
Routine Intervention #	**Description**
R1	Luer-to-bag adapter to tube set outlet connection
R2	Additive port cap removal onto SIPA swab.
R3	Luer-to-bag adapter to additive port connection.
R4	Dispensing pin to tube set inlet connection.
R5	Dispensing pin replacement.
R6	Vial staging post sanitization.
R7	Insertion of dispensing pin into pooling vial (per pooled vial utilizing repeater pump)
R8	Removal of dispensing pin from pooling vial (per pooled vial utilizing repeater pump)
R9	Additive port cap replacement post pooling.
R10	Max personnel in room: NLT 6 for NLT 2 hours.
Pooling Process - Formulation	
Routine Intervention #	Description
R11	Max # of people in room during formulation and filtration (NLT 6 people for 2 hours)
R12	Formulation within ISO8 negative storage room
R13	pH measurement/adjustment
R14	Bioburden collection
Pooling Process – Custom Filter/Bag Assembly	
Routine Intervention #	**Description**
R15	Custom filter/bag assembly
R16	Filtration within ISO8 negative storage room
R17	Filter to bag assembly disconnection within negative pressure ISO8 space

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ATTACHMENT-1: Family A Cont.

Family A – Non-Routine Interventions	
Pooling Process	
Non-Routine Intervention #	Description
NR1	Glove change
NR3	Exceed maximum non-sterile hold time
NR4	Exceed maximum dispensing, formulation and filtration duration of 4 hours
NR5	Exceed maximum pooling bag hold time of 120 hours
NR6	Entry and exit from Ante to De-gown with line open.
NR7	Exceed maximum sterile to sterile pooling duration of 3 hours.
Family A – Routine Interventions	
Filling Process	
Routine Intervention #	Description
R18	Pool bag filling lead to luer-to-luer tube set.
R19	Simulate a break in filling by exiting the cleanroom and re-entering to resume process.
R20	Priming syringe to luer-to-luer adapter connection.
R21	Tube set to luer-to-luer adapter connection.
R22	Priming syringe with luer-to-luer adapter disconnection.
R23	Fill within ISO5 BSC within positive pressure ISO7 buffer room.
R24	Manual filling of cassette from syringe
R25	Disconnection of syringe from final container/closure during air extraction (per cassette)
R26	Tube set connection to final container/closure (per cassette)
R27	Tube set disconnection from final container/closure (per cassette)
R28	Exceed maximum filling duration of 8 hours.
R29	Wrapping of fill line around CADD cassette
R30	Passing of CADD cassette to operator 2 for deairing
R31	Attachment of syringe to final container/closure during air extraction (per cassette)

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ATTACHMENT-1: Family A Cont.

Family A – Non-Routine Interventions	
Filling Process	
Non-Routine Intervention #	Description
NR8	Simulated spill
NR9	Glove change
NR10	Reverse pump prior to filling tube change
NR11	Exceed maximum filling duration
NR12	Secondary filling tube set used
NR13	Exceed maximum batch size of 320
NR14	Entry and exit from Ante to De-gown with line open.
NR15	Items passed into hood without being sanitized. Items removed, deck sanitized, impacted items sanitized prior to proceeding with production processes.
NR16	Change Out Repeater Pump

Media Fill Design

The Family A media fill is designed to challenge the aseptic processing required to produce the drug products represented within Family A. The design is a direct simulation of the pooling and filling processes representative of the drug products contained within Family A.

During the pooling process outlined per **GMP-PDTMethods-0013,** not less than 400 pooled vials using a repeater pump, not less than 12 pooled IV bags using a repeater pump, and not less than 12 pooled vials using syringes will be used to produce 4 pooling bags to simulate the Family A maximum number of pooled units. During the pooling portion of the aseptic process, all routine and non-routine interventions will be incorporated in an attempt to challenge the manufacturing process and the controls established.

During the filling process outlined per **GMP-PDTMethods-0014,** not less than 400 final units, in the form of cassettes, will be filled to simulate the Family A maximum defined batch size. During the filling portion of the aseptic process, all routine and non-routine interventions will be incorporated in an attempt to challenge the manufacturing process and the controls established.

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ATTACHMENT-2: Family B

Pooling Process

Bulk raw materials are formulated per drug product specific instructions with the approved master production record. The non-sterile solution is sterilized through filtration utilizing a transfer pump and a custom designed filter/bag assembly. There are no routine or non-routine interventions associated with the Family B pooling process impacting drug product sterility. **R1** and **R2** are controlled through the approved master production record of the associated drug product within Family B. The design of the custom, pre-sterilized filter/bag assembly is intended to sterilize drug product through solution transfer within an ISO8 classified environment.

Filling Process

Sterile, bulk drug product is filled into a final container/closure in the form of a syringe utilizing a repeater pump and luer-to-luer adapter within the ISO5 classified environment.

Family B – Drug Products

Drug Product	FID	Final Container / Closure	Fill Volume (mL)	Pooling Manipulations		# of Pooled Units	Filling Manipulations		Theoretical # of Final Units
				Setup	Pooling		Setup	Filling	
Fentanyl Citrate 2.5 mg	1007	50 mL Syringe	50	2	0	1	6	3	1,000
Fentanyl Citrate 2 mcg/mL / Bupivacaine HCl 0.125% in 0.9% Sodium Chloride	1004	50 mL Syringe	50	2	0	1	6	3	1,000
Morphine Sulfate (1mg/mL)	1020	30 mL BD Syringe	30	2	0	1	6	3	1,200
Morphine Sulfate (1mg/mL)	1021	35 mL Monoject Syringe	30	2	0	1	6	3	1,200
Morphine Sulfate (1mg/mL)	1022	35 mL Plunger-less	30	2	0	1	6	3	1,200
Hydromorphone HCl (0.2mg/mL)	1032	30 mL BD Syringe	30	2	0	1	6	3	1,200
Hydromorphone HCl (0.2mg/mL)	1033	35 mL Monoject Syringe	30	2	0	1	6	3	1,200

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Hydromorphone HCl (0.2mg/mL)	1034	35 mL Plunger-less	30	2	0	1	6	3	1,200
Hydromorphone HCl (1mg/mL)	1042	30 mL BD Syringe	30	2	0	1	6	3	1,200
Hydromorphone HCl (1mg/mL)	1043	35 mL Monoject Syringe	30	2	0	1	6	3	1,200
Hydromorphone HCl (1mg/mL)	1044	35 mL Plunger-less	30	2	0	1	6	3	1,200
Ketamine HCl 25 mg / 0.5 mL	2000-02	3 mL Syringe	0.5	3	2	1	6	3	2,100
Ketamine HCl 50 mg / 1 mL	2000-01	3 mL Syringe	1	3	2	1	6	3	2,100

Family B – Routine Interventions	
Formulation	
Routine Intervention #	**Description**
R1	Max # of people in room during formulation and filtration for NLT 2 hours
R2	Formulation within ISO8 negative storage room
R3	pH measurement/adjustment
R4	Bioburden collection
Filtration- Custom filter/bag assembly	
Routine Intervention #	Description
R5	Custom filter/bag assembly
R6	Filtration within ISO8 negative storage room
R7	Filter to bag assembly disconnection within negative pressure ISO8 space
Pooling Process- Sterile to Sterile	
Routine Intervention #	**Description**

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R8	Max # of people in room during pooling for NLT 2 hours
R9	Dispensing pin to pooling tube set connection during setup
R10	Pooling tube set to luer lock-to-bag adapter connection during setup
R11	Empty bag to luer lock-to-bag adapter connection during setup
R12	Air removal from pooling bag during pooling
R13	Insertion of dispensing pin into pooling vial (per pooled vial utilizing repeater pump)
R14	Removal of dispensing pin from pooling vial (per pooled vial utilizing repeater pump)
Filling Process	
Routine Intervention #	Description
R15	Max # of people in room during filling for NLT 2 hours
R16	Pooling bag to transfer tube set connection during setup
R17	Filling tube set to luer-to-luer adapter connection during setup (replaced as needed during filling)
R18	Priming syringe to luer-to-luer adapter connection during setup
R19	Priming syringe disconnection from luer-to-luer adapter following tube set priming
R20	Calibration syringe to luer-to-luer adapter connection following tube set priming
R21	Calibration syringe disconnection from luer-to-luer adapter during pump calibration
R22	Manual syringe to syringe transfer
R23	Syringe to luer-to-luer adapter connection for filling (per syringe)
R24	Syringe to luer-to-luer adapter disconnection for capping (per syringe)
R25	Capping syringe (per syringe)
R26	Simulated Break in filling process (exit and re-entry of classified environment)

ATTACHMENT-2: Family B

Family B – Non-Routine Interventions	
Dispensing, Formulation and Filtration Process	
Non-Routine Intervention #	Description
NR1	Exceed maximum non-sterile hold time of 120 minutes
NR2	Exceed maximum dispensing, formulation and filtration duration of 6 hours

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NR3	Exceed maximum pooling bag hold time of 120 hours
Pooling Process	
Non-Routine Intervention #	Description
NR4	Secondary pooling tube set used
NR5	Change out repeater pump
NR6	Glove Change
NR7	Entry from Ante Room (pooling line open)
NR8	Exit to degown (pooling line open)
NR9	Exceed maximum pool bag hold time of 120 hours
Filling Process	
Non-Routine Intervention #	Discripition
NR10	Simulated spill
NR11	Glove change
NR12	Exceed maximum filling duration of 24-hours
NR13	Reverse pump filling prior to filling tube change
NR14	Secondary filling tube set used

Media Fill Design

The Family B media fill is designed to challenge the aseptic processing required to produce the drug products represented within Family B. The design is a direct simulation of the pooling and filling processes representative of the drug products contained within Family B.

During the pooling process outlined per **GMP-PDTMethods-0023**, formulation is performed at a batch size of 50 kg of non-sterile growth media. The non-sterile growth media is sterilized during solution transfer utilizing a transfer pump and a custom filter/bag assembly. During the pooling portion of the aseptic process, all routine and non-routine interventions will be incorporated in an attempt to challenge the manufacturing process and the controls established.

During the filling process outlined per **GMP-PDTMethods-0023,** not less than 2,100 final units, in the form of syringes, will be filled to simulate the Family B maximum defined batch size. During the filling portion of the aseptic process, all routine and non-routine interventions will be incorporated in an attempt to challenge the manufacturing process and the controls established.

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ATTACHMENT-3: Family C

Pooling Process

Bulk raw materials are formulated per drug product specific instructions with the approved master production record. The non-sterile solution is sterilized through filtration utilizing a transfer pump.

Use of Custom Filter/Bag Assembly:
There are no routine or non-routine interventions associated with the Family C pooling process impacting drug product sterility when utilizing the custom filter/bag assembly. **R1** and **R2** are controlled through the approved master production record of the associated drug product within Family C. The design of the custom, pre-sterilized filter/bag assembly is intended to sterilize drug product through solution transfer within an ISO8 classified environment.

Use of Filter:
The use of a single filter requires multiple routine interventions associated with the Family C pooling process specifically setup for filtration impacting drug product sterility. **RA** and **RB** are controlled through the approved master production record of the associated drug product within Family C. The design of the filter is intended to sterilize drug product through solution transfer within an ISO5 classified environment.

Filling Process

Sterile, bulk drug product is filled into a final container/closure in the form of IV bags utilizing a repeater pump, filling tube set, and needle within the ISO5 classified environment.

Family C – Drug Products

Drug Product	FID	Final Container / Closure	Fill Volume (mL)	Pooling Manipulations		# of Pooled Units	Filling Manipulations		Theoretical # of Final Units
				Setup	Pooling		Setup	Filling	
Fentanyl Citrate 500mcg/Bupivacaine 250mg added	1005	500 mL Bag	5 mL	5	1	1	7	2	1100
Fentanyl Citrate 500mcg/Bupivacaine 312mg added to 250mL 0.9% NaCl bag	1014	250 mL Bag	15 mL	5	1	1	7	2	1100
Fentanyl Citrate 1mg added to 100mL 0.9% NaCl bag	1013	100 mL Bag	5 mL	5	1	1	7	2	1100
Fentanyl 2.5mg added to 250mL NS Bag	1016	250mL Bag	5mL	5	1	1	7	2	1100

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Family C – Routine Interventions	
Pooling Process	
Formulation	
Routine Intervention #	Description
R1	Max # of people in room during formulation and filtration
R2	Formulation within ISO8 negative storage room
R3	pH measurement/adjustment
R4	Bioburden collection
Custom Filter / Bag Assembly	
Routine Intervention #	Description
R5	Custom filter/bag assembly
R6	Filtration within ISO8 negative storage room
R7	Filter to bag assembly disconnection within negative pressure ISO8 space
Stand Alone Filter	
Routine Intervention #	Description
RA	Filling bag, luer-to-bag adapter, extension tube set, and filter
RB	Filtration within ISO5 BSC within positive pressure ISO7 buffer room
RC	Filling bag to luer-to-bag adapter connection
RD	Luer-to-bag adapter to extension tube set connection
RE	Filter outlet to extension tube set connection
RF	Filling bag from luer-to-bag adapter disconnection following filtration
RG	Max # of people in room during filtration
Filling Process	
Routine Intervention #	Description
R8	Filling within ISO5 BSC within positive pressure ISO7 buffer room
R9	Pooling bag to filling tube set connection during setup
R10	Filling tube set to luer-to-luer adapter connection during setup
R11	Priming syringe to luer-to-luer adapter connection during setup
R12	Priming syringe disconnection from luer-to-luer adapter following tube set priming

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R13	Repeater pump calibration setup
R14	Calibration unit disconnection during calibration
R15	Re-calibration of the repeater pump
R16	Needle to filling tube set connection during filling (repeated as needed during filling)
R17	Needle to bag connection during filling (per filled unit)
R18	Needle to bag disconnection during filling (per filled unit)
R19	Sterile wipe below operator, in direct compounding area to collect drips
R20	Max # of people in room during filling
R21	Break in filling process

ATTACHMENT-3: Family C

Family C – Non-Routine Interventions	
Pooling Process	
Non-Routine Intervention #	Description
NR1	Exceed maximum non-sterile hold time
NR2	Exceed maximum dispensing, formulation and filtration duration of 6 hours
NR3	Exceed maximum pooling bag hold time of 120 hours
Family C – Non-Routine Interventions	
Filling Process	
Non-Routine Intervention #	Description
NR4	Simulated spill
NR5	Glove change
NR6	Reverse pump filling prior to filling tube change
NR7	Secondary filling tube set used
NR8	Exceed maximum filling duration
NR9	Exceed maximum batch size of 1000
NR10	Entry from Ante Room (filling line open)
NR11	Exit to degown (filling line open)

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NR12	Items passed into hood without being sanitized. Items removed, deck sanitized, impacted items sanitized prior to proceeding with production processes.
NR13	Change Out Repeater Pump
NR14	Exceed maximum gowning duration of 5 hours

Media Fill Design

The Family C media fill is designed to challenge the aseptic processing required to produce the drug products represented within Family C. The design is a direct simulation of the pooling and filling processes representative of the drug products contained within Family C.

During the pooling process outlined per **GMP-PDTMethods-0024**, formulation is performed at a batch size of 25 kg of non-sterile growth media. 20L of the non-sterile growth media is sterilized during solution transfer utilizing a transfer pump and a custom filter/bag assembly. 5L of the non-sterile growth media is sterilized during solution transfer utilizing a stand alone filter. During the pooling portion of the aseptic process, all routine and non-routine interventions will be incorporated in an attempt to challenge the manufacturing process and the controls established.

During the filling process outlined per **GMP-PDTMethods-0024**, not less than 1100 final accepted units, in the form of IV bags, will be filled to simulate the Family C maximum defined batch size. During the filling portion of the aseptic process, all routine and non-routine interventions will be incorporated in an attempt to challenge the manufacturing process and the controls established.

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ATTACHMENT-4: Family D

Pooling Process

Bulk raw materials are formulated per drug product specific instructions with the approved master production record. The non-sterile solution is sterilized through filtration utilizing a transfer pump.

Use of Custom Filter/Bag Assembly:
There are no routine or non-routine interventions associated with the Family D pooling process impacting drug product sterility when utilizing the custom filter/bag assembly. **R1** and **R2** are controlled through the approved master production record of the associated drug product within Family D. The design of the custom, pre-sterilized filter/bag assembly is intended to sterilize drug product through solution transfer within an ISO8 classified environment.

Filling Process

Sterile, bulk drug product is filled into a final container/closure in the form of PCA vials utilizing a repeater pump, filling tube set, and needle within the ISO5 classified environment.

Family D– Drug Products

Drug Product	FID	Final Container / Closure	Fill Volume (mL)	Pooling Manipulations		# of Pooled Units	Filling Manipulations		Theoretical # of Final Units
				Setup	Pooling		Setup	Filling	
Morphine Sulfate 1mg/mL 30mL PCA Vial	1010	30 mL PCA Vial	30 mL	2	0	1	7	4	667
Hydromorphone 0.2mg/mL 30mL PCA Vial	1035	30 mL PCA Vial	30 mL	2	0	1	7	4	667
Hydromorphone 1.0mg/mL 30mL PCA Vial	1045	30 mL PCA Vial	30 mL	2	0	1	7	4	667

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Family D – Routine Interventions	
Pooling Process	
Custom Filter / Bag Assembly	
Routine Intervention #	Description
R1	Custom filter/bag assembly
R2	Filter to bag assembly disconnection within ISO8
Filling Process	
Routine Intervention #	Description
R3	Pooling bag to filling tube set connection during setup
R4	Filling tube set to luer-to-luer adapter connection during setup
R5	Priming syringe to luer-to-luer adapter connection during setup
R6	Priming syringe disconnection from luer-to-luer adapter following tube set priming
R7	Repeater pump calibration setup
R8	Calibration unit disconnection during calibration
R9	Filling tube set connection during filling (repeated as needed during filling)
R10	Filling tube set disconnection during filling (per filled unit)
R11	Capping PCA Vial
R12	Manual Fill of PCA Vial
R13	All filling within same BSC

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ATTACHMENT-4: Family D

Family D – Non-Routine Interventions	
Pooling Process	
Non-Routine Intervention #	Description
NR1	Exceed maximum pooling bag hold time of 120 hours

Family D – Non-Routine Interventions	
Filling Process	
Non-Routine Intervention #	Description
NR2	All filling conducted within the same ISO5 BSC
NR3	Simulated spill
NR4	Glove change
NR5	Simulated break in filling process (Exit and Re-Entry of classified environment)
NR6	Re-calibration of the repeater pump
NR7	Maximum filling duration exceeded

Media Fill Design

The Family D media fill is designed to challenge the aseptic processing required to produce the drug products represented within Family D. The design is a direct simulation of the pooling and filling processes representative of the drug products contained within Family D.

During the pooling process outlined per **GMP-PDTMethods-0060**, formulation is performed at a batch size of 20 kg of non-sterile growth media. The non-sterile growth media is sterilized during solution transfer utilizing a transfer pump and a custom filter/bag assembly. During the pooling portion of the aseptic process, all routine and non-routine interventions will be incorporated in an attempt to challenge the manufacturing process and the controls established.

During the filling process outlined per **GMP-PDTMethods-0060**, not less than 667 final units, in the form of PCA Vials, will be filled to simulate the Family D maximum defined batch size. During the filling portion of the aseptic process, all routine and non-routine interventions will be incorporated in an attempt to challenge the manufacturing process and the controls established.

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ASEPTIC PERSONNEL QUALIFICATION

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Table of Contents

1. PURPOSE 3
2. SCOPE 3
3. DEFINITIONS 3
4. RESPONSIBILITIES 3
5. FREQUENCY 4
6. APPROACH 4
7. INSTRUCTIONS 5
8. APPLICABLE REFERENCES 7
9. ATTACHMENTS 7

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1. PURPOSE

1.1. This procedure outlines the approach and process utilized by OurPharma, LLC for aseptic personnel qualification and requalification.

2. SCOPE

2.1. This procedure applies to personnel performing aseptic processing in support of cGMP processes at the OurPharma, LLC, 2512 S. City Lake Rd., Fayetteville, AR 72701.

2.2. This procedure does not apply to Aseptic Process Qualification. Refer to **GMP-SOP-0115** *Aseptic Process Validation*.

3. DEFINITIONS

3.1. None

4. RESPONSIBILITIES

4.1. Production Management

4.1.1. Execution of media fill batch records and protocols

4.1.2. Ensure all aseptic personnel are qualified and requalified as required

4.2. Quality Assurance (QA)

4.2.1. Issuance of media fill batch records

4.2.2. Verify and ensure all aseptic personnel are qualified and requalified as required

4.2.3. Issuing and maintaining media fill numbers based on **GMP-Form-0227** *Aseptic Personnel Qualification Log*.

4.3. Quality Control (QC)

4.3.1. Execution of incubation and reading of results associated with media fill protocol execution

4.4. All personnel

4.4.1. Participating in the execution of media fill qualifications as required

5. FREQUENCY

5.1. Initial Aseptic Personnel Qualification

5.1.1. Initial aseptic personnel qualification shall consist of three (3) consecutively successful media fills executed of **GMP-PDTMethods-0076** *MFBR Aseptic Personnel Qualification* prior to participation as an aseptic operator in production of cGMP drug products.

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5.1.2. This level of qualification is required to demonstrate proficiency in the required techniques and manipulations required for each product family.

5.2. Aseptic Personnel Requalification

5.2.1. Aseptic personnel requalification shall consist of a single successful media fill of **GMP-PDTMethods-0076** performed biannually or not less than every six (6) months + 14 days, following the initial qualification.

5.3. Supervisor Qualification

5.3.1. Aseptic Supervisor qualification shall consist of a single successful media fill of **GMP-PDTMethods-0076** for initial qualification and biannually thereafter.

5.3.2. This level of qualification does not permit these individuals to perform aseptic operations in the GMP production of drug products intended for distribution and only serves to demonstrate basic proficiency in the required techniques and manipulations required for each product family as would be appropriate to supervise the production activities.

5.3.3. Aseptic Supervisors may participate in GMP production activities as aseptic operators, if necessary, after successfully completing the aseptic personnel qualification described in this procedure.

6. APPROACH

6.1. All aseptic personnel qualification activities shall simulate routine and non-routine interventions associated with each specific family of drug products. Associated interventions are defined in **Attachment 1**.

6.2. Drug product families are defined per **GMP-SOP-0115** *Aseptic Process Validation*.

6.3. Each personnel qualification shall be assigned a unique aseptic personnel qualification (APQ) number.

6.3.1. QA will assign the qualification number in the format APQ-YY-XXX where:

6.3.1.1. YY designates the 2-digit year code (i.e., 2022 is assigned 22)

6.3.1.2. XXX designates a sequential number based on **GMP-Form-0227** *Aseptic Personnel Qualification Log*, which will start with 001 for each associated year.

6.3.2. Upon the completion of **GMP-PDTMethods-0076**, QA will record the acceptance or rejection of the qualification on **GMP-Form-0227** *Aseptic Personnel Qualification Log* and **GMP-Form-0226** *Aseptic Personnel Qualification Coversheet*.

7. REQUIREMENTS: GMP-PDTMETHODS-0076

7.1. 3% tryptic soy broth will be utilized in place of drug products during aseptic personnel qualification or requalification as a growth media for challenging the sterile nature of drug products produced through aseptic processing.

7.2. The scope of the aseptic personnel qualification execution shall include the qualification of personnel compounding products categorized into Families A (Cassettes), B (Syringes), C (Bags) and D (PCA vials).

7.3. Aseptic personnel qualification consists of test cases designed to challenge the pooling and filling processes defined for each family for each person being qualified and to test the operator under normal compounding conditions.

7.3.1. The pooling portion will be divided into two sections. The first section represents bulk formulation processes and personnel will use 3% TSB powder to formulate 10 liters of liquid media. This will then be filtered, and personnel will begin the second portion. The second section represents sterile-to-sterile formulation processes and personnel will pool sterile 3% TSB media vials into a 5 liter pool bag to simulate sterile-to-sterile processes.

7.3.2. The filling process is designed to so that personnel will fill not less than 50 accepted cassettes and PCA vials, not less than 100 accepted syringes and IV bags. The total number of accepted units shall be not less than 300.

7.4. Each personnel qualification packet shall include a completed **GMP-Form-0226** *Aseptic Personnel Qualification Coversheet.*

7.4.1. Each coversheet shall contain the following attachments:

7.4.1.1. Executed Batch Record(s)

7.4.1.2. Environmental and Personnel Monitoring Results

7.4.1.3. Any positive recovery obtained within the during execution of a media fill outside of the defined criteria for environmental and personnel monitoring shall be identified to the species level and used in support of any circumstances observed outside of routine operations per **GMP-SOP-0025** *Environmental and Personnel Monitoring.*

7.4.1.4. Lighthouse data of the rooms and suites used during the pooling and filling of the the personnel qualification.

7.4.1.5. Growth promotion data provided by the third-party testing laboratory.

7.4.1.6. A reference to any investigations associated with the personnel qualification.

7.4.2. A copy of **GMP-Form-0226** shall be placed in the training file of the staff member performing the media fill upon approval of the qualification packet.

7.5. Acceptance Criteria

7.5.1. In order for execution of aseptic personnel qualification to be deemed successful, the following conditions must be met:

7.5.1.1. Requirements of **Table 1** and **Attachment 1** shall be met. If any criteria are not met, an incident shall be initiated per ***GMP-SOP-0202*** *Incidents, Deviations, and Non-Conformances.*

7.5.1.2. Any deviations shall be closed by the Quality Unit prior to final disposition.

7.5.1.3. All required supporting documentation shall be present.

TABLE-1: ASEPTIC PERSONNEL QUALIFICATION ACCEPTANCE CRITERIA

Parameter	Acceptance Criteria
ISO 5 BSC	All sterile-to-sterile pooling conducted within the same ISO 5 BSC
ISO 8 Bulk Compounding Room	All bulk compounding pooling conducted within the same ISO 8 room
Repeater Pump Pooling of Vials	NLT 75 vials
Repeater Pump Pooling of IV Bags	NLT 2 IV bags
Syringe Pooling of Vials	NLT 3 vials
Technicians Pooling	1 technician
10L Pooling Bag	1 – 10L pooling bag
5L Pooling Bag	1– 5L pooling bag
10L and 5L Pooling Bag Evaluation	All Pooling Bags Reported as PASS – No Evidence of Growth
ISO 5 BSC	All filling conducted within the same ISO 5 BSC
Cassettes Filled	NLT 50 cassettes
PCA Vials Filled	NLT 50 PCA vials
Syringes Filled	NLT 100 syringes
IV Bags Filled	NLT 100 bags
Technicians Filling	1 technician
GMP-PDTMethods-0076	Reviewed and Approved by Quality
Accepted Unit Evaluation	All Accepted Units Reported as PASS – No Evidence of Growth
Growth Promotion	PASS – Growth Observed for All Test Organisms
Deviations	Refer to **GMP-SOP-0202.**

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7.6. Failure Investigation

7.6.1. All media fills for aseptic personnel qualification or requalification that fail to meet the defined acceptance criteria shall be accompanied by an investigation per **GMP-SOP-0202** *Incidents, Deviations, and Non-Conformances.*

7.6.2. In the event a media fill associated with the initial aseptic personnel qualification is reported as rejected, the person to be qualified requires three (3) consecutively successful media fill executions.

7.6.3. In the event a media fill associated with aseptic personnel requalification is reported as rejected, the person to be qualified shall be deemed disqualified until three (3) consecutively successful media fill executions have been completed.

7.6.4. All units identified as positive for growth during the reading of results shall be identified for the observed organism.

7.7. Aseptic Personnel Qualification Record

7.7.1. Aseptic personnel qualifications participation and results shall be stored within the document archive.

8. APPLICABLE REFERENCES

8.1.GMP-SOP-0115 *Aseptic Process Qualification*

***8.2.*GMP-SOP-0116** *Incubation and Evaluation of Media Filled Units*

8.3.GMP-SOP-0202 *Incidents, Deviations, and Non-Conformances*

8.4.GMP-Form-0226 *Aseptic Personnel Qualification Cover Sheet*

8.5.GMP-Form-0227 *Aseptic Personnel Qualification Log*

9. ATTACHMENTS

ATTACHMENT-1: Intervention Tables

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Attachment 1:

Routine Interventions Pooling Process- Bulk Compounding	
Stand Alone Filter	
Routine Intervention #	Description
R1	Filling bag, luer-to-bag adapter, extension tube set, and filter
R2	Filtration routine interventions within ISO5
R3	Filling bag to luer-to-bag adapter connection
R4	Luer-to-bag adapter to extension tube set connection
R5	Filter outlet to extension tube set connection
R6	Filling bag from luer-to-bag adapter disconnection following filtration
Routine Interventions Pooling Process- Sterile to Sterile	
Routine Intervention #	Description
R7	Dispensing pin to pooling tube set connection during setup
R8	Pooling tube set to luer lock-to-bag adapter connection during setup
R9	Empty bag to luer lock-to-bag adapter connection during setup
R10	Needle to syringe connection during setup
R11	Air removal from pooling bag during pooling
R12	Insertion of dispensing pin into pooling vial (per pooled vial utilizing repeater pump)
R13	Removal of dispensing pin from pooling vial (per pooled vial utilizing repeater pump)
R14	Diluent bag change during pooling (per pooled IV bag)
R15	Needle to pooling bag connection (per pooled vial utilizing manual syringe)
R16	Needle to pooling bag disconnection (per pooled vial utilizing manual syringe)
Non-Routine Interventions Pooling Process- Sterile to Sterile	
Non-Routine Intervention #	Description
NR1	Glove change
NR2	Pooling tube set change

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Routine Interventions Filling Process- Family A	
Routine Intervention #	Description
R17	Filling tube set to luer-to-luer adapter connection during setup (replaced as needed during filling)
R18	Priming syringe to luer-to-luer adapter connection during setup
R19	Priming syringe disconnection from luer-to-luer adapter following tube set priming
R20	Calibration syringe to luer-to-luer adapter connection following tube set priming
R21	Calibration syringe disconnection from luer-to-luer adapter during pump calibration
R22	Luer-to-luer adapter disconnection from filling tube set following pump calibration
R23	Filling tube set connection to final container/closure (per cassette)
R24	Filling tube set disconnection from final container/closure (per cassette)
R25	Wrapping of fill line around CADD cassette
R26	Simulated passing of CADD cassette for deairing
R27	Attachment of syringe to cassette during air extraction
R28	Disconnection of syringe from cassette
R29	Manual filling of cassette from waste syringe
Routine Interventions Filling Process- Family B	
Routine Intervention #	Description
R30	Repeater pump calibration setup
R31	Calibration unit disconnection during calibration
R32	Pooling bag to filling tube set connection during setup
R33	Syringe to luer-to-luer adapter connection for filling
R34	Syringe to luer-to-luer adapter disconnection for capping
R35	Capping syringe
R36	Syringe to syringe transfer

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Routine Interventions Filling Process- Family C	
Routine Intervention #	Description
R37	Repeater pump calibration setup
R38	Calibration unit disconnection during calibration
R39	Needle to filling tube set connection during filling (repeated as needed during filling)
Routine Interventions Filling Process- Family C Continued	
Routine Intervention #	Description
R40	Needle to bag connection during filling (per filled unit)
R41	Needle to bag disconnection during filling (per filled unit)
Routine Interventions Filling Process- Family D	
Routine Intervention #	Description
R42	Repeater pump calibration setup
R43	Calibration unit disconnection during calibration
R44	Filling tube set connection during filling (repeated as needed during filling)
R45	Filling tube set disconnection during filling (per filled unit)
R46	Capping PCA Vial
R47	Manual Fill of PCA Vial
Non-Routine Interventions Filling Process	
Non-Routine Intervention #	Description
NR3	Glove change
NR4	Re-calibration of the repeater pump
NR5	Simulated Spill

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Media Fill Design- Pooling

During the bulk compounding pooling process outlined per **GMP-PDTMethods-0076**, bulk compounding formulation is performed at a batch size of 10 kg of non-sterile growth media. The non-sterile growth media is sterilized during solution transfer utilizing a transfer pump and a custom filter/bag assembly and/or stand alone filter.

During the sterile-to-sterile pooling process outlined per **GMP-PDTMethods-0076**, not less than 75 pooled vials using a repeater pump, not less than 2 pooled IV bags using a repeater pump, and not less than 3 pooled vials using syringes will be used to produce 1 pooling bag.

During the pooling portion of the aseptic qualification, both routine and non-routine interventions will be incorporated to challenge the personnel qualifying.

Media Fill Design- Filling

During the filling process outlined per **GMP-PDTMethods-0076,** not less than 50 final units, in the form of cassettes, not less than 50 final units, in the form of PCA vials, not less than 100 final units, in the form of syringes, not less than 100 final units, in the form of IV bags, will be filled to challenge the personnel qualifying.

During the filling portion of the aseptic qualification, both routine and non-routine interventions will be incorporated to challenge the personnel qualifying.

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CLEANROOM GOWNING QUALIFICATION

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Table of Contents

1.0 PURPOSE 3
2.0 SCOPE 3
3.0 DEFINITIONS 3
4.0 RESPONSIBILITIES 3
5.0 PROCEDURE 3
6.0 APPLICABLE REFERENCES 6

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1.0 PURPOSE

1.1 The purpose of this procedure is to verify that each person entering the ISO 5 and 7 areas is capable of successfully and consistently executing the aseptic gowning procedure. Gowning for the ISO 7 and 5 cleanroom areas should be donned in a manner that minimizes or prevents microbial contamination that could subsequently pose a risk to the aseptic integrity of sterile drug products.

2.0 SCOPE

2.1 This procedure applies to all personnel at OurPharma that will work in the ISO 5 and 7 areas.

3.0 DEFINITIONS

3.1 CFU – Colony Forming Unit

4.0 RESPONSIBILITIES

4.1 The Quality Unit shall maintain all original files related to gowning qualification.

4.2 Operations Management shall be responsible for ensuring that only qualified personnel are allowed to work in the sterile compounding area.

5.0 PROCEDURE

5.1 General Information

5.1.1 All personnel entering the ISO 7 suite shall successfully complete an initial competency evaluation through a gloved fingertip/thumb and a five-point gown sampling procedure in triplicate before being allowed to aseptically process sterile preparations.

5.1.1.1 All personnel operating in the ISO 5 and 7 areas must pass an initial gowning qualification prior to entering the cleanroom unescorted.

5.1.2 Following initial qualification, personnel will be required to requalify on an annual basis.

5.1.3 Outside contractors, inspectors, or other personnel who need to enter the ISO 7 areas should be trained on appropriate gowning technique prior to entry, but do not have to be formally qualified since they are not performing aseptic operations.

5.1.3.1 When possible, entry should be scheduled when aseptic processing is not occurring. If needed, viewing of ISO 7 buffer rooms is available from windows in the anterooms and corridors.

5.1.3.2 If outside personnel must enter the buffer room during aseptic processing, a monthly clean in the affected area(s) may be required before aseptic

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operations can resume, if deemed necessary by department management or Quality. Any time entry into the ISO 7 suite occurs by someone not gowning qualified, a deviation should be written to capture and assess any potential impact on environmental control and in-process product.

5.1.4 Qualification includes plate samples resulting in zero CFUs on a gloved fingertip/thumb sample and equal to or less than three CFUs total on a five-point gown sample per attempt.

5.2 Conditional Qualification:

5.2.1 After the successful completion of the first of three executions, production personnel will be allowed to enter the ISO7 buffer room, while escorted by a qualified individual, to participate in cleanroom sanitization activities.

5.3 Initial Qualification

5.3.1 Initial qualification includes three successful, successive iterations of gowning followed by a gloved fingertip/thumb and five-point plate sampling.

5.3.2 The three gowning iterations should occur on at least two separate days in the area where routine gowning will occur.

5.3.3 The operator is not permitted to disinfect the second pair of sterile gloves after donning prior to sampling of gloved fingertips/thumbs.

5.3.4 To prevent microbial contamination, neither the sampler nor the person to be qualified should talk during the gowning qualification procedure.

5.3.5 The table below describes the action taken if the cleanroom operating personnel do not successfully pass the qualification.

	Gowning Qual	Status	Action
1st Failure	Cannot enter the cleanroom	Conditionally disqualified	Retraining – basic review of general concepts
2nd Failure	Cannot enter the cleanroom	Conditionally disqualified	Investigation into RCA, focused retraining that is more intensive
3rd Failure	Cannot enter the cleanroom	Formally disqualified	Not eligible for requalification attempt until two weeks after last failure. Employee will practice and undergo training with production management and/or quality in the interim.

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5.3.6 Regardless of retraining, a maximum of 5 failed attempts results in formal disqualification.

5.4 Requalification

5.4.1 Re-qualification includes one successful evaluation every year with plate samples resulting in zero CFUs on a gloved fingertip/thumb sample and equal to or less than three total CFUs on a five-point gown sample.

5.4.2 Re-qualification shall also occur if the cleanroom operator has not entered the ISO classified space for a period of two months or greater.

5.4.3 If an employee should fail two re-qualification attempts, the personnel will be required to fully requalify via the initial qualification as described above.

5.4.3.1 If full requalification of an operator is required, the Quality Unit shall perform an investigation into potential product impact.

	Gowning Qual	Status	Action
1st Failure	Cannot enter the cleanroom	Conditionally disqualified	Retraining – basic review of general concepts Observation of Technique
2nd Failure	Cannot enter the cleanroom	Conditionally disqualified	Gown based on initial qualification procedure; Quality Unit to investigate

5.5 Procedure

5.5.1 A trained quality technician begins the procedure by evaluating the general hygiene of the cleanroom operator performing the gowning qualification. This observation is documented on **GMP-Form-0013** *Hand Washing Procedure Checklist.*

5.5.2 Following the initial evaluation, the quality technician observes the handwashing technique (outlined in **GMP-SOP-0017** *Hand Washing Procedure*) of the cleanroom operator performing the qualification. This observation is documented on **GMP-Form-0013** *Hand Washing Procedure Checklist.*

5.5.3 Following the handwashing procedure, the quality technician observes the gowning technique of the cleanroom operator performing the qualification. This observation is documented on **GMP-Form-0014** *Cleanroom Gowning Qualification Checklist.*

5.5.3.1 If any non-compliance or suggestions for improvement are noted, the quality technician should make note and discuss with the cleanroom operator after sampling is complete. The cleanroom operator should initial and date next to any comments on the form.

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5.5.4 Upon completion of the gowning procedure, the quality technician obtains TSA contact plate samples from the left and right forearms, chest (2), and forehead as well as rolled impressions of each fingertip and thumb.

5.5.5 The plate samples shall be incubated at 20-25°C for three to five days and then 30-35°C for three to five days. Incubation start and stop times shall be documented on form **GMP-Form-0012** *Cleanroom Gowning Qualification Form.*

5.5.6 At the end of the incubation period, the CFUs on each TSA plate shall be counted by a member of the Quality Unit and documented on **GMP-Form-0012** *Cleanroom Gowning Qualification Form*. A designation of Pass/Fail should be indicated.

5.5.7 All documentation and the incubated TSA plates should be verified by a second member of the Quality Unit.

5.5.7.1 If the second member of the Quality Unit is unable to perform the review and verification on the same day, the TSA plates shall be refrigerated at 2-8°C so the plates can be read the following business day.

6.0 APPLICABLE REFERENCES

6.1 **GMP-SOP-0016** *Cleanroom Gowning Procedure*

6.2 **GMP-SOP-0017** *Hand Washing Procedure*

6.3 **GMP-Form-0012** *Cleanroom Gowning Qualification Form*

6.4 **GMP-Form-0013** *Hand Washing Procedure Checklist*

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INCIDENTS, DEVIATIONS, AND NON-CONFORMANCES

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Table of Contents

1.0 PURPOSE 3
2.0 SCOPE 3
3.0 DEFINITIONS 3
4.0 RESPONSIBILITIES 3
5.0 PROCEDURE 4
6.0 APPLICABLE REFERENCES 17
7.0 QUALITY RECORDS 17

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1.0 PURPOSE

1.1 This procedure outlines the general process by which incidents, deviation, Out of Specifications, and non-conformances are defined, identified, reported, logged, documented, investigated, and escalated as required by the Quality Unit.

2.0 SCOPE

2.1 This procedure applies to all incidents, deviations, and non-conformances which are generated as a result of operations which support cGMP processes and drug products.

2.2 This procedure does not apply to planned deviations.

2.2.1 Refer to **GMP-SOP-0203** *Planned Deviations*.

3.0 DEFINITIONS

3.1 CAPA – Corrective and Preventive Action

3.2 Incident – any event or occurrence observed during a cGMP process that has the potential to impact product quality.

3.3 Deviation – an observed incident in which an action occurs that is a departure from the established process or procedure.

3.4 Non-Conformance – an observed incident in which data generated was reported to be outside of the specified acceptance criteria for a production process

3.5 Out of Specification- an observed incident in which data generated was reported to be outside of the specified acceptance criteria for drug product testing.

4.0 RESPONSIBILITIES

4.1 All Personnel

4.1.1 Initiating an incident record promptly, when applicable on **GMP-FORM-0173** *Incident Record*

4.1.2 Assisting with investigations as required

4.1.3 Assisting with determining corrective actions associated with incidents, deviations, and non-conformances

4.2 Investigation Owner

4.2.1 Conducting phase 1 investigation

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4.3 Quality

4.3.1 Maintaining and assigning incident ID numbers based on **GMP-FORM-0174** *Incident Log* and **GMP-FORM-0173** *Incident Record*

4.3.2 Maintaining and assigning deviation ID numbers based on **GMP-FORM-0078** Deviation Identification Log

4.3.3 Maintaining and assigning non-conformance ID numbers based on **GMP-FORM-0176** Non-Conformance Log

4.3.4 Maintaining and assigning out of specification ID numbers based on **GMP-FORM-0172** Out of Specification Log

4.3.5 Conducting phase 2 investigations

4.4 Quality Management

4.4.1 Review and dispositioning of incident record on **GMP-FORM-0173** *Incident Record*

4.4.2 Initiating investigations on **GMP-FORM-0175** *Investigation Record*

4.4.3 Assigning investigation owner(s) and due dates on **GMP-FORM-0175** *Investigation Record*

4.4.4 Approving investigation extension(s) on **GMP-FORM-0175** *Investigation Record*

4.4.5 Determining corrective actions associated with incidents, deviations, out of specifications and non-conformances

4.4.6 Performing investigation dispositioning on **GMP-FORM-0175** *Investigation Record*

5.0 PROCEDURE

5.1 Incident Initiation

5.1.1 Print **GMP-FORM-0173** *Incident Record* for reporting an observed incident.

5.1.2 Incidents are reported to Quality by completing Section 1 of **GMP-FORM-0173** *Incident Record*.

5.1.3 The incident initiator is responsible for fully explaining the observed incident and providing details of actions taken at the time the incident was observed.

5.1.4 Efforts shall be made to ensure all incidents are reported in a timely manner with a target of less than 8-hours or within the same shift in which the observation was made.

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5.1.5 The incident initiator is responsible for completing Section 1 of **GMP-FORM-0173** *Incident Record* and delivering the completed form to Quality for incident identification.

5.2 Incident Identification

5.2.1 Quality shall review the completed Section 1 of **GMP-FORM-0173** *Incident Record* and assign an incident identification number in the format of INC-YY-MM-XXX where:

5.2.1.1 INC indicates an incident

5.2.1.2 YY designates the two (2) digit year code (ex: 2021 is assigned 21)

5.2.1.3 MM designates the two (2) digit month code

5.2.1.4 XXX designates a sequential number based on **GMP-FORM-0174** *Incident Log*, which shall start with 001 for each associated month.

5.2.1.5 Quality shall make an entry **GMP-FORM-0174** *Incident Log* and complete Section 2 of **GMP-FORM-0173** *Incident Record*.

5.2.1.6 **GMP-FORM-0173** *Incident Record* with completed Section 2 shall be delivered to Quality Management immediately following completion and in a timely manner with a target of less than 8-hours or within the same shift in which the observation was made.

5.3 Incident Disposition

5.3.1 Quality Management shall review the completed Sections 1 and 2 of **GMP-FORM-0173** *Incident Record* and shall disposition the incident as one of the following:

5.3.1.1 Closure

5.3.1.1.1 Closure shall be selected in **GMP-FORM-0173** *Incident Record* Section 3 in the event Quality Management determines the root cause of the incident is obvious based on the initiators provided details and the incident has no impact to the quality of cGMP drug products or processes.

5.3.1.1.2 Quality Management shall complete Section 3 of **GMP-FORM-0173** *Incident Record* and provide justification for closure.

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5.3.1.2 Deviation

5.3.1.2.1 Deviation shall be selected in **GMP-FORM-0173** *Incident Record* Section 3 in the event Quality Management determines that the observed incident requires further investigation and is a result of departure from an established process or procedure.

5.3.1.2.2 The incident record shall be closed by completing **GMP-FORM-0173** *Incident Record* specifically Section 3 with the corrective action referencing the deviation number and providing details of the corrective actions taken.

5.3.1.2.3 All deviations require an investigation on **GMP-FORM-0175** *Investigation Record.*

5.3.1.3 Non-Conformance

5.3.1.3.1 Non-Conformance shall be selected in **GMP-FORM-0173** *Incident Record* Section 3 in the event Quality Management determines that the observed incident requires further investigation and is a result of data generated outside of defined acceptable limits.

5.3.1.3.2 The incident record shall be closed by completing **GMP-FORM-0173** *Incident Record* specifically Section 3 with the corrective action referencing the non-conformance number and providing details of the corrective actions taken.

5.3.1.3.3 All non-conformances require an investigation on **GMP-FORM-0175** *Investigation Record.*

5.3.1.4 Out of Specification

5.3.1.4.1 Out of Specification shall be selected in **GMP-FORM-0173** *Incident Record* Section 3 in the event Quality Management determines that the observed incident requires further investigation and is a result of release data generated outside of defined acceptable limits.

5.3.1.4.2 The incident record shall be closed by completing **GMP-FORM-0173** *Incident Record* specifically Section 3 with the corrective action referencing the out of specification number and providing details of the corrective actions taken.

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5.3.1.4.3 All out of specifications require an investigation per GMP-SOP-0047 *Out of Specification SOP* and shall be documented on **GMP-FORM-0175** *Investigation Record.*

5.3.1.5 Out of Trend

5.3.1.5.1 Out of Trend shall be selected in **GMP-FORM-0173** *Incident Record* Section 3 in the event Quality Management determines that the observed incident requires further investigation and is a result of data generated outside of anticipated limits.

5.3.1.5.2 The incident record shall be closed by completing **GMP-FORM-0173** *Incident Record* specifically Section 3 with the corrective action referencing the out of trend number and providing details of the corrective actions taken.

5.3.1.6 CAPA

5.3.1.6.1 CAPA shall be selected in **GMP-FORM-0173** *Incident Record* Section 3 in the event Quality Management determines that further actions are required to prevent the occurrence of similar incidents.

5.3.1.6.2 Refer to **GMP-SOP-0003** *CAPA Procedure* for further instructions.

5.3.1.6.3 The incident report shall be closed by completing **GMP-FORM-0173** *Incident Record* specifically Section 3 with the corrective actions referencing the CAPA number.

5.4 Investigations

5.4.1 An investigation is required for all deviations, out of specifications and non-conformances as determined by Quality Management.

5.4.2 Investigations are initiated by Quality Management by completing Section 1 of **GMP-FORM-0175** *Investigation Record.*

5.4.3 Deviations shall be identified in the format of DR-YY-MM-XXX whereas:

5.4.3.1 DR signifies a deviation

5.4.3.2 YY designates the two (2) digit year code (ex: 2021 is assigned 21)

5.4.3.3 MM designates the two (2) digit month code

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5.4.3.4 XXX designates a sequential number based on **GMP-FORM-0078** *Deviation Identification Log*, which shall start with 001 for each associated month.

5.4.3.5 Quality shall complete an entry in **GMP-FORM-0078** *Deviation Identification Log*.

5.4.4 Non-Conformance shall be identified in the format of NCR-YY-MM-XXX whereas:

5.4.4.1 NCR signifies a non-conformance

5.4.4.2 YY designates the two (2) digit year code (2021 is assigned 21)

5.4.4.3 MM designates the two (2) digit month code

5.4.4.4 XXX designates a sequential number based on **GMP-FORM-0176** *Non-conformance Identification Log*, which shall start with 001 for each associated month.

5.4.4.5 Quality Unit shall complete an entry in on **GMP-FORM-0176** *Non-conformance Identification Log*.

5.4.5 Out of Specification Results shall be identified in the format of OOS-YY-MM-XXX whereas:

5.4.5.1 OOS signifies a out of specification

5.4.5.2 YY designates the two (2) digit year code (2021 is assigned 21)

5.4.5.3 MM designates the two (2) digit month code

5.4.5.4 XXX designates a sequential number based on **GMP-FORM-0172** *Out of Specification Identification Log*, which shall start with 001 for each associated month.

5.4.5.5 Quality Unit shall complete an entry in on **GMP-FORM-0172**

5.4.6 Out of Trend Results shall be identified in the format of OOT-YY-MM-XXX whereas:

5.4.6.1 OOT signifies a out of trend

5.4.6.2 YY designates the two (2) digit year code (2021 is assigned 21)

5.4.6.3 MM designates the two (2) digit month code

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5.4.6.4 XXX designates a sequential number based on **GMP-FORM-0192** *Out of Trend Identification Log*, which shall start with 001 for each associated month.

5.4.6.5 Quality Unit shall complete an entry in on **GMP-FORM-0172**

5.4.7 Quality Management shall assign personnel responsible for executing the phase 1 investigation (Investigation Owner) and associated phase 1 investigation due date.

5.4.7.1 In the event the investigation is associated with an out of specification result specific to approved 3rd party testing, Quality shall be the Investigation Owner.

5.4.7.2 As a minimum requirement of a 3rd party phase 1 investigation, a review of the completed associated documentation shall be internally conducted.

5.4.7.3 In the event laboratory error is ruled out as a root cause, a phase 2 investigation is required.

5.4.7.4 Due dates are established based on each investigation. Typically, investigations are due 30 days from initiation.

5.4.7.5 The phase 1 investigation owner may request an extension to the due date by completing the appropriate section of **GMP-FORM-0175** *Investigation Record* and providing adequate justification and a proposed due date, as agreed upon by the Quality Management.

5.5 Phase 1 Investigation

5.5.1 The phase 1 investigation shall be conducted by the phase 1 investigation owner and documented through a phase 1 report.

5.5.2 Typically, the phase 1 investigation owner is the supervisor or manager of the department or area in which the incident occurred.

5.5.3 In the event the investigation is associated with an OOS result specific to approved 3rd party testing, the 3rd party investigation utilized in lieu of an internal phase 1 investigation shall require minimally a manufacturing review of the executed batch record and/or governing document, study, or protocol.

5.5.4 The phase 1 report shall address the following minimum requirements:

5.5.4.1 Detailed description of the observed incident

5.5.4.2 Impact assessment

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5.5.4.3 Impact assessment to similar cGMP processes inclusive of similar products, lot/batch numbers, drug product quantities, and equipment

5.5.4.4 Detailed description of similar incidents, deviations, out of specifications and/or non-conformances

5.5.4.5 List of personnel interviewed and/or assisting in the investigation.

5.5.4.5.1 Interviews shall be documented on **GMP-FORM-0171** *Investigation Interview Form.*

5.5.4.6 Description of investigation activities performed including associated investigation methodologies and techniques, if applicable (6M, fishbone diagram, root cause analysis)

5.5.4.7 Detailed description of the root cause and/or probable causes

5.5.4.8 Detailed list of proposed corrective and preventive actions

5.5.4.9 Additional information as requested by Quality Management.

5.5.4.10 Section 2 of **GMP-FORM-0175** *Investigation Record* shall be completed by the investigation owner and forwarded to Quality Management for dispositioning.

5.5.5 Phase 1 Investigation Disposition

5.5.5.1 Following completion of investigation activities, Quality Management shall review the completed Section 1 and 2 of **GMP-FORM-0175** *Investigation Record.*

5.5.5.2 Quality management shall complete Section 3 of **GMP-FORM-0175** *Investigation Record* and document the actions taken specifically regarding impacted drug product.

5.5.5.3 Quality Management is responsible for dispositioning the investigation as one of the following and providing justification for the actions taken and disposition:

5.5.5.3.1 Closure

5.5.5.3.1.1 Closure shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines the root cause has been identified and that the investigation conducted adequately addresses the observed incident.

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5.5.5.3.1.2 Quality Management shall complete the appropriate Section 3 of **GMP-FORM-0175** *Investigation Record* and provide justification for closure.

5.5.5.3.1.3 Sections 4, and 5 of **GMP-FORM-0175** *Investigation Record* shall be marked N/A.

5.5.5.3.2 CAPA

5.5.5.3.2.1 CAPA shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines that further actions are required to prevent the occurrence of similar incidents.

5.5.5.3.2.2 Refer to **GMP-SOP-0003** *CAPA Procedure* for further instructions.

5.5.5.3.2.3 The investigation record shall be closed by completing **GMP-FORM-0175** *Investigation Record* specifically Section 3 with the justification referencing the CAPA number.

5.5.5.3.2.4 Dispositioning as CAPA serves as closure for the investigation record.

5.5.5.3.2.5 If a phase 2 investigation is not required, N/A **GMP-FORM-0175** *Investigation Record* Sections 4 and 5

5.5.5.3.3 Deviation

5.5.5.3.3.1 Deviation shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines that additional deviations were identified during the phase 1 investigation as a result of departure from an established process or procedure.

5.5.5.3.3.2 Additional deviations identified shall be managed per this procedure.

5.5.5.3.3.3 Multiple deviations may be documented within a single investigation but are required to be assigned separate deviation numbers (DR-YY-MM-XXX).

5.5.5.3.3.4 Quality Management shall additionally determine and disposition the investigation as deemed appropriate.

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5.5.5.3.4 Non-Conformance

5.5.5.3.4.1 Non-Conformance shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines that additional non-conformances were identified during the phase 1 investigation as a result of data generated outside of defined acceptable limits.

5.5.5.3.4.2 Additional non-conformances identified shall be managed per this procedure.

5.5.5.3.4.3 Multiple non-conformance may be documented within a single investigation but are required to be assigned separate non-conformance numbers (NCR-YY-MM-XXX).

5.5.5.3.4.4 Quality Management shall additionally determine and disposition the investigation as deemed appropriate.

5.5.5.3.5 Out of Specification

5.5.5.3.5.1 Out of Specification shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines that additional out of specification results were identified during the phase 1 investigation as a result of data generated outside of defined acceptable limits.

5.5.5.3.5.2 Additional OOS results identified shall be managed per this procedure.

5.5.5.3.5.3 Multiple OOS results may be documented within a single investigation but are required to be assigned separate OOS numbers (OOS-YY-MM-XXX).

5.5.5.3.5.4 Quality Management shall additionally determine and disposition the investigation as deemed appropriate.

5.5.5.3.6 Out of Trend

5.5.5.3.6.1 Out of Trend shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines that additional out of specification results were identified during the phase 1 investigation as a result of data generated outside of anticipated limits.

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5.5.5.3.6.2 Additional OOT results identified shall be managed per this procedure.

5.5.5.3.6.3 Multiple OOT results may be documented within a single investigation but are required to be assigned separate OOT numbers (OOT-YY-MM-XXX).

5.5.5.3.6.4 Quality Management shall additionally determine and disposition the investigation as deemed appropriate.

5.5.5.3.7 Phase 2 Required

5.5.5.3.7.1 Phase 2 Required disposition is only applicable to dispositioning of a Phase 1 investigation.

5.5.5.3.7.2 Phase 2 Required shall be selected in Section 3 of **GMP-FORM-0175** *Investigation Record* and Quality Management shall assign a phase 2 investigation owner (Quality) and due date.

5.5.6 Phase 2 Investigation

5.5.6.1 A phase 2 investigation is only required when the Quality Unit determines that additional investigation is required beyond the activities performed during the phase 1 investigation.

5.5.6.2 The phase 2 investigation shall be conducted by Quality and documented through a phase 2 report.

5.5.6.3 The phase 2 report shall address the following minimum requirements:

5.5.6.3.1 Detailed description of similar incidents, deviations, out of specifications and/or non-conformances

5.5.6.3.2 Impact assessment of the observed incident, if applicable

5.5.6.3.3 Impact assessment to similar cGMP processes inclusive of similar products, lot/batch numbers, drug product quantities, and equipment, if applicable

5.5.6.3.4 Detailed description of personnel involved in the incident associated with personnel training

5.5.6.3.5 Detailed description of the calibration and maintenance status of equipment and instrumentation associated with the incident

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5.5.6.3.6 Description of investigation activities performed including associated investigation methodologies and techniques, if applicable

5.5.6.3.7 Additional information as requested by Quality Management.

5.5.7 Phase 2 Investigation Disposition

5.5.7.1 Following completion of investigation activities, Quality Management shall review the completed Section 4 of **GMP-FORM-0175** *Investigation Record*.

5.5.7.2 Quality management shall complete Section 5 of **GMP-FORM-0175** *Investigation Record* and document the actions taken specifically regarding impacted drug product.

5.5.7.3 Quality Management responsible for dispositioning the investigation as one of the following and providing justification for the actions taken and disposition:

5.5.7.3.1 Closure

5.5.7.3.1.1 Closure shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines the root cause has been identified and that the investigation conducted adequately addresses the observed incident.

5.5.7.3.1.2 Quality Management shall complete the appropriate Section 5 of **GMP-FORM-0175** *Investigation Record* and provide justification for closure.

5.5.7.3.2 CAPA

5.5.7.3.2.1 CAPA shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines that further actions are required to prevent the occurrence of similar incidents.

5.5.7.3.2.2 Refer to **GMP-SOP-0003** *CAPA Procedure* for further instructions.

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5.5.7.3.2.3 The investigation record shall be closed by completing **GMP-FORM-0175** *Investigation Record* specifically Section 5 with the justification referencing the CAPA number.

5.5.7.3.2.4 Dispositioning as CAPA serves as closure for the investigation record.

5.5.7.3.3 Deviation

5.5.7.3.3.1 Deviation shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines that additional deviations were identified during the phase 2 investigation as a result of departure from an established process or procedure.

5.5.7.3.3.2 Additional deviations identified shall be managed per this procedure.

5.5.7.3.3.3 Multiple deviations may be documented within a single investigation but are required to be assigned separate deviation numbers (DR-YY-MM-XXX).

5.5.7.3.3.4 Quality Management shall additionally determine and disposition the investigation as deemed appropriate.

5.5.7.3.4 Non-Conformance

5.5.7.3.4.1 Non-Conformance shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines that additional non-conformances were identified during the phase 2 investigation as a result of data generated outside of defined acceptable limits.

5.5.7.3.4.2 Additional non-conformances identified shall be managed per this procedure.

5.5.7.3.4.3 Multiple non-conformance may be documented within a single investigation but are required to be assigned separate non-conformance numbers (NCR-YY-MM-XXX).

5.5.7.3.4.4 Quality Management shall additionally determine and disposition the investigation as deemed appropriate.

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5.5.7.3.5 Out of Specification

5.5.7.3.5.1 Out of Specification shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines that additional OOS results were identified during the phase 2 investigation as a result of release data generated outside of defined acceptable limits.

5.5.7.3.5.2 Additional OOS results identified shall be managed per this procedure.

5.5.7.3.5.3 Multiple OOS results may be documented within a single investigation but are required to be assigned separate OOS numbers (OOS-YY-MM-XXX).

5.5.7.3.5.4 Quality Management shall additionally determine and disposition the investigation as deemed appropriate.

5.5.7.3.6 Out of Trend

5.5.7.3.6.1 Out of Trend shall be selected in **GMP-FORM-0175** *Investigation Record* in the event Quality Management determines that additional OOT results were identified during the phase 2 investigation as a result of release data generated outside of defined acceptable limits.

5.5.7.3.6.2 Additional OOT results identified shall be managed per this procedure.

5.5.7.3.6.3 Multiple OOT results may be documented within a single investigation but are required to be assigned separate OOT numbers (OOT-YY-MM-XXX).

5.5.7.3.6.4 Quality Management shall additionally determine and disposition the investigation as deemed appropriate.

5.5.8 Incident, Deviation, Out of Specification, and Non-Conformance Records and Logs

5.5.8.1 All executed forms and logs shall be maintained by the Quality.

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5.5.8.2 All documentation shall be kept up to date with the current status of associated incidents, deviations, Out of Specification, and non-conformances.

6.0 APPLICABLE REFERENCES

6.1 **GMP-FORM-0173** *Incident Record*

6.2 **GMP-FORM-0174** *Incident Log*

6.3 **GMP-FORM-0175** Investigation Record

6.4 **GMP-FORM-0172** *OOT Identification Log*

6.5 **GMP-FORM-0192** *OOT Log*

6.6 **GMP-FORM-0078** *Deviation Identification Log*

6.7 **GMP-FORM-0176** *Non-conformance Identification Log*

6.8 **GMP-SOP-0003** *CAPA Procedure*

6.9 **GMP-FORM-0171** *Investigation Interview Form*

6.10 **GMP-SOP-0047** *Out of Specification SOP*

6.11 **GMP-SOP-0203** *Planned Deviations.*

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EMPLOYEE TRAINING PROGRAM

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Table of Contents

1.0 PURPOSE 3
2.0 SCOPE 3
3.0 DEFINITIONS 3
4.0 RESPONSIBILITIES 3
5.0 PROCEDURE 3
6.0 REFERENCES 5

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1.0 PURPOSE

1.1 This procedure defines the requirements for managing the training program at OurPharma.

2.0 SCOPE

2.1 This procedure applies to all OurPharma employees. The scope of this procedure covers new employee orientation along with training requirements for existing employees.

3.0 DEFINITIONS

3.1 CV – Curriculum Vitae

3.2 MasterControl™ - Quality management software deployed at OurPharma. MasterControl™ houses the training module.

3.3 Qualified trainer – An employee that possesses the proficiency and technique (where applicable) to train employees on a specific task or procedure. Document owners and managers are also qualified to serve as trainers.

4.0 RESPONSIBILITIES

4.1 It is the responsibility of management and Quality to ensure that employees are trained on this procedure.

4.2 It is the responsibility of each employee to be aware of the training required for his or her position and to help assure that training is administered prior to the completion of tasks.

5.0 PROCEDURE

5.1 General Information

5.1.1 Training records shall be electronically maintained in MasterControl™ for each employee.

5.1.1.1 A paper copy of **GMP-Form-0007** *Training Attendance Form* will be used to document training if MasterControl™ is down or unavailable for use.

5.1.2 Training on all job-related tasks shall be completed before the employee performs any function without direct supervision.

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5.1.3 Job Qualification Records/CVs shall be maintained by the Quality department as documented evidence that each employee is qualified to perform his/her function.

5.2 Types of Training

5.2.1 Self-Training – requires personnel to read a document and sign off on the document in MasterControl™.

5.2.2 Performance-Based Training – requires personnel to correctly perform a job-related task without assistance while a qualified trainer observes completion of the task. The trainer will document the event in MasterControl™.

5.2.3 Competency Quiz – requires personnel to answer a series of questions after reading the associated procedure in MasterControl™. A passing score of 100% must be achieved before the task can be marked as complete.

5.2.4 Instructor-Led Training – Group or individual training facilitated by an instructor using a classroom format. The trainer will document the event on GMP-Form-0007 Training Attendance Form or in MasterControl™.

5.2.4.1 Only qualified trainers may administer training.

5.3 Retraining

5.3.1 Re-training shall be performed on Standard Operating Procedures (SOPs) after content revisions.

5.3.2 Additional training or re-training may be necessary for any one of the following reasons: personnel development, new technology or equipment, an investigation, or changes in personnel roles and responsibilities.

5.3.3 Employees must receive annual training on the following:

5.3.3.1 cGMP and Quality Systems

5.3.3.2 Safety

5.3.4 Competency checks must be completed annually, no later than 14 days after due date.

5.3.4.1 In case 14 days have been exceeded:

5.3.4.1.1 Employee cannot perform task until competency check is complete.

5.3.4.1.2 Initiate an incident per GMP-SOP-0202 *Incidents, Deviations, and Non-Conformances SOP.*

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5.3.4.2 In case of competency check failure:

5.3.4.2.1 Employee cannot perform task until competency check is passed.

5.3.4.2.2 Initiate a deviation investigation per GMP-SOP-0202 *Incidents, Deviations, and Non-Conformances SOP.*

5.3.4.2.3 Perform targeted retraining.

5.4 External Training Courses

5.4.1 When personnel attend onsite training or complete remote training provided by a third-party, personnel shall supply a copy of any applicable certificates or documents indicating attendance at the training.

5.4.2 All external trainings will also be documented in MasterControl™ upon completion.

5.5 Monitoring Program for Training

5.5.1 Training records shall be monitored for completeness by the Quality Unit.

5.5.2 Any deficiencies found in the training program shall be communicated to management. Deficiencies found in an individual employees training record shall be communicated to the affected employee and their supervisor for remediation.

5.5.3 Area management is responsible for working with Quality to review specific training deficiencies noted during routine gap assessments conducted by the Compliance department, or designee.

6.0 REFERENCES

6.1 21 CFR 210 & 211: cGMP in Manufacturing, Processing, Packing, or Holding of Drugs and Finished Pharmaceuticals

6.2 GMP-Form-0007 *Training Attendance Form*

6.3 GMP-SOP-0202 *Incidents, Deviations, and Non-Conformances SOP*

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CLEANROOM SANITIZATION PROCEDURE

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Table of Contents

1.0 PURPOSE 3
2.0 SCOPE 3
3.0 DEFINITIONS 3
4.0 RESPONSIBILITIES 4
5.0 PROCEDURE 4
6.0 BSC HOOD CLEANING: 16
7.0 POWDER HOOD BSC CLEANING: 18
8.0 PASSTHROUGH CLEANING: 20
9.0 APPLICABLE REFERENCES 21

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1.0 PURPOSE

1.1 This procedure describes cleaning and disinfecting of the ISO-classified spaces.

2.0 SCOPE

2.1 This procedure applies to all ISO-classified spaces.

3.0 DEFINITIONS

3.1 BSC – Biological Safety Cabinet

3.2 IPA – Isopropyl Alcohol

3.3 SIPA – Sterile Isopropyl Alcohol

3.4 Production Week – Generally Monday through Friday, excluding holidays. For the purposes of this procedure, "daily" is intended to mean each day of the production week.

3.5 Cleaning – The act of using a chemical agent to remove accumulated material on a surface until the surface is visibly clean and free of residue. This accumulated material/residue can include dirt, residual disinfectant, and extraneous process material.

3.6 Sanitizing – The act of using a chemical agent to reduce the microbial bioburden on a surface. Sanitizing requires that the surface is visibly clean.

3.7 Disinfecting – The act of using a chemical agent to kill the microbial bioburden on a surface.

3.8 Sporicidal Agent – A chemical agent that is utilized to reduce the bioburden of spore-forming microbes. Unless otherwise specified, this is DECON-SPORE 200 Plus.

3.9 Triple Clean – The act of performing the cleaning/disinfecting requirements in triplicate, as a layer each of the applicable monthly solution, the off-month solution, followed by DECON-SPORE 200 Plus.

3.10 API – Active Pharmaceutical Ingredient

3.11 ALCOA – Attributable, Legible, Contemporaneous, Original, Accurate

3.12 Work Surfaces – Horizontal work surfaces of carts and tables, cart handles, equipment, chairs, pens, clipboards.

3.13 Full Work Surfaces- all surfaces of carts, tables, chairs, etc.

3.14 cGMP Processes – Aseptic material transfer, batch filling in buffer rooms, batch pooling in negative storage, media fills, EMPM sampling, material sanitization.

3.15 Plenum- open space beneath deck of BSC.

3.16 True bottom- area of deck below the plenum.

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4.0 RESPONSIBILITIES

4.1 It is the responsibility of all appropriately assigned OurPharma employees to follow this procedure for cleaning and disinfecting all ISO-classified spaces.

4.2 It is the responsibility of OurPharma management to ensure that assigned employees are properly trained and qualified on this procedure and the appropriate documentation thereof.

4.3 It is the responsibility of the Quality Unit to perform a regular review of all cleaning activity documentation and to immediately notify the applicable manager of any deficiencies.

5.0 PROCEDURE

5.1 Training

5.1.1 All personnel must be trained and qualified before engaging in unsupervised ISO-classified disinfecting and cleaning activities using **GMP-Form-0058** *Facility Cleaning Qualification Checklist*. Requalification is required annually.

5.1.1.1 All personnel must be trained and qualified on each competency below prior to performing independently. Requalification is required annually on each competency.

5.1.1.1.1 **GMP-Form-0187** *Vileda Mopping System Mop Prep – Competency Check*

5.1.1.1.2 **GMP-Form-0194** *Competency Check – Passthrough Sanitization*

5.1.1.1.3 **GMP-Form-0146** *Powder Hood Sanitization – Competency Check*

5.1.1.1.4 **GMP-Form-0219** *Competency Check – BSC Sanitization*

5.2 Chemical Solutions

5.2.1 Only approved cleaners, disinfectants, deactivation agents, decontaminants, and sporicidal solutions shall be used in the ISO-classified spaces.

5.2.2 DECON-CYCLE and DECON-QUAT are the regularly scheduled monthly rotating disinfectants for cleaning/disinfecting of all surfaces and fixed equipment within the ISO-classified spaces. DECON-SPORE is the regularly scheduled sporicidal agent.

5.2.2.1 Monthly rotation of disinfectants shall follow the schedule below (**Table 1**).

Table 1

Month	Disinfectant 1	Disinfectant 2
Jan, Mar, May, Jul, Sep, Nov	DECON-QUAT	
Feb, Apr, Jun, Aug, Oct, Dec		DECON-CYCLE

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5.2.3 In the event that the chemical of the month is not available due to supply issues, the alternate chemical of the month may be substituted (ex: Decon Quat in place of Decon Cycle) with Quality management approval. If approved, an annotation is required within the associated cleaning log(s).

5.2.4 Substitution of another chemical solution must follow **GMP-SOP-0002** *Change Control* and be documented on **GMP-Form-0011** *Change Control Documentation Form*.

5.2.5 Dry, sterile wipes used for material sanitization shall be routinely discarded and replaced to prevent the accumulation of bioburden. The frequencies of replacement are listed below:

5.2.5.1 ***ISO8 corridor*** and ***material transfer room*** wipes shall be replaced prior to each weekly and monthly clean.

5.2.5.2 ***ISO7 buffer room*** wipes shall be replaced daily if the space is used for production activities.

5.2.6 Chemical spray bottles and solution containers shall be labeled with a 30-day expiry from date of opening.

5.2.6.1 Expiry dates should be checked prior to using any chemical spray bottles or solution containers to ensure they are within expiry.

5.2.7 When opening a new chemical spray bottle or solution container, the active ingredient shall be added, and the bottle marked to indicate that the mixing of the active ingredient with the inert material took place.

5.2.7.1 All opened chemical spray bottles or solution containers shall be labeled with the opened date, beyond use date, and the initial set of the person opening the container.

5.2.8 Pre-saturated wipes used in ISO7 and ISO8 areas shall be labeled with a 7-day expiry from date of opening.

5.2.8.1 All opened pre-saturated wipes shall be labeled with the opened date, beyond use date, and the initial set of the person opening the container.

5.2.8.2 Pre-saturated wipes may only be used in the ISO classification they were opened in or a higher classification.

5.2.8.3 Pre-saturated wipes opened within the ISO5 BSC shall remain on the BSC deck during compounding activities. These wipes will be used for routine deck sanitization. Any remaining wipes shall be removed from the BSC and labeled with a 7-day expiry from the date of opening to be used in the ISO7 buffer room.

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5.2.8.4 If pre-saturated wipe *packages* are moved to a room of a higher ISO classification (i.e., opened in ISO 7 then moving the package into ISO8), the wipes shall not be used again in the ISO 7 classified space.

5.3 General Requirements

5.3.1 Always sanitize from cleanest to dirtiest. Begin at the cleanest part of the room, furthest point from the exit door, and work towards the dirtiest part of the room near the exit door.

5.3.1.1 Equipment/Furniture may be cleaned in any order within the room as long as the requirements of cleaning from cleanest to dirtiest for each piece of equipment/furniture is followed.

5.3.2 When cleaning/disinfecting the entire room, work should be performed from top to bottom, beginning with ceilings, followed by walls/pass-throughs, then equipment/furniture surfaces, and finishing with floors.

5.3.2.1 Cleaning of walls may commence only once the ceiling above the wall has been completed. The area of the wall being cleaned shall never pass the last cleaned area of the ceiling as cleaning shall always been performed from cleanest to dirtiest.

5.3.2.2 The FFU grates on the ceiling shall not be mopped to avoid potential damage to the filters.

5.3.2.3 If there are multiple people cleaning one room, it is acceptable to clean surfaces of equipment/furniture while cleaning the walls/pass-throughs as long as the cleaning of the ceiling above the area where equipment/furniture has been completed.

5.3.2.4 Mops shall not be shared between different types of surfaces (e.g. wall/pass-through mops shall not be used on surfaces of equipment/furniture and vice-versa).

5.3.3 When cleaning/disinfecting more than one room, begin in the most critical room and proceed toward the least critical room.

5.3.4 Personnel should mop themselves out of a room while making an effort to not walk on a floor surface that has already been cleaned.

5.3.4.1 Corridor floors should be cleaned in an order to prevent personnel from walking over a clean floor surface as they exit suites. Personnel should mop themselves out of the corridor and into the change room.

5.3.5 In order to efficiently clean furniture, there may be times when materials/supplies (including non-routine items such as tools and caulk guns) need to be placed

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onto an already cleaned surface. This is acceptable only if the materials/supplies have been wiped down appropriately with a 70% SIPA wipe prior to placing on the clean surface.

5.4 Sanitization Frequency

5.4.1 Daily cleaning/disinfecting must be performed each day in areas accessed.

5.4.1.1 Quality Management may waive the daily clean requirement, on a case-by-case basis. In this case, an annotation is required on Facility Cleaning Log(s) to document impacted areas and justification.

5.4.2 Weekly cleaning/disinfecting must be performed within each calendar week, not to exceed 9 days between cleans.

5.4.2.1 Plenums/grates of BSCs and powder hoods shall be removed and sanitized during each weekly clean.

5.4.3 Monthly cleaning/disinfecting must not exceed 35 days between cleans.

5.4.3.1 Plenums/grates of BSCs and powder hoods shall be removed and sanitized during each monthly clean.

5.4.4 In the event negative storage is used for the concurrent formulation of products with no change in APIs and excipients, then a 70% SIPA wipe down of the powder containment hood and any weighing equipment shall be completed after the dispensing of the first batch's powders but prior to beginning the dispensing of the bulk powders for the following batch.

5.4.4.1 Examples:

5.4.4.1.1 Formulations such as morphine 1mg/mL for syringes and morphine 1mg/mL for PCA vials can be formulated together.

5.4.4.1.2 Formulations such as hydromorphone 0.2mg/mL can be formulated concurrently with hydromorphone 1mg/mL.

5.4.4.1.3 Formulations of fentanyl and fentanyl & ropivacaine cannot be formulated together.

5.4.4.2 If the space will then be used for the formulation of products with different APIs and/or excipients, or media powder within the same day, a daily clean of the room followed by a pre-production hood clean shall be completed prior to beginning the next batch to prevent cross contamination of bulk powders.

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5.4.5 On the last day of the production week, a wipe down of the BSC deck with 70% SIPA may be completed in lieu of a daily clean within the ISO7 buffer rooms, ante rooms, and degown rooms, provided that:

5.4.5.1 A monthly or weekly clean is performed the following week prior to resumption of production activities.

5.4.5.2 The time between the delayed clean and the mitigating clean does not exceed 5 days.

5.4.5.3 Delayed cleans are NOT APPROVED for:

5.4.5.3.1 ISO8 corridors, ISO8 material transfer rooms, negative storage, or negative handwash.

5.4.5.3.2 Any suites used for aseptic process validations or aseptic personnel qualifications.

5.5 Non-Routine Sanitization Activities

5.5.1 When pooling and filling processes occur back-to-back within the same BSC, 70% SIPA may be used to clean/disinfect the deck between pooling activities and filling activities, rather than completing a second pre-production hood clean.

5.5.2 If a BSC powder hood is used for the production of multiple lots of identical drug products within the same day, the daily clean may be performed at the end of the last batch of the day.

5.5.3 A monthly clean is required in affected BSC after media fill batches are complete. In the event that the suite will be exclusively used to complete media fill batches for multiple days within 1 calendar week, it is acceptable to complete the monthly clean of the affected areas after the last scheduled media fill is complete. The monthly clean shall be completed prior to initiating production activities.

5.5.4 A monthly clean is required in affected areas after extensive maintenance work, smoke studies, or HEPA certifications are completed.

5.5.4.1 In the event that HEPA certification is performed, a daily clean is not required post execution, provided that a monthly clean is performed prior to initiating production activities.

5.5.5 A triple clean is required to return affected areas to service following an extensive HVAC shutdown. A triple clean may also be required per Quality Management for incidents that lead to a breach of the ISO-classified space.

5.5.5.1 A gross clean may be performed before a triple clean, as needed.

5.5.6 In the event that drug product or media is sprayed onto the diffuser grate within the BSC, the grate will be removed to inspect the filter. After inspection, the entire

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grate shall be cleaned with Decon-Spore, rinsed with SIPA, and replaced. The required clean of the BSC can commence after the replacement of the grate.

5.5.7 Additional cleans may be performed on an as needed basis as approved by Quality Management.

5.6 Cleaning and Disinfection Technique

5.6.1 All personnel must complete the appropriate section(s) of Facility Cleaning Log(s), with initial set and date as promptly as possible following cleaning of each area within the cleanrooms.

5.6.2 Approved techniques utilizing side to side or up and down overlapping strokes are depicted in **Figure 1** and **Figure 2**.

Figure 1 – Pull and Lift Method

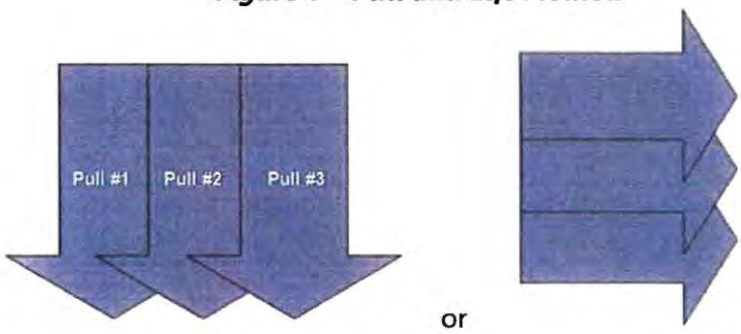
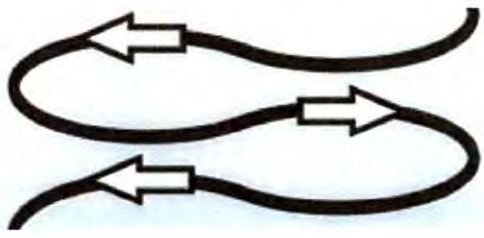


Figure 2 – Figure Eight Method



5.7 Contact Times

5.7.1 All applied chemicals must achieve the appropriate contact time as shown in **Table 2**.

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Table 2

Chemical	Contact Time
Decon – Quat	NLT 10 minutes
Decon – Cycle	NLT 10 minutes
Decon – Spore	NLT 5 minutes

5.8 Preparation Activities

5.8.1 Enter the cleanroom per **GMP-Drawing-0002** *Clean Room People, Material, and Waste Flow Diagrams.*

5.8.2 Mops shall be prepared per **GMP-WI-0005** *Aramark Vileda Mopping System Work Instruction.*

5.8.3 Disinfect all mop handles by wiping with a 70% SIPA saturated wipe and allow to air dry.

5.9 Sanitization Activities

5.9.1 Cleanroom sanitization activities shall be performed as outlined in **Table 3**.

5.9.2 During monthly cleans, or the sporicidal rotation of the triple clean, respirators shall be worn by all employees participating.

5.9.3 Enclosed containers stored in the classified space and the contents within those containers shall be sanitized during the monthly cleans. The exterior of the containers ONLY will be sanitized during the weekly cleans.

5.9.3.1 Items will be removed from the container, then the container and the items will be sanitized with the appropriate cleaning solution, and then placed back inside the container.

5.9.3.2 During the daily cleans, the handles and the bottom of the totes shall be sanitized.

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TABLE 3

Type of Clean	Location	Surfaces	Chemical(s) Used	Reference
PRE-PRODUCTION	BSC	All surfaces inside the BSC above the plenum (excluding diffuser)	DECON-SPORE followed by 70% SIPA after 5-minute contact time	**Appx. 1, Pgs. 14-15**
	BSC Powder Hood	All surfaces inside the BSC powder hood (excluding area behind grate)		**Appx. 2, Pg. 16**
	Scales/Printers inside BSC Powder Hood	Exterior only	70% SIPA	N/A
POST-PRODUCTION PRIOR TO DAILY CLEAN	BSC	Deck	70% SIPA	N/A
POST-PRODUCTION PRIOR TO DAILY CLEAN	BSC Powder Hood	Deck	70% SIPA	N/A
DAILY	All areas accessed* * Quality Management may waive the daily clean requirement, on a case-by-case basis, in the event that the room is briefly accessed for non-cGMP processes and access is found to be non-product impacting. In this case, an annotation is required on Facility Cleaning Log(s).	All surfaces inside the BSC above the plenum (excluding diffuser)	Applicable monthly solution (DECON-CYCLE or DECON-QUAT)	**Appx. 1, Pgs. 14-15**
		All surfaces inside the BSC powder hood (excluding area behind grate)		
		Floors		N/A
		Work Surfaces		N/A
		Passthroughs		**Appx. 3, Pgs. 17-18**
		Equipment (excluding scales/printers)		N/A

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TABLE 3 CONTINUED

Type of Clean	Location	Surfaces	Chemical(s) Used	Reference
DAILY Continued	All areas accessed*	Sinks	DECON-SPORE followed by 70% SIPA after 5-minute contact time	N/A
		Scales and Printers Exterior Only	70% SIPA	N/A
WEEKLY	All areas within ISO Classified Space	Walls *All TRANE and Lighthouse equipment shall be cleaned by hand with a saturated sterile wipe	Applicable monthly solution (DECON-CYCLE or DECON-QUAT)	N/A
		Floors		N/A
		Work Surfaces (including exterior of containers)		N/A
		Passthroughs		**Appx. 3, Pgs. 17-18**
		Equipment (excluding scales/printers)		N/A
		All surfaces inside the BSC above the plenum (excluding diffuser)	DECON-SPORE followed by 70% SIPA after 5-minute contact time	**Appx. 1, Pgs. 14-15**
		Plenum/Grate		**Appx. 1, Pgs. 14-15** **Appx. 2, Pg. 16**
		Sinks (full inner basin)		N/A
		Scales and Printers Exterior Only	70% SIPA	N/A
		Windows/Doors (glass)	70% SIPA followed by applicable monthly solution, as needed	**Pg. 12, Sec. 5.11**

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TABLE 3 CONTINUED

Type of Clean	Location	Surfaces	Chemical(s) Used	Reference
MONTHLY	All within ISO Classified Space *A gross clean maybe be performed before a monthly clean, as needed.	Ceilings (excluding diffuser)	DECON-SPORE followed by 70% SIPA after 5-minute contact time on stainless steel surfaces	N/A
		Walls, including ledges *All TRANE and Lighthouse equipment shall be cleaned by hand with a saturated sterile wipe		N/A
		Floors		N/A
		Full Work Surfaces (including items stored in containers and exterior of container)		N/A
		Passthroughs		**Appx. 3, Pgs. 17-18**
		Equipment		N/A
		All surfaces inside the BSC above the plenum (excluding diffuser)		**Appx. 1, Pgs. 14-15**
		Plenum/Grate		**Appx. 1, Pgs. 14-15** **Appx. 2, Pg. 16**
		Sinks (inside and outside)		N/A
		Scales and Printers Exterior Only	70% SIPA	N/A
		Windows/Doors (glass)	70% SIPA followed by DECON-SPORE	**Pg. 12, Sec. 5.11**
TRIPLE CLEAN	All areas within ISO Classified Space *A gross clean maybe be performed before a triple clean, as needed.	Ceilings (excluding diffuser)	Gross clean, followed by ON-month chemical, followed by OFF-month chemical, followed by DECON-SPORE, followed by 70% SIPA after 5-minute contact time on stainless steel surfaces	N/A
		Walls		N/A
		Floors		N/A
		Full Work Surfaces (including items stored in containers		N/A
		Passthroughs		**Appx. 3, Pgs. 17-18**
		Equipment		N/A

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TABLE 3 CONTINUED

Type of Clean	Location	Surfaces	Chemical(s) Used	Reference
TRIPLE CLEAN Continued	All areas within ISO Classified Space *A gross clean maybe be performed before a triple clean, as needed.	All surfaces inside the BSC above the plenum (excluding diffuser)		**Appx. 1, Pgs. 14-15**
		Plenum/Grate		**Appx. 1, Pgs. 14-15** **Appx. 2, Pg. 16**
		Sinks		N/A
		Scales and Printers Exterior Only	70% SIPA	N/A

5.10 Decontamination

5.10.1 If different bulk drug products are made on the same day, a daily clean of negative storage is required prior to executing the next batch.

5.10.2 If bulk media powder is used, a monthly clean of negative storage shall be performed.

5.11 Residue Removal

5.11.1 70% SIPA applied with a mop or spray bottle followed by removal with a squeegee ***may*** be used to remove chemical solution residue from windows/doors during weekly cleans on an as needed basis. This step must be performed prior to application of chemical of the month.

5.11.2 70% SIPA applied with a mop or spray bottle followed by removal with a squeegee ***shall*** be used to remove chemical solution residue from windows/doors during each monthly clean. This step must be performed prior to application of DECON-SPORE.

5.12 Post Sanitization Activities

5.12.1 Review Facility Cleaning Log(s) for completeness.

5.12.2 Ensure all furniture and equipment is put back in position neatly.

5.12.3 Collect all soiled mopheads.

5.12.4 Dispose of all trash and empty chemical bottles.

5.12.5 Disinfect all used mop buckets, sieves, measuring cups, and mop handles with 70% SIPA and remove excess 70% SIPA with dry wipes to mechanically facilitate drying items such as buckets.

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5.13 Spill Response

5.13.1 Minor Spills (≤50mL) of non-hazardous drugs inside or outside of the ISO5 BSC must first be cleaned using a dry, sterile, non-shedding wipe to absorb the liquid. After the material has been removed using dry wipes, the area shall then be disinfected with 70% SIPA.

5.13.2 Non-hazardous liquid drug spills containing dextrose shall be treated as above, except that the area must be cleaned with sterile water after removing the spilled material with a non-shedding wipe, then disinfected with 70% SIPA.

5.13.3 Media spills shall be treated as above, except that the area must be cleaned with DECON-SPORE followed by 70% SIPA.

5.13.4 In the event that a spill occurs on scales/balances, the scale/balance shall be cleaned both above and below the weigh pan.

5.13.5 Larger spills of liquid or powder of non-hazardous drugs inside or outside of the ISO5 BSC shall be treated as follows:

5.13.5.1 Alert others to the spill and use appropriate signage to restrict access to the area of the spill. Do not leave the spill unattended.

5.13.5.2 Obtain the nearest Spill Kit, if required.

5.13.5.3 If spill occurs outside of the buffer room, don the following PPE: safety glasses, frock, two pairs of sterile gloves.

5.13.5.4 Perform spill cleanup per Spill Kit instructions.

5.13.5.5 Once spill has been removed, decontaminate the area(s) of the spill with DECON-SPORE and then disinfect with 70% SIPA after 5-minute contact time.

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Appendix 1

6.0 BSC HOOD CLEANING:

6.1 When performing clean, always clean from cleanest-to-dirtiest (back-to-front, side-to-side, and top-to-bottom). (See **Figures 3 and 4**)

6.1.1 Cleaning the Interior of the BSC:

6.1.1.1 Saturated wipes should be folded into quarters and flipped to a new quarter each time a new surface of the BSC is cleaned.

6.1.1.2 Using a wipe, clean the IV bar and brackets, flip to next quarter. Clean the space around the IV bar on the walls. Flip to the second side of the wipe, clean the camera on the right wall of the hood and the space around it. With the last quarter of the wipe, clean the grommet. Discard wipe.

6.1.1.3 Using the mop, first clean the back wall and then the right wall. Leave the mop on the deck for later use.

6.1.1.4 Using a new wipe, clean the camera and outlet, then flip to the next quarter. Then proceed to clean the rest of the left wall. Flip to the second side of the wipe and clean the sash. With the last quarter of the wipe clean the samplers. Move the samplers to the front half of the deck and discard wipe.

6.1.1.4.1 For detailed instructions regarding how to clean the left wall, refer to **Appendix 3**.

6.1.1.5 Using a new wipe, clean the corners/edges of the perimeter of the deck (not the grill/armrest), set the wipe aside on the deck.

6.1.1.6 Using the mop from previous steps, wipe the back half of the deck.

6.1.1.7 Using the previous wipe, flip to the next quarter and clean the bottoms of the samplers and move them to the back of the deck. Place the wipe on the grate.

6.1.1.8 Clean the front half of the deck with the mop. Discard mop. Using the wipe, flip to the next quarter and clean the grill and armrest from side-to-side. Discard wipe.

6.1.2 Performing a clean of the plenum of the BSC:

6.1.2.1 To access the plenum, first remove the armrest by lifting the deck using the circular handles. Place the armrest on a table or carts. Next, pull the deck out of the hood halfway to expose the true bottom and place the samplers on the true bottom. Once the samplers have been moved, completely remove the deck, and position it upside down on a flat surface.

6.1.2.2 Using a mop, clean the sides of the walls where the deck sits, then clean the true bottom.

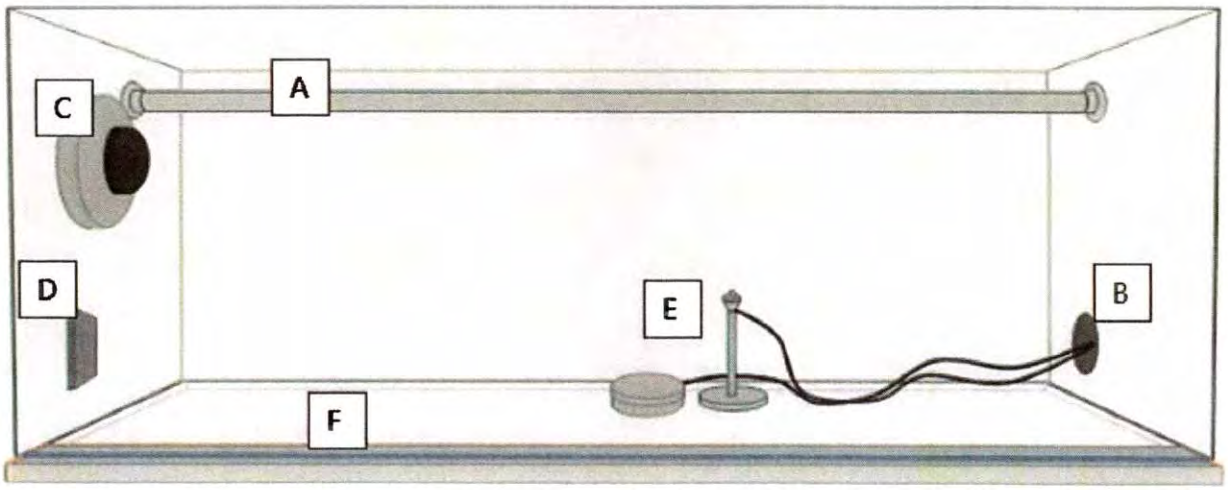
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6.1.2.3 Using a mop, clean the underside (now facing up) of the armrest and deck.

6.1.2.4 Using a wipe or mop, remove and clean each bracket, placing them on the newly cleaned underside of the deck.

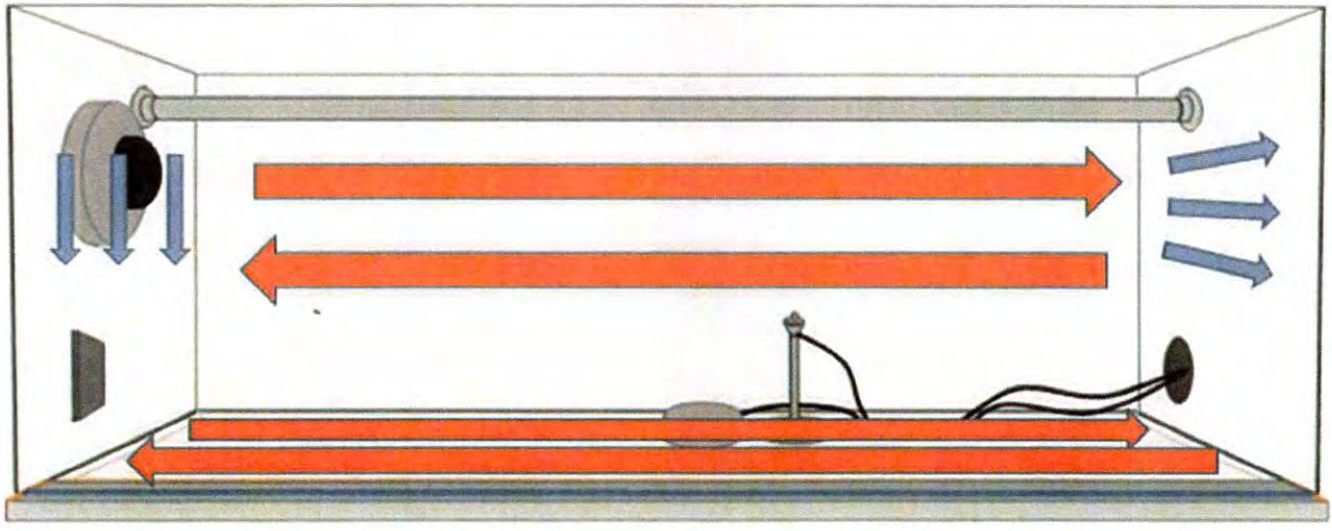
6.1.2.5 Once all parts have been cleaned, put them back into position and clean the rest of the hood as outlined above.

Figure 3



Parts of the hood: A – IV Bar, B – Grommet, C – Camera, D – Outlet, E – Samplers, F – Grill and Armrest

Figure 4



Orange: Figure Eight Method (Back wall, deck), and Blue: Pull and Lift Method (side walls, IV bar and brackets, camera, outlet, samplers with tubing, grommet, grill, and armrest

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APPENDIX 2

7.0 POWDER HOOD BSC CLEANING:

7.1 Cleaning the Interior of the Powder Hood BSC:

7.1.1 Saturated wipes should be folded into quarters. A new quarter should be used for each new surface.

7.1.2 Equipment within the powder hood, such as scales and printers, shall be carefully moved out of the hood when cleaning to access all areas.

7.1.3 Using a mop, clean the ceiling, then back wall, then side walls, then inside of the sash, and lastly the deck and bottom of equipment. Mop the deck from side-to-side, back-to-front.

7.1.4 Use a wipe to clean the outside of the elbow rest, side-to-side.

7.1.5 Lastly, use a wipe to clean the collection tray in front of the elbow rest, side-to-side.

7.1.6 Using a new wipe, clean exterior of the necessary hood equipment needed for compounding with 70% SIPA before placing back into the powder hood. Flip to a new side of the wipe after each piece of equipment cleaned.

7.2 Performing a clean behind the grate of the Powder Hood BSC:

7.2.1 Saturated wipes should be folded into quarters. A new quarter should be used for each new surface.

7.2.2 Equipment within the powder hood, such as scales and printers, shall be carefully moved when cleaning to access all areas.

7.2.3 Detach the grate by unscrewing the two screws located in the top corners of the grate surface.

7.2.4 Proceed to clean all newly exposed areas with a mop or wipes, top-to-bottom, side-to-side, cleanest-to-dirtiest.

7.2.5 After the back of the grate and areas behind it have been cleaned, replace the grate and screws to proceed with standard BSC powder hood clean as described above.

7.2.6 If a hood is used in the production of different drug products, the grate shall be cleaned/disinfected with the applicable monthly solution between their production if a drug has sprayed or leaked behind the grate. Otherwise, the grate shall be fully accessed and cleaned as described In **Table 3**.

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APPENDIX 3

8.0 LEFT BSC WALL CLEAN



Cleaning order: Red, Orange, Yellow

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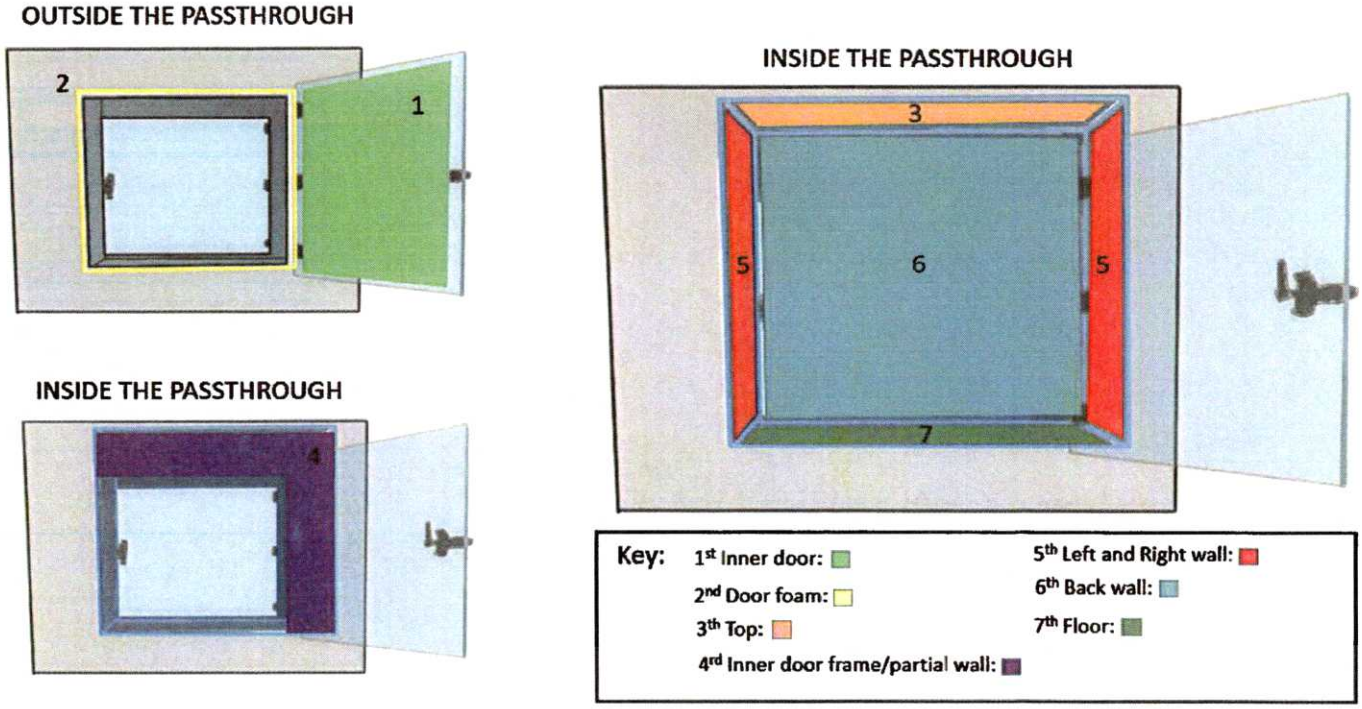
APPENDIX 4

9.0 PASSTHROUGH CLEANING:

9.1 Passthroughs are to be cleaned from each side accessed per **Figures 5 and 6**.

Figure 5

Cleaning a Passthrough from the "Clean" Side

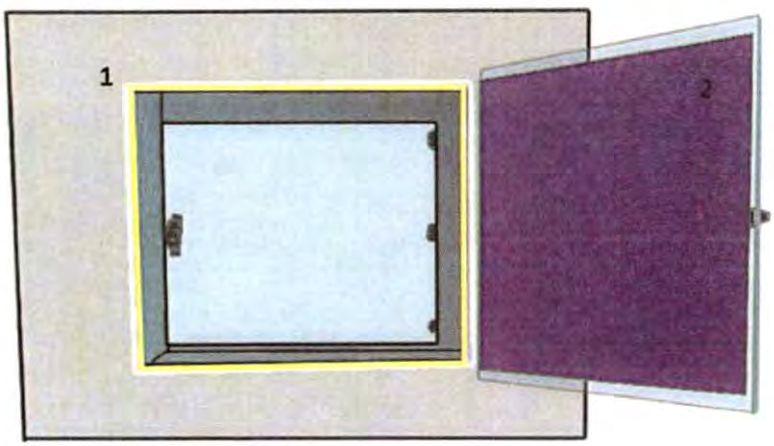


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Figure 6

Cleaning a Passthrough from the "Dirty" Side



10.0 APPLICABLE REFERENCES

10.1 **GMP-SOP-0002** *Change Control*

10.2 **GMP-Form-0011** *Change Control Documentation Form*

10.3 **GMP-WI-0005** *Aramark Vileda Mopping System Work Instruction*

10.4 **GMP-Form-0207, GMP-Form-0208, GMP-Form-0209** *Facility Cleaning Logs*

10.5 **GMP-SOP-0006** *Good Documentation Practices Procedure*

10.6 **GMP-Drawing-0002** *Clean Room People, Material, and Waste Flow Diagrams*

10.7 **GMP-Form-0058** *Facility Cleaning Qualification Checklist*

10.8 **GMP-Form-0187** *Vileda Mopping System Mop Prep – Competency Check*

10.9 **GMP-Form-0194** *Competency Check – Passthrough Sanitization*

10.10 **GMP-Form-0146** *Powder Hood Sanitization – Competency Check*

10.11 **GMP-Form-0219** *Competency Check – BSC Sanitization*

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PACKAGING AND SHIPPING

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Table of Contents

1.0 PURPOSE 3
2.0 SCOPE 3
3.0 DEFINITIONS 3
4.0 RESPONSIBILITIES 3
5.0 PROCEDURE 3
6.0 PRODUCT PACKAGING 5
7.0 QUALITY RECORDS 13
8.0 APPLICABLE REFERENCES 13

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1.0 PURPOSE

1.1 This Standard Operating Procedure (SOP) describes the packaging and shipping procedures to be used by OurPharma staff to ensure the safe arrival of the products to customers or the laboratory for analyses. These procedures have been developed to reduce the risk of damage to the products (i.e., breakage of the containers) and prevent spillage of the material should a container be broken.

2.0 SCOPE

2.1 This procedure applies to all OurPharma employees involved in the packaging and/or shipping process.

2.2 This procedure applies to all finished drug products being shipped to customers or samples being sent to third party contract labs.

3.0 DEFINITIONS

3.1 Box (Inner Box) – A box that holds units of finished drug product or product samples being packaged for shipment or distribution. These may be shipped as is or placed inside a shipper in multiples.

3.2 Shipper – An outer box that contains one or more inner boxes.

3.3 NMT – No More Than

3.4 Primary Packaging- the packaging with direct contact with product container

4.0 RESPONSIBILITIES

4.1 It is the responsibility of all OurPharma employees involved in packaging and/or shipping to follow this procedure.

4.2 It is the responsibility of the Pharmacist to supervise the packaging of controlled substance products per **GMP-SOP-0165** *Pharmacist Supervision*.

5.0 PROCEDURE

5.1 General Requirements:

5.1.1 During the packaging and shipping process, units shall be handled gently to avoid manipulation of critical components and to ensure the integrity of the container closure is not compromised.

5.1.2 Personnel shall don a hairnet, mask, and gloves prior to packaging into primary packaging.

5.1.2.1 PPE is not required once units have been packaged into primary packaging.

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5.1.3 Controlled Substances shall be handled per **GMP-SOP-0038** *Compounding and Distribution of Controlled and Listed Substances.*

5.1.4 All personnel shall utilize the supplied bubble wrap to fill void space in boxes and shippers to ensure the integrity of the package shipment (see **Figures 1-6**). The only exception to this is when there are fewer than 30 PCA vials being shipped in a PCA box (see PCA Vials 6.1.4.1 below).

5.1.5 All boxes and shippers shall be taped with secure, reinforced packing tape from the water activated tape dispenser in the shipping area after contents of order are confirmed by area supervisor, pharmacist, or designee.

5.1.5.1 Prior to beginning the process, the tape dispenser reservoir should be checked to ensure there is adequate water present.

Table-1: Shipping Materials

Item	Description			
Box – Option 1	Cardboard Box – 12" x 10" x 4"			
Box – Option 2	Cardboard Box – 12" x 10" x 10"			
Box – Option 3	Cardboard box – 13" x 11" x 13"			
Shipper	Carboard box – 14" x 14" x 14"			
PCA Vial Box	Cardboard Box - 8-7/16"x7"x4-1/4"			
PCA Vial/ 3mL Syringe Shipper	Cardboard Box - 11-1/8"x9"x11-1/8"			
Ziploc Bag	6"x9"	3- & 5-mL syringes	12"x15" Clear Ziploc **UVI/UVA Protected**	3/5/30/35/50mL syringes, 100/250 mL IV bags
Heat Sealed Bag	All CADD cassettes and all bag products			
Bubble Wrap	Used to fill void space in both boxes and shippers			
Sealed Bag	Heat-Sealed Tamper Evident Bag or Non-Tamper Evident Sealed Ziploc Bag			
Tape	Reinforced tape from water activated tape dispenser			

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6.0 PRODUCT PACKAGING:

6.1.1 Cassettes

6.1.1.1 Cassettes shall be packaged in tamper evident Ziploc bags that will be heat sealed closed after a cassette is placed in the bag. Refer to **GMP-SOP-0163** *Impulse Heat Sealer SOP* for instructions on proper heat-sealer use. See **Figure-1** for example.

6.1.1.1.1 **NOTE:** A layer of bubble wrap shall be placed in between each layer of 50mL or 100mL cassettes to prevent movement during transit.

Container Type Cassettes (Family A)	# units per *heat sealed* bag	# *heat sealed* units (NMT) per box (12"x10"x4")	# *heat sealed* units (NMT) per box (12"x10"x10")
50mL	1	30	70
100mL	1	12	42

Figure-1: CADD Cassette Packout

50 mL CADD Cassettes	100 mL CADD Cassettes
	

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6.1.2 Syringes

6.1.2.1 Syringe sizes whose primary labels do not contain adequate room for all required label content per **GMP-SOP-0033** *Compounded Sterile Product Label SOP*, shall have a secondary product label placed on the outside of each secondary package Ziploc bag that includes content omitted from the primary label.

6.1.2.1.1 Reference batch record for those products requiring secondary labels.

6.1.2.1.2 **NOTE:** Large bubble wrap shall be used to line the 13" x 11" x 13" box used for 50mL syringes.

Syringes (Family B)	# units (NMT) per Ziploc bag	# Ziploc bags (NMT) per primary box (12"x10"x10" or 11-1/8"x9"x11-1/8" or 13"x11"x13")
3mL / 5mL (up to 100 units)	10 **(6"x9" bag)**	10 – 6"x9" bag(s) in 12"x15" clear UV-protected bag; 100 units total per box **Box Size**: 12"x10"x4"
3mL / 5mL (101 to 300 units)	10 **(6"x9" bag)**	10 – 6"x9" bag(s) in 12"x15" clear UV-protected bag; 300 units (3 x 12"x15" bags) total per box **Box Size:** 11-1/8"x9"x11-1/8"
30mL / 35mL Syringe	10 **(12"x15" bag)**	7 – 12"x15" clear UV protected bags; 70 units total per box **Box Size**: 12"x10"x10"
30mL Plungerless Syringe	10 **(12"x15" bag)**	12 – 12"x15" clear UV protected bags; 120 units total per box **Box Size**: 12"x10"x10"
50mL	5 **(12"x15" bag)**	10 – 12"x15" clear UV protected bags; 50 units total per box **Box Size**: 13"x11"x13"

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Figure-2: Syringe Packout

3mL Syringes	5 mL Syringes
	
50 mL Syringes	**30mL / 35mL Syringes**
	
30 mL Plungerless Syringe	
	

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6.1.3 IV Bags

6.1.3.1 IV bags shall be packaged in tamper evident Ziploc bags that will be heat sealed closed after an IV bag is placed in the bag. Refer to **GMP-SOP-0163** *Impulse Heat Sealer SOP* for instructions on proper heat-sealer use. See **Figure-3** for example.

6.1.3.2 Individually heat-sealed IV bags shall be packaged with TEC injection port covers and placed in a large Ziploc bag. See **Figure-3** for example.

6.1.3.3 **NOTE:** If only one 12"x10"x4" box is needed, it does not need to be placed in a shipper box (14"x14"x14")

IV Bags (Family C)	**# units per *heat sealed* bag**	**# *heat sealed* units (NMT) per Ziploc bag (12"x15" bag)**	**# Ziploc bags (NMT) per box**
100mL (1 – 20 units) **(12"x10"x4")**	1	10	2
100mL (21 – 60 units) **(12"x10"x10")**	1	10	6
250mL (1 – 10 units) **(12"x10"x4")**	1	10	1
250mL (11 – 30 units) **(12"x10"x10")**	1	10	3

Figure-3: IV Bag Packout

100mL Bags	**250mL Bags**
	

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6.1.4 PCA Vials

6.1.4.1 PCA vials shall be packaged with: one (1) layer of thin bubble wrap placed under the grid-forming partition/insert and one (1) layer on top of the partition/insert. See **Figure-4** as an example.

6.1.4.1.1 Most outer box of the shipment shall be labeled with a "*Fragile*" sticker.

6.1.4.1.2 **NOTE:** If 30, or fewer PCA vials are shipped, the primary PCA box does not need to be placed in a shipper box.

PCA Vials (Family D)	# units (NMT) per PCA box (8-7/16"x7"x4-1/4")	# PCA boxes (NMT) per shipper (11-1/8"x9"x11-1/8")
30mL	30	2

Figure-4: PCA Vial Packout

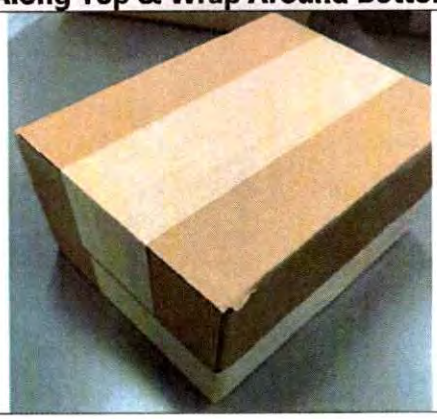
PCA BOX with Grid Insert



Bubble Wrap Below and Above Vials



Tape Along Top & Wrap Around Bottom Flap



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6.2 Shipper Packaging

6.2.1 Void space in shippers shall be filled with an adequate amount of bubble wrap to prevent movement of inner boxes during shipping and distribution. See **Figure-6.**

6.2.1.1 **Note:** The void space in the top of the box on the right would be filled with bubble wrap prior to shipment. It was excluded from this picture for the purpose of displaying how the void space along the sides of the box should be filled.

Figure-6: Shipper Packaging

Shipper with Three (3) Boxes	**PCA Shipper with Two (2) PCA Boxes**
	

6.3 Packing Slips:

6.3.1 When an order is received, and the product is available for sale, a packing slip should be generated.

6.3.2 When an order is received it shall be entered into Syspro per **GMP-SOP-0096** *Sales Order.*

6.3.3 When the product is ready to ship, the packing slip is then printed, and the order closed within Syspro.

6.3.4 The packing slip shall contain the company logo and the following information:

6.3.4.1 Ship date

6.3.4.2 Order data

6.3.4.3 PO #

6.3.4.4 Ordered by "Company" Name

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6.3.4.5 Ship to address (as stated on the DEA registration, if the product sold is a controlled substance)

6.3.4.6 Product NDC#

6.3.4.7 Item Description

6.3.4.8 Drug Classification

6.3.4.9 Order Quantity

6.3.4.10 Ship Quantity

6.3.5 Two copies of the packing slip should print.

6.3.5.1 One copy should be given to the Pharmacy Manager, and one given to Customer Service Manager or designee once the package is shipped.

6.3.5.2 The original packing slip should be placed inside the package before being sealed.

6.4 Shipping:

6.4.1 Packages must bear the appropriate hazard and handling labels.

6.4.2 All product shipments shall require an entry on **GMP-Form-0139**, *Product Shipment Log.*

6.5 Shipping Labels

6.5.1 A computer is designated in Shipping for use with FedEx Ship Manager software. This program is used to prepare and maintain shipping labels using stored databases of addresses.

6.5.2 Shipping labels will be printed from FedEx Ship Manager and placed on package(s).

6.5.3 Setups – FedEx – FedEx software is installed and updated by FedEx through a web interface. Updates for rates occur on a periodic basis and do not need review from IT. Program updates are applied by IT as needed with proper review of any functional changes.

6.5.4 Setups –ShipLink – ShipLink is installed on the local PC with a cloud configuration backup. ShipLink starts the process of shipping a Syspro order and launches the FedEx application to provide an integrated shipping solution. Packages shipped with ShipLink will have the FedEx tracking information stored on the order and printed on the invoice.

6.6 Package pickup:

6.6.1 FedEx pickups are scheduled daily as a regularly scheduled stop on FedEx route. If there is no regularly scheduled package pickup, an employee with FedEx login credentials can schedule a FedEx pickup.

6.6.1.1 If there is no regularly scheduled package pickup, an employee with FedEx login credentials can schedule a FedEx pickup by going online to https://www.fedex.com/en-us/service-guide/pickup-

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delivery.html#:~:text=Select%20Schedule%20a%20Pickup%20or,qualify%20for%20regular%20scheduled%20pickups. to request date and time for package pickup. Anyone can schedule a pickup by calling FedEx Customer Support at 1.800.463.3339.

6.6.1.2 You must enter pickup address and designate the service needed - express or ground. Enter package information which includes total number of packages, weight, pickup date, ready time, and latest time available.

6.6.1.3 Pickups can only be scheduled two business days out. Same day express pickup requests should be made at least 1.5 hours before closing time. Ground pickups must be requested one business day prior.

6.6.2 A computer is designated in Shipping for use with FedEx Ship Manager software. This program is used to prepare and maintain shipping labels using stored databases of addresses. For Syspro related orders, it also contains the Shiplink application. To initiate the Fedex program to generate a label, enter order number into Shiplink.

6.6.3 The following steps are to be used to prepare shipping label using FedEx Ship Manager:

6.6.3.1 In the "Shipment Details" tab, check accuracy of shipping address under Recipient Information (system can perform detailed address check). When you enter entity in the "Recipient ID" field, it will populate if address was stored in the database.

6.6.3.2 Under "Sender Information," check the return address for OurPharma (automated).

6.6.3.3 Package and shipment details:

6.6.3.4 Number of packages for this address (can mark if multiple and if identical in size & weight)

6.6.3.5 Weight (pulls information from scale connected to system)

6.6.3.6 Service type – It is very important to select appropriate service (Note: FedEx Priority Overnight delivery guaranteed by 10:30am to most U.S. addresses; Standard Overnight delivery guaranteed by 4:30pm to most U.S. addresses)
5.6.3.6.1 Packages containing finished drug products should be shipped Priority Overnight to both customers and contract labs.

6.6.3.7 Package type – If using own packaging, can enter dimensions.

6.6.3.8 Ship date (automatically puts today's date but can be changed accordingly)

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6.6.3.9 Declared value

6.6.3.10 Enter the PO number in "Reference" so that information prints on the shipping label.

6.6.3.11 Select "Options" tab at top and under "Signature Options," choose Direct Signature Required from the drop-down menu.

6.6.3.12 Select "Ship Alert" tab at top. Enter email address of Customer Service Manager to send email notifications regarding:

6.6.3.12.1 Shipment Notification

6.6.3.12.2 Exception Notification

6.6.3.12.3 Delivery Notification

5.6.3.13 Print shipping label and place on package(s). The small, attached label that prints with tracking # is placed on the packing slip copy going to customer service. This will be used to print the Invoice.

7.0 QUALITY RECORDS

6.1 GMP-SOP-0165 *Pharmacist Supervision*
6.2 GMP-Form-0139 *Product Shipment Log*
6.3 GMP-SOP-0038 *Compounding and Distribution of Controlled and Listed Substances.*
6.4 GMP-SOP-0163 *Impulse Heat Sealer SOP*
6.5 GMP-Form-0139 *Product Shipment Log*
6.6 GMP-SOP-0033 *Compounded Sterile Product Label SOP*
6.7 GMP-SOP-0058 *Stability Program*

8.0 APPLICABLE REFERENCES

7.1 N/A

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12

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Daiichi Sankyo, Inc.

Physical Address: 211 Mount Airy Road

City: Basking Ridge State: NJ Zip: 07920

Mailing Address (if different from physical address): (Same)

City: _____ State: _____ Zip: _____

Telephone: 862-344-0516 Website: https://daiichisankyo.us/

Name of Designated Representative (DR): Richard Muskus

Licensing Company Email: Statelicensing@dsi.com DR Email: Statelicensing@dsi.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer- Virtual
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Jan. 2020		NV		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	Nevada Dept. of Health & Human Services

Reason/Charge
Failure to timely submit certain information required by NV Revised Statute (NRS) 439B.600-439B.695

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
Daiichi Sankyo, Inc.

Provide explanation below:

In January 2020, the Nevada Department of Health & Human Services (DHHS) imposed a penalty in the amount of $31,350 on Daiichi Sankyo, Inc. for its failure to timely submit certain information required by the Nevada Revised Statutes (NRS) 439B.600 through 439B.695 concerning transparency in the pricing of certain diabetes medications.

In January 2015, DSI entered into a settlement agreement with various agencies of the United States government related to allegations that DSI submitted false claims to federal healthcare programs by inducing physicians to prescribe certain DSI products (Benicar, Benicar HCT, Azor, Tribenzor and Welchol) in the form of honoraria payments and meals related to certain speaker programs. The resolution resulted in DSI paying a settlement amount of $39 million in 2015 (to settle federal and state Medicaid matters, including Nevada) and entering into a Corporate Integrity Agreement with the Office of Inspector General for a period of five years. DSI was released from the Corporate Integrity Agreement in 2020, having fulfilled the obligations therein. (See U.S. ex rel. Fragoules v. Daiichi Sankyo, Inc., Civil Action No. 10-10420 (D. Mass.)).

Original Signature (electronic, copies or stamps not accepted)
Patricia A. Barbieri, Secretary

3/6/2023
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Please see the attached list.

Address: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Daiichi Sankyo U.S. Holdings, Inc.

Corporation/Organization Name: _____

Mailing Address: 211 Mount Airy Road

City: Basking Ridge State: NJ Zip: 07920

Telephone: 862-344-0516 Email: Statelicensing@dsi.com

Contact Person Name: Theodora Bonelli

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List of all Officers and Directors.	✓	✓		
• List the top four corporation shareholders and their percent ownership.	✓			
• List of all corporation shareholders and their percent ownership.		✓		
• List of all partners and their percent ownership.			✓	
• Certificate of Corporate Status or Certificate of Good Standing obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last 12 months.	✓	✓	✓	✓
• Designated Representative form must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• Personal History Record Application must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• Copy of DEA certificate if handling controlled substances	✓	✓	✓	✓
• Copy of current SEC 10K or 8K (First 15 pages only)	✓			
• List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.	✓	✓	✓	✓
• Copy of your license, certification, permit or registration issued to your wholesaler business from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. (REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)	✓	✓	✓	✓
• *Medical Devices, Equipment and Gases (MDEG) Administrator form must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• If providing *Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957). The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• Submit Fingerprints following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• Copy of a bond in an amount of $100,000 made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the Surety Bond form at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Daiichi Sankyo, Inc.

Facility Name

Patricia A. Barbieri, Secretary

Print Name of Authorized Person Submitting Application

P. A. Barbieri

Original signature of Authorized Person (copies or stamps not accepted)

3/6/23

Date

Board Use Only	Date Received: 3·8·23	Amount: 1,000	CHECK # 3068133

Attachment to Daiichi Sankyo, Inc.'s Out-of-State Wholesaler New Application (Nevada Board of Pharmacy)

Parent Company - Ownership 100%

Daiichi Sankyo U.S. Holdings, Inc.

Description of Operations

Daiichi Sankyo, Inc. ("DSI") is a virtual manufacturer selling prescription oncology drugs **to other wholesalers**. As a virtual manufacturer, DSI does not manufacture, maintain or warehouse any non-controlled or controlled substances at its Basking Ridge, NJ facility. DSI does not have a DEA registration.

The Basking Ridge, New Jersey, facility is DSI's corporate headquarters. DSI's hours of operations are Monday through Friday from 8:30 a.m. to 5:00 p.m.

Corporate Officers

Name	Title	Residence
Joseph Kenneth Keller	President	[redacted] Thaynes Canyon Drive Park City, UT 84060
Mila Tartakovsky	Treasurer	[redacted] Ocean Ave, Unit 10 Sea Bright NJ 07760
Patricia A. Barbieri	Secretary	[redacted] Evans Place Saddle Brook, NJ 07663
Amy Klug	Assistant Secretary	[redacted] Wood Road Morristown, NJ 07960

CMOs – Finished Product

American Regent, Inc. 6610 New Albany Road East New Albany, OH 43054 027223179	Packaging Coordinators, LLC 3001 Red Lion Road Philadelphia, PA 19114 1000522077 // Duns 078525133
Sharp Packaging Services, LLC 7451 Keebler Way Allentown, PA 18106 3004161147 // 143696495	Sharp Clinical Services, LLC 2400 Baglyos Circle Bethlehem, PA 18020 3003673570

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 3/6/2023

Registration Number: 5003624 **Registered as:** Manufacturer
Name: DAIICHI SANKYO, INC
DBA:
Address: 211 MOUNT AIRY RD, BASKING RIDGE, NJ 07920
Original Issue Date: 04/15/2008 **Expiration Date:** 01/31/2024
Current Issue Date: 12/15/2022
Disciplines: No

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DAIICHI SANKYO, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF FEBRUARY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2675816 8300

SR# 20230641742

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202765820

Date: 02-22-23

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0748559

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☐ wholesaler which conducts business at the following locations in this State:

211 MOUNT AIRY RD BASKING RIDGE NJ 07920-

Reg. No.
5003624

DAIICHI SANKYO, INC
ATTN: CANDY MINGST
211 MOUNT AIRY RD
BASKING RIDGE, NJ 07920-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2024

Establishment Copy

NDC/NHRIC Labeler Code	Firm Name
63395	Daiichi Sankyo, Inc.

✓ verified
MH 3/23/23

National Drug Code Directory

Current through March 06, 2023

You have searched Finished drug products

Search Results: *'Daiichi'*

Back to Search Page () | Search Again ()

CSV Excel

Display All **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Azor	65597-111-11	10 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-111	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	08/31/2024	NDA	1000 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-111-11)
+ Azor	65597-112-30	5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-112	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	10/31/2023	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-112-30)
+ Azor	65597-110-07	5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-110	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	05/31/2023	NDA	7 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-110-07)
+ Azor	65597-111-07	10 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-111	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	08/31/2024	NDA	7 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-111-07)
+ Azor	65597-113-07	10 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-113	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	02/28/2025	NDA	7 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-113-07)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Azor	65597-112-90	5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-112	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	10/31/2023	NDA	90 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-112-90)
+ Azor	65597-113-10	10 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-113	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	02/28/2025	NDA	10 BLISTER PACK in 1 BOX (65597-113-10) / 10 TABLET, FILM COATED in 1 BLISTER PACK
+ Azor	65597-112-07	5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-112	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	10/31/2023	NDA	7 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-112-07)
+ Azor	65597-110-11	5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-110	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	05/31/2023	NDA	1000 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-110-11)
+ Azor	65597-111-10	10 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-111	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	08/31/2024	NDA	10 BLISTER PACK in 1 BOX (65597-111-10) / 10 TABLET, FILM COATED in 1 BLISTER PACK
+ Azor	65597-113-11	10 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-113	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	02/28/2025	NDA	1000 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-113-11)
+ Azor	65597-113-90	10 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-113	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	02/28/2025	NDA	90 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-113-90)
+ Azor	65597-110-10	5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-110	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	05/31/2023	NDA	10 BLISTER PACK in 1 BOX (65597-110-10) / 10 TABLET, FILM COATED in 1 BLISTER PACK

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Azor	65597-110-30	5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-110	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	05/31/2023	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-110-30)
+ Azor	65597-110-90	5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-110	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	05/31/2023	NDA	90 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-110-90)
+ Azor	65597-111-30	10 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-111	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	08/31/2024	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-111-30)
+ Azor	65597-112-10	5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-112	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	10/31/2023	NDA	10 BLISTER PACK in 1 BOX (65597-112-10) / 10 TABLET, FILM COATED in 1 BLISTER PACK
+ Azor	65597-112-11	5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-112	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	10/31/2023	NDA	1000 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-112-11)
+ Azor	65597-111-90	10 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-111	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	08/31/2024	NDA	90 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-111-90)
+ Azor	65597-113-30	10 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA022100	Daiichi Sankyo Inc.	65597-113	amlodipine besylate and olmesartan medoxomil	AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	09/26/2007	02/28/2025	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-113-30)
+ Benicar	65597-101-30	5 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-101	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/25/2002	01/31/2024	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-101-30)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Benicar	65597-103-10	20 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-103	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/25/2002	03/31/2024	NDA	100 TABLET, FILM COATED in 1 BOX (65597-103-10)
+ Benicar	65597-103-30	20 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-103	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/25/2002	03/31/2024	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-103-30)
+ Benicar	65597-104-06	40 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-104	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/25/2002	03/31/2024	NDA	180 TABLET, FILM COATED in 1 BOX (65597-104-06)
+ Benicar	65597-103-06	20 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-103	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/25/2002	03/31/2024	NDA	180 TABLET, FILM COATED in 1 BOX (65597-103-06)
+ Benicar	65597-104-30	40 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-104	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/25/2002	03/31/2024	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-104-30)
+ Benicar	65597-104-03	40 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-104	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/03/2014	03/31/2024	NDA	30 TABLET, FILM COATED in 1 BOX, UNIT-DOSE (65597-104-03)
+ Benicar	65597-103-03	20 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-103	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/03/2014	03/31/2024	NDA	30 TABLET, FILM COATED in 1 BOX, UNIT-DOSE (65597-103-03)
+ Benicar	65597-104-90	40 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-104	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/25/2002	03/31/2024	NDA	90 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-104-90)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Benicar	65597-103-90	20 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-103	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/25/2002	03/31/2024	NDA	90 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-103-90)
+ Benicar	65597-104-10	40 mg/1	TABLET, FILM COATED	ORAL	NDA021286	Daiichi Sankyo, Inc.	65597-104	olmesartan medoxomil	OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	04/25/2002	03/31/2024	NDA	100 TABLET, FILM COATED in 1 BOX (65597-104-10)
+ Benicar HCT	65597-106-11	12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-106	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	12/31/2023	NDA	1000 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-106-11)
+ Benicar HCT	65597-106-90	12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-106	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	12/31/2023	NDA	90 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-106-90)
+ Benicar HCT	65597-105-30	12.5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-105	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	09/30/2023	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-105-30)
+ Benicar HCT	65597-107-07	25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-107	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	02/29/2024	NDA	7 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-107-07)
+ Benicar HCT	65597-106-30	12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-106	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	12/31/2023	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-106-30)
+ Benicar HCT	65597-107-30	25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-107	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	02/29/2024	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-107-30)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Benicar HCT	65597-107-90	25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-107	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	02/29/2024	NDA	90 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-107-90)
+ Benicar HCT	65597-105-07	12.5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-105	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	09/30/2023	NDA	7 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-105-07)
+ Benicar HCT	65597-105-11	12.5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-105	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	09/30/2023	NDA	1000 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-105-11)
+ Benicar HCT	65597-106-07	12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-106	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	12/31/2023	NDA	7 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-106-07)
+ Benicar HCT	65597-105-90	12.5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-105	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	09/30/2023	NDA	90 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-105-90)
+ Benicar HCT	65597-107-11	25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA021532	Daiichi Sankyo, Inc.	65597-107	olmesartan medoxomil-hydrochlorothiazide	HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/30/2003	02/29/2024	NDA	1000 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (65597-107-11)
+ Effient	65597-601-30	5 mg/1	TABLET, COATED	ORAL	NDA022307	Daiichi Sankyo, Inc.	65597-601	Prasugrel Hydrochloride	PRASUGREL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	07/01/2021	12/31/2023	NDA	30 TABLET, COATED in 1 BOTTLE (65597-601-30)
+ Effient	65597-602-30	10 mg/1	TABLET, COATED	ORAL	NDA022307	Daiichi Sankyo, Inc.	65597-602	Prasugrel Hydrochloride	PRASUGREL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	07/01/2021	12/31/2023	NDA	30 TABLET, COATED in 1 BOTTLE (65597-602-30)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Enhertu	65597-406-01	100 mg/5mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA761139	Daiichi Sankyo, Inc.	65597-406	fam-trastuzumab deruxtecan-nxki	TRASTUZUMAB DERUXTECAN	HUMAN PRESCRIPTION DRUG	12/20/2019	N/A	BLA	1 VIAL, SINGLE-DOSE in 1 CARTON (65597-406-01) / 5 mL in 1 VIAL, SINGLE-DOSE
+ Evoxac	63395-201-13	30 mg/1	CAPSULE	ORAL	NDA020989	Daiichi Sankyo, Inc.	63395-201	cevimeline hydrochloride	CEVIMELINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	01/12/2000	08/31/2025	NDA	100 CAPSULE in 1 BOTTLE, PLASTIC (63395-201-13)
+ SAVAYSA	65597-203-05	60 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-203	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	50 BLISTER PACK in 1 CARTON (65597-203-05) / 1 TABLET, FILM COATED in 1 BLISTER PACK
+ SAVAYSA	65597-201-07	15 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-201	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	7 TABLET, FILM COATED in 1 BOTTLE (65597-201-07)
+ SAVAYSA	65597-201-10	15 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-201	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	10 TABLET, FILM COATED in 1 BLISTER PACK (65597-201-10)
+ SAVAYSA	65597-202-50	30 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-202	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	500 TABLET, FILM COATED in 1 BOTTLE (65597-202-50)
+ SAVAYSA	65597-201-90	15 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-201	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	90 TABLET, FILM COATED in 1 BOTTLE (65597-201-90)
+ SAVAYSA	65597-202-70	30 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-202	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	7 TABLET, FILM COATED in 1 BLISTER PACK (65597-202-70)
+ SAVAYSA	65597-201-30	15 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-201	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE (65597-201-30)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ SAVAYSA	65597-202-07	30 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-202	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	7 TABLET, FILM COATED in 1 BOTTLE (65597-202-07)
+ SAVAYSA	65597-203-10	60 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-203	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	100 BLISTER PACK in 1 CARTON (65597-203-10) / 1 TABLET, FILM COATED in 1 BLISTER PACK
+ SAVAYSA	65597-202-30	30 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-202	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE (65597-202-30)
+ SAVAYSA	65597-202-90	30 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-202	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	90 TABLET, FILM COATED in 1 BOTTLE (65597-202-90)
+ SAVAYSA	65597-201-50	15 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-201	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	500 TABLET, FILM COATED in 1 BOTTLE (65597-201-50)
+ SAVAYSA	65597-201-70	15 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-201	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	7 TABLET, FILM COATED in 1 BLISTER PACK (65597-201-70)
+ SAVAYSA	65597-203-07	60 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-203	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	7 TABLET, FILM COATED in 1 BOTTLE (65597-203-07)
+ SAVAYSA	65597-203-50	60 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-203	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	500 TABLET, FILM COATED in 1 BOTTLE (65597-203-50)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ SAVAYSA	65597-202-05	30 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-202	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	50 BLISTER PACK in 1 CARTON (65597-202-05) / 1 TABLET, FILM COATED in 1 BLISTER PACK
+ SAVAYSA	65597-203-90	60 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-203	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	90 TABLET, FILM COATED in 1 BOTTLE (65597-203-90)
+ SAVAYSA	65597-202-10	30 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-202	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	100 BLISTER PACK in 1 CARTON (65597-202-10) / 1 TABLET, FILM COATED in 1 BLISTER PACK
+ SAVAYSA	65597-203-30	60 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-203	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE (65597-203-30)
+ SAVAYSA	65597-203-70	60 mg/1	TABLET, FILM COATED	ORAL	NDA206316	Daiichi Sankyo	65597-203	EDOXABAN TOSYLATE	EDOXABAN TOSYLATE	HUMAN PRESCRIPTION DRUG	01/31/2015	N/A	NDA	7 TABLET, FILM COATED in 1 BLISTER PACK (65597-203-70)
+ Tribenzor	65597-114-07	5 mg/1, 12.5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-114	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	08/31/2024	NDA	7 TABLET, FILM COATED in 1 BOTTLE (65597-114-07)
+ Tribenzor	65597-114-10	5 mg/1, 12.5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-114	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	08/31/2024	NDA	10 BLISTER PACK in 1 BOX (65597-114-10) / 10 TABLET, FILM COATED in 1 BLISTER PACK
+ Tribenzor	65597-115-10	5 mg/1, 12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-115	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	07/31/2023	NDA	10 BLISTER PACK in 1 BOX (65597-115-10) / 10 TABLET, FILM COATED in 1 BLISTER PACK

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Tribenzor	65597-116-70	5 mg/1, 25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-116	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	06/30/2024	NDA	7 TABLET, FILM COATED in 1 BLISTER PACK (65597-116-70)
+ Tribenzor	65597-117-10	10 mg/1, 12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-117	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	05/31/2024	NDA	10 BLISTER PACK in 1 BOX (65597-117-10) / 10 TABLET, FILM COATED in 1 BLISTER PACK
+ Tribenzor	65597-118-30	10 mg/1, 25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-118	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	02/29/2024	NDA	30 TABLET, FILM COATED in 1 BOTTLE (65597-118-30)
+ Tribenzor	65597-115-70	5 mg/1, 12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-115	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	07/31/2023	NDA	7 TABLET, FILM COATED in 1 BLISTER PACK (65597-115-70)
+ Tribenzor	65597-116-07	5 mg/1, 25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-116	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	06/30/2024	NDA	7 TABLET, FILM COATED in 1 BOTTLE (65597-116-07)
+ Tribenzor	65597-117-90	10 mg/1, 12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-117	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	05/31/2024	NDA	90 TABLET, FILM COATED in 1 BOTTLE (65597-117-90)
+ Tribenzor	65597-118-90	10 mg/1, 25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-118	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	02/29/2024	NDA	90 TABLET, FILM COATED in 1 BOTTLE (65597-118-90)
+ Tribenzor	65597-114-30	5 mg/1, 12.5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-114	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	08/31/2024	NDA	30 TABLET, FILM COATED in 1 BOTTLE (65597-114-30)
+ Tribenzor	65597-114-70	5 mg/1, 12.5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-114	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	08/31/2024	NDA	7 TABLET, FILM COATED in 1 BLISTER PACK (65597-114-70)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Tribenzor	65597-116-30	5 mg/1, 25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-116	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	06/30/2024	NDA	30 TABLET, FILM COATED in 1 BOTTLE (65597-116-30)
+ Tribenzor	65597-116-90	5 mg/1, 25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-116	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	06/30/2024	NDA	90 TABLET, FILM COATED in 1 BOTTLE (65597-116-90)
+ Tribenzor	65597-117-30	10 mg/1, 12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-117	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	05/31/2024	NDA	30 TABLET, FILM COATED in 1 BOTTLE (65597-117-30)
+ Tribenzor	65597-114-90	5 mg/1, 12.5 mg/1, 20 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-114	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	08/31/2024	NDA	90 TABLET, FILM COATED in 1 BOTTLE (65597-114-90)
+ Tribenzor	65597-118-07	10 mg/1, 25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-118	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	02/29/2024	NDA	7 TABLET, FILM COATED in 1 BOTTLE (65597-118-07)
+ Tribenzor	65597-117-07	10 mg/1, 12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-117	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	05/31/2024	NDA	7 TABLET, FILM COATED in 1 BOTTLE (65597-117-07)
+ Tribenzor	65597-118-70	10 mg/1, 25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-118	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	02/29/2024	NDA	7 TABLET, FILM COATED in 1 BLISTER PACK (65597-118-70)
+ Tribenzor	65597-115-07	5 mg/1, 12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-115	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	07/31/2023	NDA	7 TABLET, FILM COATED in 1 BOTTLE (65597-115-07)
+ Tribenzor	65597-115-30	5 mg/1, 12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-115	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	07/31/2023	NDA	30 TABLET, FILM COATED in 1 BOTTLE (65597-115-30)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Tribenzor	65597-115-90	5 mg/1, 12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-115	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	07/31/2023	NDA	90 TABLET, FILM COATED in 1 BOTTLE (65597-115-90)
+ Tribenzor	65597-116-10	5 mg/1, 25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-116	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	06/30/2024	NDA	10 BLISTER PACK in 1 BOX (65597-116-10) / 10 TABLET, FILM COATED in 1 BLISTER PACK
+ Tribenzor	65597-117-70	10 mg/1, 12.5 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-117	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	05/31/2024	NDA	7 TABLET, FILM COATED in 1 BLISTER PACK (65597-117-70)
+ Tribenzor	65597-118-10	10 mg/1, 25 mg/1, 40 mg/1	TABLET, FILM COATED	ORAL	NDA200175	Daiichi Sankyo, Inc.	65597-118	olmesartan medoxomil / amlodipine besylate / hydrochlorothiazide	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	HUMAN PRESCRIPTION DRUG	07/31/2010	02/29/2024	NDA	10 BLISTER PACK in 1 BOX (65597-118-10) / 10 TABLET, FILM COATED in 1 BLISTER PACK
+ Turalio	65597-407-20	125 mg/1	CAPSULE	ORAL	NDA211810	Daiichi Sankyo, Inc.	65597-407	pexidartinib hydrochloride	PEXIDARTINIB HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	02/01/2023	N/A	NDA	1 BOTTLE in 1 CARTON (65597-407-20) / 120 CAPSULE in 1 BOTTLE
+ Turalio	65597-407-28	125 mg/1	CAPSULE	ORAL	NDA211810	Daiichi Sankyo, Inc.	65597-407	pexidartinib hydrochloride	PEXIDARTINIB HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	02/01/2023	N/A	NDA	1 BOTTLE in 1 CARTON (65597-407-28) / 28 CAPSULE in 1 BOTTLE
+ Turalio	65597-402-20	200 mg/1	CAPSULE	ORAL	NDA211810	Daiichi Sankyo, Inc.	65597-402	pexidartinib	PEXIDARTINIB HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/02/2019	N/A	NDA	1 BOTTLE in 1 CARTON (65597-402-20) / 120 CAPSULE in 1 BOTTLE
+ Turalio	65597-402-28	200 mg/1	CAPSULE	ORAL	NDA211810	Daiichi Sankyo, Inc.	65597-402	pexidartinib	PEXIDARTINIB HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/02/2019	N/A	NDA	1 BOTTLE in 1 CARTON (65597-402-28) / 28 CAPSULE in 1 BOTTLE

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
+ Welchol	65597-701-18	625 mg/1	TABLET, FILM COATED	ORAL	NDA021176	Daiichi Sankyo Inc.	65597-701	colesevelam hydrochloride	COLESEVELAM HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/01/2000	09/30/2025	NDA	180 TABLET, FILM COATED in 1 BOTTLE (65597-701-18)
+ Welchol	65597-902-30	3.75 g/1	FOR SUSPENSION	ORAL	NDA022362	Daiichi Sankyo Inc.	65597-902	colesevelam hydrochloride	COLESEVELAM HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	01/01/2010	02/28/2026	NDA	30 PACKET in 1 CARTON (65597-902-30) / 1 FOR SUSPENSION in 1 PACKET

Showing 1 to 98 of 98 entries

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
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Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

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Daiichi Sankyo Altkirch	3001400724	262417595	API MANUFACTURE;	39 Rue Du 3e Zouave, Altkirch, Alsace 68130, France (FRA)	12/31/2023
Daiichi Sankyo Chemical Pharma Co., Ltd.	3002808054	692602767	ANALYSIS; API MANUFACTURE;	389-4, Otsurugi, Izumimachishimogawa, Iwaki, Fukushima 971-8183, Japan (JPN)	12/31/2023
Daiichi Sankyo Europe GmbH	3003282622	551338593	ANALYSIS; MANUFACTURE;	Luitpoldstr. 1, Pfaffenhofen a.d.Ilm, 85276, Germany (DEU)	12/31/2023

Showing 1 to 3 of 3 entries
Previous1Next
Data Current through: Sunday, Mar 12, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Full Name
Malissa Leah Carter Novak
John J. Jacko
Dean E. Notarnicola
Leslie A. Williams
Elizabeth M. Harquail
Jacqueline Rotante Grossman
Conor T. Wheatley
Joy Y. Thomas
Patricia L. Valdez
Erin Leigh Curcio
Chihin Lui
Ms. Diana Sirico
Koji Ogawa
Masaaki Kotaki
Melaine Reeves
Mirei Tanaka
Tatyana Samodova
Yvette Douglas-Evans
Holly R. Olm
Carey May Smith
Constance M. Dominguez
Lisa Nancy Garsetti
Christine L. Davis
Naushad Islam
Karen Dorchak
John C. Ciurczak
Guy S. Rakoski
Matthew Allegrucci
Punam Kumar
Eric J. Friedman
Eben S. Fox
Yagnesh Patel
Naoko Inoue Banker
Jeffrey Wayne Warmke
Midori Gaines
Donna Doll
Paul Engel
Patrick Joseph Keenan
Thomas Gillick
Jay K Dave
Cynthia Skowronski Kohr
Nagatomo Hamahata
Nancy Cordero Lugo
Arthur Mann
Michele Fazioli
Hung-Zhang Tao
Lynda Chrobocinski Linfante
Gail E Malnarick
Richard Muskus
Donna M Casamassina
Kelly Ann Serritella
Jennifer Langowski

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Kartik B. Shukla
Norma Ciccone
Daniel M. Switzer
Craig Porco
Linda C. Nelson
Jenny A Shire
Sherwood C Racine
Mary Sirvet
Emilio E Farina
Fabricio Huerta-Caro
Nancy Travolta
Anil Duggal
Edward Solomon
Sanjay Chandrasekhar
Stephanie Lackowitz
Stacey Zegla
William A. Maxwell
Elsa Havas
Gilles Gennevieve
Janice H Arnold
Sobeyda Good
Minggao Shi
Jianqing Jin
Kevin Menniti
Qiang Wang
Ms. Yuri Nakamizo-Squillante
Mila Tartakovsky
Melanie A. Polloway
Matthew David Ricks
Josephine Schmitt
Liasu A. Akinsuyi
Gina George-Greer
Niambi Denene Daniels Harris
Ching Hsu
Cheryl Shine
Robert Metting
Suzanne Rubino
David Ramage
Naoyuki Tajima
Robert Riso
Ling He
Zoya Borodanski
Paul Meyer-Pflug
Karen F. Vander Ploeg
Gretchen Golikov
David M. Parenti
Lisa Marie Riker
Youngsook Choi
David Claudio
Duc P. Lai
Rebecca Binai
Erin C De La Cruz
Meenakshi Arunachalam

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Isolina Natal
Karen A. Rustek
Deepalakshmi Srinivasan
Shari M. Baron
Kara Finan Reheis
Lorraine Stoute
Hubert S Chou
Kaoru S. Fahey
Victor Lau
Michelle Kosich
Lourdes Y Nieves
John Rocchi
Michael Schwartzman
Natalya Stuherck
Rose Ann Hastings
Patricia A. Barbieri
Kimberly A Wix
Timothy A Kelly
Richard M Jones
Donna M Perez
Anthony J Lorino
Joseph R Paradiso
Kim A Castellucci
Henry L Gallo
Tamy A Recchia
Donna J Kucsma
Eric Romaglino
Alyssa E Dargento
Gary William Miller
Valay Desai
Lauren DiOrio
Brenda L Wood
Ravinder Singh
Jennifer Gene Wajda-Cuhney
Giorgio Senaldi
William Russell Snell
Garvin Elmera
Amy Todd Klug
Steven Cohen
Rebecca Lynn Schultz
Michelle S. Carchia
Deborah Anne Bitsack
Kirsten Frazier
Mr. Ram Babu Challa
Makoto Takamura
Hilary L Kelly
Gaurav Beniwal
Victoria Elizabeth Amari
Soraya Ziobro
Karen Frantz
Mary Theresa Bishay
James Kerwin
Tara K Leahy

Jhansilakshmi Maguluri
Jonathan York
Rimiko Jiang
Kristin Vaneekhoven
Balaji Govindarajulu
Earl J Kiesel
Danielle Marie Vespole
Nancy Maria Peterson
Carter William Tremayne
Winghan Jacqueline Kwong
Sarah McGovern
Pamela Herforth
Jeannine Scaramella
Charles Ian Fergusson
Albert G McCormick
Candy Mingst
Jennifer Anne Brennan
Michael D London
Prasanna Kumar
Mr. Thomas James Wyka
Scott Andrew Wearley
Scott Sugarman
Mr. Sridhar Bheemanathini
Wenqin Feng
Saori Nakagawa
Tomomi Takamoto
Falguni Rathod
Rohit A Heryani
Kym Goddu
Frances Pellerito Bessette
Michael Francis Dacey
Jingdong Xie
Dale E Shuster
Michael Anthony Grosso
Elizabeth Winters
Crawford Parker
Thomas Kennedy
Kimie Nishiyama
Joseph John Shatynski
Mark Chraplyvy
Allan Ventura
Leisl L Smith
Victoria Vega
Jennifer Marie Aiello
Guneesh Bhatia
Carline Saintilien
Rebecca M Lowe
Kevin K Smith
George T Chen
Pinku C Raval
Monika M Issa
Roberto L Hernandez Jr
Patricia Petruska

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Xin Ye
Aurea Rodrigues
Radha Ramkumar
Katsuhiko Yamamoto
Andrew R Delorenzo
Lori Varty
Cheryl Denise Pingol
Sandra Wardlow Hamelsky
David P. Garbeil
Wanza I Delaney
Zenta Tsuchihashi
Kimberly Anne Caamano
Charu Bhatt
Frank J Holdampf
Elyse Anne Almeida
Eric Olszewski
Zhen Nora Tu
Swati Patel
Marielle Cohard Radice
Claude E Celestin
Barbara Gustenhoven
Rhonda W Tang
Otoniel Guevara
Kimberly L Small
Dawn Vacca
Nabil Abdulaziz Said
Michael T Gibbons
Yumi Inukai
Poonam Rajni Fredeman
Sindee Grossman
Peter Ishak
Taeko Kobayashi
Cynthia M Mamola
Anthony Perro
MaryBeth Forte
Erik Papadopolo
Kayla M Cauley
Arun Chalgeri
David Fleishman
Annemarie Hall
Lisa Allison Kisthart
Lisa Scipioni Hernandez
Kristine Ondov
Shalini Aneja
Jacqueline Wilkes
Donald Putzer
Valerie Kuehner
Leanna DeSena
Tammy K Crytzer
Kandance Cooper Hart
Jeana Parmi
Daniel Font
Michael Anthony Pignatello

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Mitsuko Isayama Thornton
Gina L Hassler
Derek Edward Mires
Kenneth R Kayel
Gus Papandrikos
Nidhi Batra
Sarah A Kwon
Daniel John Fredeman
Wanda Debski
Jacquelyn Leigh Babcock
Ruth Wambogo
Barbara Ann Tantillo
Vincent C Greco
Richard J Maloney
Michelle P Ginda-Gargiulo
Steven Spero
Maria Saraiva
Sharmila Ghosh
Elizabeth Marrett
Valerie Ann Toy
Dan Liang
Mark Lindberg
Lisa Ann LaBrode
Kevin S Douglass
Joseph Fazio
Lisa M Alexander
Cathy Zi Li Chen
Glen Nosti
John William Delaney
Christine H Lise
Kelli Hourihan
Joseph Kenneth Keller
Kimberly A. Flanagan-Bouchard
Maronda Brown
Maryann Laskowski
Michelle Poli
Natalie Collins-Decambre
Shigeno Sasaki
Tessa A Alleyne
Andal Sambandam
Sugun Dong Gokmen
Marlen Casabona-Rojas
Heather M Meyers
Koji Ishizuka
JoAnne DiAgostino
Lulu Wang
Trevor Owen Jenkins
Bonnie L Blaszak
Mrs. Heather L. Bisking
Nicole Weigel
Raymond Garguilo Jr
Robert Knapp
Maria Blender

Lynne Elaine Yancey
Lukasz Jarosz
Virag Patel
Smrithi Nair
Lena H Sciroppo
Christina M Prince
Charles Brendan Hampsey
James Allen Price
Lawrence M. Schwartz
Katherine Lourdes May
Stephen M Murcko
Pepita Beaubrun
Linda Zaretzka
Nancy Cecelia Fleming
Caroline May
Ms. Janie Hansen
Grishma Bhavesh Pandya
Maria Lizza Bowen
Susan Dee Porcella
Christina Allen
Melissa Ashley Castro
Kira J. Grant
Suzanne Lynn Anzalone
Vishaal B Patel
Jana Christine Doyle
Kelvin Yinglun Li
Allyson Lane Baccini
Morgan D Lewis
Mrs. Athira Swami Nath
Oluseun Oluwakemi Shabi
Mrs. Teesha Parikh
Ms. Michelle Marie Anderson
Laura Naranjo
Jennifer Ann Pizzo
Mary Grace Manas Stofman
Mr. Kiran More
Caleb Ching-Hsiang Lee
May Wang
Zahidul Islam
Jonathan D Wozniak
Carla Denise Griffin
Arnaud Lesegretain
Christopher James Henry
Patrick Gilchrist
Erin Stutz
Suzanne LoGalbo
Kinjal Parekh
Oladayo Oyelola
Denise Garcia
Aparna Krishna Mohan
Lillian Kelly
Jasmeet Singh
Kunal S Shah

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Karen Michele Carducci
Megan Teresa Grimes
Karen Sohn Kopp
August Frederick Manz
Rebecca Shire Loughlin
Ingrid Elizabeth Johnston
Lori Jean Frank
Mr. Makoto Kitaura
Chien-Neng Chang
Hamsini Kolpe
Teresa Uhler Reyes
Christina M Roberts
Kenjiro Konishi
Laureina Lea Greenberg
Ana C Grandinetti
Garima Sharma
Lin Zhang
Peter Morris
Dennis C Aquino
Hardik Brahmbhatt
Malaz Abutarif
Tara DeBarros
Keith Win
Sean Patrick McNeff
Bryan A O'Neill
Eric Richards
Marilia Kimberly M Dimayo
Ganesh Vaidyanathan
Jehan Poco
Kimberly McKay Fraser
Vamshi Krishna Nathi
Xiaoli Gao
Diana Benincasa
Maureen Patricia Mcnamara
Laura Bartko
Maruquel Donaire
Yong Lu
Manal H Katims
Monica Ravi Tejwani
Uma Balasubramanian
Feng Lin
Indu Mitra Bhargava
Karen Debra Kostyk
Matthew John Fenelius
Maribel Salas
Doreen Ciolek
John David Allard
Zhi Ling
Jennifer L Martin
Albert Edward Fliss
Khalid Saeed Mirza
Shaun Su
Amy Qin

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Alison Brooke Serwedes
Preena Patel Balani
Choon-Soo Rim
James J Graziano
Maryam Ali-Grimaldi
Puja I Shah
Paul Ricigliano
Caitlin Barnabo
Pamela Downs
Deana Abadir
Lucja Lai
Ellen G. Borak
Jacqueline M Coulthrust
Neel Parikh
Christian Blin
Ms. Jamie Lewis
Sangeet Khullar
Tushar Garimella
Jamie Grauso
Chirag Navinchandra Jani
Zhenming Shun
Lori Isabel Aynat-Mastalia
Laura Carr
Lisa M Blair
Ben Hakhyun Kim
Minseok Lee
Christine Fassano
Tanya Marie Alvino
Katie Anne Raustad
Usha Kidambi
Kristen M Sarlo
Lisa Chwieroth
Gissoo DeCotiis
Dalila Sellami
Brandon Joel Fox
Gladys Jalbuena
Yensy Schurig
Yojana Gupte
Liju Varughese
Gina Marie Brogan
Jyoti P Patel
Raymond Dale Bedeaux
Deborah E Stapleton
Meng Pan
Amita Chaudhari
Krystyna V Govgalenko-Litton
Peter M Price
Penny Elizabeth Phillips
Ryo Arakane
Jaya Krishna Sirigineedi
Anila Ndreu
Debanjan Paul
Brianna Treacy

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Amanda J Love
Debra A Hyde
Yuhu Yan
Jillian M Cathcart
Sarita Muttreja
Najd David Maksad
Alan Joseph Mart
Linda Tamburello
Colleen Elizabeth Carter
Mary M Isgro
Karen Sue Weaver
Anne M Drelles
Mitchell Crawford LeSueur
Harini Kunduru
Sunny Kumar
Tomasz Szczudlo
Amit Khatri
Robin Rolser
Shabber Agha Abbas
Serhan Gokmen
Yasong Lu
Sunilkumar Sourapu
Minimol Mathew
Thomas Jude Turner
Shirin Khambata Ford
John Richard Czapor
Lihui Zhao
Zhenhao Qi
Nicola G Romano
Temeka Scoon
Chirag Bharat Desai
Kei Kubota
Tetsuo Matsui
Ryota Shiga
Christine Muse
John E Ruggiero
Kimberley Gertsen
Mrs. Wanda Szott
Diego Bolanos
Andrew Steinberg
Amanda Tawfik
Daphne Aime
Kaley Rose Lugo
Bincy K Augustine
Ms. Bei Xie
Stephen R. Esker
Rina Matsushima
Nila Das
Gopika Unnikrishnan
Scott P Macaulay
Jonathan Yuen
Chanderbhan Vasandani
Richard Paul Smith

Suzanne Renee Volkert
Abraham Joseph Tak
Margaret Wooddell
Mary Beth Wilusz
Mackenzie Catherine Henderson
Francisco Llopis
Shari J Catalano
Sam T John
Maria Angela Rubinacci
Erinne Catherine Wasalski
Alvileen W Diggs
Rolando Atienza
Vidhya Ramani
Pranav J Patel
Sofia M. Litos
Brandon Kent
Pomy Shrestha
ANUDEEP DEVABATHINA
Edyta Czaplicki
Yuji Okihori
Eduardo Mascari Tozzi
Chan Sok Nam
Kaevon Stewart
Estrellita Silvestre Acampado
Jennifer Dawn Leclaire
Parul Patel
Simon Andrew King
Giselle Cortez
Poul Christian Nielsen
Lee Anne McLean
Corina Candiani Taitt
Joshua Ronald Boyd
Jennifer Christine Samp
Rosa Wang
Zheng Lu
Michele Sue-Ann Woo
Daniel Edwin Weihmiller
Stephanie M Ressell
Daniel Lee
Joseph Morris Van Kirk
Sudarshan Phani
Wen Gu
Toshiyuki Sato
Raymond Favata
Aruna Kumari Mallavalli
Yira Bermudez
Yingkai Cheng
Joe Hernand Ronquillo Chichioco
Walter John Wienckowski
Bernadette Baron
Charles F Kearns II
Molly Yeager Romano
Min Xu

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Yali Liu
Cathleen Begley
Keshia Renee Johnson
Patrik Vitazka
Amy Tulli Schinagl
Lauren Michelle Greene
Naveeda Fatima
Yoshinori Kawaguchi
Kunihiko Sueishi
Heather Lee Kotzen
Sandhya Mehta
Luis Chia
Edgar Morales Felix
Justin Edge
Li-An Xu
Maurizio Anthony DiPuma
Karen D. Borick
Charmi Amin
Ying Hong
Petya Georgieva Krasteva
Ms. Irina Brekhman
Jim M. Chan
Xiaozhong Qian
Mark Paris
Maha Karnoub
Michele Anne Schmidt
Li Liu
Christine Sofia Lande
William Bayona
Jacqueline Rebbel
Ronald Alan Fleming
Heather Leigh Smith
Lauren Elizabeth Fields
Ana Escudero
Margaret Chan
David Rusnak
Meera Gopal Sundararajan
Brenton DeWayne Burnett
Fiona Jane Jeitner
Lori Ann Jukofsky
Edward Vazquez
Pamela Johnson
Keiko Nakajima
Ghassan Al-Mamlouk
Brian Charles Kessler
Balazs Flink
Ming Zheng
Harvey Damien Kahlil Hirsch
Feng Chen
Min Zhou
Vimala Sudhakar
Michela Sazhin
Dante Joers Pestano

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Chanchal G Patel
Marc Frederick DeCristofaro
Hayes Lewis Williams
Joanna Elzbieta Soban
Casene Alecia Fletcher
David W Sternberg
Diane Hooper
Melissa Maas Alvarez
Liren Huang
Udoka Emenuga
Srinidhi Busarajan
Jennifer Rose Foley
Nancy Nader Milik
Bethyl L. Thomas
Thomas Mollica
Jean Audra Rahoi
Itaru Endo
Sota Fukui
Chinami Kanayama
Kazuishi Kubota
Yusuke Myobatake
Kaku Saito
Jun Tanaka
Yoshiko Kaguragi
Kei Kiuchi
Katsuyoshi Chiba
Ko Watanabe
Kristine Ann Granger
Mr. Tarun Katipalli
Ms. Neha Pannuri
Meng Qian
Elton George Mathias
Neil R. Albuja
Dhiraj Devidas Gambhire
Matthew James Stoudemayer
Terry L Katz
Yan Yao
Dario D'Attilio
Mary Isabel Liberis Chazoule
Rachel Kim
Elizabeth Quiroga
Laura Morcos
Janice Burke
Keith Mills Demmerle
April L Larsen
Ekaterine Alexandris
Harry Hugh Suiter
John Walter Calindas
Desmon R Swanston
Amy Marie Miller
Payal Arora
Michael J. Orsini
Grace Eunhye Kwon

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Thomas Malieckal
Michael Thomas Lambariello
Chandrabhan Dharmani
Jaime Elizabeth Connolly Rohrbach
Rutu Shah
Yi Yang Lau
Gina Stampone Terrana
Abdur Rahim Soherwardy
Shalem Lakkepogu
Shiming Tang
Antoinette Jean McGowan
Kameel Tahir Khan
Julie Gregory
Donna Bilanych
Christopher Andrew Defedele
Gizella Gay Kronstat
Chiragkumar Kapatel
Joseph Cheng
Glenn Sokaloski
Dr. Eric Wang
Marina Mathew
Kelly Rose Gibbs
Gerold Hans-Gerd Meinhardt
Priyanka Basak
Matthew Ryan Coppola
Cindy Li
Jonathan Paul Valenzano
Cristina Monic Rodriguez-Paz
Jill Desai
Olivia Andreczski
Jennifer A Voorhees
Ronald Elamparo
April Marie Adiletta
Esther Olufisayo Adeyinka
Arya Ann Mathew
Kelly Ann Hoagland
Abderrahmane Laadem
Manuel Espinosa
Sara Ann Kimball
Fuad Omar Juma
Joy Nnenna Nkenke
Pang-Dian Fan
Adam M Petrich
Elke Stein
Aleksandar Francki
Yong Zhang
Ms. Amy Beth Kornicke
Qian Dong
Mr. Philippe Lourenco
Meredith Ann Muller
Jesus Morales
Noel Herrera Leal
Sudhir Krishnan Unni

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Ai Inoue
Yong Lin
Bethany Joy Sardinha
Jin Jin
Jacob Steven Martin
Thomas Martin Jacobsen
Kristy Tran Burns
Rosario Garrido
Ketty Belizaire
Naoto Yoshizuka
Avagail A. Morgan
Prasanti Repaka
Lisa Kosakowski Wasley
Noha Biserna
Mary Louann Szekeres
Nataliya Bazhina
Benjamin Kadransky Bender
Alexander Elias Tanasy
Felipe Kellermann Hurtado
Antonio Bengiamin Meo
Melissa Jean Puno
Lara E Phillips
Nicole McGuire
Donald Robert Murphy
Christina Swierczek
Elizabeth Briganta Bean
Anjum Malkana
Robert Norman McLeod
Sharon Leigh Allen
Tiffany Kawai
Thang B Trieu
Madan Gopal Kundu
Pia Guinto Lopresti
Portia Brown
Kevin Szczypiorski
Mr. Aaditya Peri
Lan Lan
Mary Elizabeth Palmer
Melissa Maxine Benedict
Chenchao Gao
Susie Jannette Flores
Adrianne Ling-Chuan Wong
Sreeja Sarojini Nair
Rupal Bhagat
Damien Forde
Suqin Yao
Shuang Liang
Lauren Mutz
Meghan Imperatore
Niyo Kato
Akira Moh
Dorothy Chisum Saewert
Marvi I Mizrahi

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Julie Dajung Kim
Winnee Lee
Danny Chul Kim
Yi Jia
Nicolle Dzuba
Alexandra Grace Vasile
Eduardo Jose Sera
Divyesh M Chauhan
Lotus Yung
Qurish Khan Mohemmad
Tayyeb Din
Chetna Arvind Hirpara
Padma Chandran Iyer
Rajinder Kaur Sidhu
Daniel James DiSanto
Tarek A Abouel-Leil
Danielle Ann McLaughlin
Elizabeth Feuerbach
Heena Chetan Patel
Fu-Chih Cheng
Catherine Ann Walter
Everest Ifeanyi Nwakamma
Craig Steven Leonardi
Alix Kate Poeton
Kaline Medeiros Costa Pereira
LaQuana Bizzell
Fay Marie Dunbar
Keiichi Harada
Shinichi Inoue
Nanae Izumi
Reina Kaneko
Kazuaki Kanno
Yui Tanaka
Rie Yonemochi
John Gerard Harkins
Michele Ann Sharr-McMahon
Ms. Rochelle L Fountain
Changan Chu
Yoshimi Tanaka
Joseph M Rosamilia
Siddhartha Rawat
Andrew L Felicio
Jessica Ricciardi
Ellen Tillman
Shaista Hasan
Madhura M Gurjar
Anu Santhanagopal
Andrew Charles Stewart
Timothy Davis
Pradeep Kumar Vuppala
Jane Tanlamai
Brian Wildermuth
Kenichi Takeshita

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Carla Rose Lewandowski
Xin Jin
Jean Anne Dunlea
Anupama Mitta
Margaret Baker
Fiona W Lau-Phua
Hardik S Patel
Katie Lee
Kristin Ashley Morgan
Frank Zixing Fang
Ravikumar Agrawal
Leanne Marie Huang
Vicki Lynn Yosh
Yoany Lozanguiez
Naoto Ii
Mika Ikeda
Yoshifumi Kawashima
Ryo Nakamura
Satoshi Nakashima
Taishi Yoshida
Hayato Sakaki
Fumitaka Suto
Naoko Ikeda
Kiyoshi Arai
Chiharu Funaki
Katsunobu Hagihara
Kosuke Itagaki
Aya Kuno
Ryo Muto
Koji Sato
Yeon Hoo Seong
Pavan Kumar Vaddady
Jason Devenezia
Jessica Gargiulo
Gunasekaran Singaravelu
Denise P. Milot
Ken Murata
Kiichiro Yano
Masakatsu Suzuki
Eika Takahashi
Ms. Jan Lindsay Hedden
Mrs. Amy Rose
Jenishkumar Patel
Christopher Angeles Poon
Linda Chong
Mona Patel
Blair Bak
Norman Sung
Talora C. Stewart-Mickens
Krystal Louise Saintil
Theresa Mary Creedon
Ang Liu
Natsuko Kitamura

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Takahiro Kamio
Caroline A. Harris
Sophie Soseul Kim
Ravindra C Patni
Salvatore Marino
Dipali Patel
Purnima Verma Singh
Mohammad Farooq
Hyewon Youm
Divi Alagappan
Daisy Lin
Yougan Cheng
Takaya Moriyama
Amninder K. Malik
Yan Xiong
Joseph A Mostillo
Mike Ran Zou
Mrs. Wendy Turell
Osarumen Urhoghide
Carolyn Federici
Preeti Chouksey
Karen Marie Scheetz
Gina S Mckendry
Timothy Koch
Jenilee C. Cueto
Lauren Kathryn Persad
Girma M Ayele
Sae Hyung Lee
Lucia Dzuba
Amanda Lynn Hall
Ruth Elizabeth Abrams
Joseph E. Burke
Teresa Akersten
Stacey A. Brady
Julianne Birsner
Cindy S. Lau
Li Li
Minal Caliskan Baker
Dong Dai
Junmin Shi
Christopher Sharry
Dechamma P Madappa
Cuixia Zhang
Khaja Waheeduddin Syed
Anandika Dhaliwal
Rabob Abdou
Michael Brett Flaschen
Hazel A Cruz Henriquez
Fang Mao
Ikenna Anyanwu
Nathan E. Sciortino
Miaoyan Zhang
Zachary Cain

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Julie Fraunhoffer
Lynn Ann O'Connell
Sheryl Barrett
Hiroyuki OKADA
Kashif Dastagir Butts
Dario Garcia-Carracedo
Susan Lee
Danielle J Banks
Xiaofang Li
Can Pham
Umang Jitendrabhai Trivedi
Deep Patel
Karen Arena
Xiaohui Xu
Yue Shentu
Ruoyang Zhang
Madhavi S. Patel
Dr. Xiaodong Li
Jaclyn Douglas
Dr. Abhinav Kurumaddali
Alisa Lyons Bradley
Bryan Cardona
Philip He
Shunxiang Ren
Gregory Anagnostos
Dr. Serom Lee
Jennifer Bretz
Irina Ramachandran
NEZIMA ALLIE
Ana Ines Wong
Amit Aggarwal
Shannon E. Todd
Sharon M. Porubsky
Michael Adjei
Ms. Danielle Rosen
Sashikala Nadanaciva
Ms. Rosina Talarico
Ms. Diane Lescota
Ting Cai
Mr. Eric L. Moore
Robin Edwards
Jeremy K. Letchford
Wenzui Jin
Ryan Chung
Catherine Marie Brown
Mr. Sean F. Sullivan
Carlie Flynn
Dr. Nilma Rupani
Dr. Enoch Cobbina
Cynthia J Kolodzinski
Rajendra Hemant Kale
Mrs. Alexandra Borchard
Mr. Mark Paul Laskowski

GUPSA B BASHCOUR
Dr. Robert A Lersch
Wenzhe Liu
Ms. Larissa Rosenberg
Patricia A Ferris
Srividya Desiraju
Shannon Leigh Higgins-Gruber
Anna Felisiak-Golabek
Y-Lan Nguyen
Heather McAuley Marrison
Daichi Baba
TAKUYA MURAYAMA
Dr. Narasimha Midde
Tatsunari KURATA
TOSHIYUKI NAKAHASHI
Hsiang-En (Sharon) Chang （ChangHsiang-En (Sharon)）
Masashi Sato
Dan Saotome
Yukihiko Wakimoto
Hanami Kamikawa
Yui Serizawa(Kawasaki)
EMIKO MATSUURA
Mr. Steve D. Kim
Mariko Kanno
Mr. Danqing Yu
Xiang Cao
Dr. Holly Karen Hilton
Dr. Erika Y Chung
Chihiro Wakahara
Sayoko Miyagawa
Akiyo Oshima
Ruchitbhai Mukesh Shah
Dr. Richard Wayne Joseph Jr.
Dalal Nesheiwat
Mr. Bryan Barnes
Dr. Geoffrey S Johnson
Tracy Lehman
Peng Wang
Stephanie Sharkey
Tomoko Shibata
Mr. Sachin Aggarwal
Michelle Rassavong
Mr. Sean B. O'Neill
Dr. Talia Muram
Yusuke Kuwahara
Hitoshi Miyashita
Shinji Tsutsumi
Dr. Suyuan Zhang
Samir Patel
Ms. Janvi D. Lagdiwala
Lara E. Warner
Mr. Nilay Patel
Mrs. Elizabeth Bruno

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Ashley Yvette Lawson
Kun Xu
Mengjun Cao
Vinit Kumar
Mr. Yannick Berman
Xuya Wang
Ms. Hao Zheng
Cassondra Paige Nice
Kala Lakshminarayanan
Michael Heesters
Mr. Sai Ronith Reddy Bongunoori
Mr. Parth Madane
Amit Mahadevia
Carrie Chuck
Zhengkang Liang
Dr. Savitha Gounder
Edward ODonnell
Dr. Alexandria P Cogdill
Kshitiz Shekhawat
Mary-Margaret Antalics
Mrs. Tao Duan
Tsuyoshi Hirata
Shiho Shiina
Yasuo Fukushima
Marie Hisamoto
Dr. MOHINI RAJASAGI
Chloe Stern
Matthew Oppenheim
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Ms. Michele Gallo
Ms. Nicole Rose
Ms. Lynn Williams
Mr. Peter Saraiya Bennett
Marc Carrier
Dr. Esther Pang
Ms. Linda Francis
Bhumika Katudia
Waley Chen
Yuichi Ochiai
Ms. Felicia Yvette Ford-Rice
Mr. Michael Gerard Donnelly Jr.
Sajid Ahmed
Mr. Sampath Billakanti
Mr. Kyle Alexander Calder
Dr. Deise Uema
Mr. Charan Sundar Telaganeni
Dr. Sivadasan Krishnan
Samantha H. Johnson
Delshonda Boswell
Jia Peng
Mr. Andrew Genecki
Ana Paun
Andrea Ringen

Satoshi Nishioka
Mrs. Nandini Chakraborty
Feng Xiao
Aiying Chen
Dr. Yang Chen
Russell Segreto
Brandon Cunningham
Delia Banu
Sandra Velez
Xiaoyang Ma
Yingdong Lu
Sheryl Lynn Beauchamp
Pei Ren
Mrs. Bhumika Pant
Takayuki ISHIDA
Eriko Kioi
Kenichi Sakakura
Wataru Tomisato
Taketoshi Ogawa
Ms. Jennifer L. Nast
Angela Ghattas
Mr. Richard C. Park
Kimberly Vogel
Francesca Cafaro
Dr. Anthony Murphy
Min Kang
Mr. Robert R. Mellinkoff
Akimitsu IWAMA
Yutaro Maekawa
Dr. Nicholas J. Huby
Dr. John Juheon Lee
Matthew Mignone
Ms. EWELINA Anna JAWOR
Molly Gondolf
TAYRN HECHT
Dr. Chuntao Wu
Dr. Charu Indoria
Sophia L. Nittoli
Kendall Sullivan
Helena Cascella
Amruta Ashtekar
Ms. Claire H Li
Qiaofu Sun
Mr. Kevin Dec
Kyoichi Ebata
Satoshi Muneoka
Dr. Quan Lin
Mrs. Amanda M. Hudson
Takahiko Seki
Karine Truchon
Sonia Luther
Shovan Saha
Mrs. Krista Sauls

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Mr. Jonathan-Joy Gohil-Weiner
MARK RUTSTEIN
Lauren Szuter
Mr. Greg Raphel Jr.
Valerie Hall
Ms. Jinali Patel Dhebariya
Jennifer Karolina Pina
Jessica Steinhart
Mr. Venkat Jagan Mohan Thodima
Ms. Daria R. Blanco
Joyce Abdelmeseh
Mrs. Melissa Barnacz
Mrs. Stefanie Anne Schoff
Jennifer C. Lin
Dr. Joseph Dudash Jr.
Dr. Graham David Clinthorne
Mr. Jeffrey Paul Stein Jr.
Mrs. Jennifer Bartley
Connor John McNamara
Deborah Modlin
Ms. Renee Lee
Alicia Palomino Mosquera
Dr. Christina Michele Bender
Mr. Pyae Tun
Ms. Maha Kandis
Mr. Ankit Goyal
Julie Jeanes
Dr. Inez Ruiz-White
Erin Kay Young
Yenlik Zheteyeva
Mrs. Allison Lane Hupka
Dr. Rachel Anna Chiaverelli
Ms. Karen A Psaryanos
Theodora Bonelli
Dr. Nadia Cervoni
Xiaopeng Cai
Yuya Watanabe
Kazuki Yokoi
Staci Heise
Sandra B. Gonzalez
Ms. Aislyn Dara Wist Boran
Dr. Akash Lavani
Justine Nessim
Joseph Coculo
Sue Yueh
Mrs. Noelia A. Plaza
Srikanth Sharma Thota
Leia Stephenson
Mei Tang
Liliya Wohltman
Mr. Christopher Swatt
Dr. Justin Nguyen
Mrs. Renu Nambiar

Daiichi Sankyo, Inc. - List of Employees (2/6/2023)

Ms. JANELLE S. COLON
Michael Hannon
Dr. Eddie Hom
Mr. Lance Wilson
Sonali Trivedi
Tatiane Cristine Ishida
Mr. Ian Myre
Ms. Sarena M Enriquez
Dr. Lia Kostiuk
Adrienne G. Natrillo
Ricardo de Freitas Zwirtes
Jeremy O'Hanlon
Mrs. Dana Cedeno
Yutaka Noguchi
Yoshihiro Emura
Atsushi Tsukamoto

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Daiichi Sankyo, Inc.

Physical Address 211 Mount Airy Road

City Basking Ridge State NJ Zip 07920

Mailing Address (if different from physical address) (Same)

City _____ State _____ Zip _____

Telephone 908-992-6634 Website https://daiichisankyo.us/

Licensing Company Email Statelicensing@dsi.com

Section 2: Personal Information

First Richard Middle Alan Last Muskus

Alias(es, nicknames, name changes, etc.) Rich Muskus

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Lake Ave

City Scotch Plains State NJ Zip 07076

Telephone 908-992-6634 Email Statelicensing@dsi.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials _____

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
ARTHUR L. JOHNSON			09/72 - 06/76
Address	**City**	**State**	**Zip**
365 WESTFIELD AVE	CLARK	NJ	07066
Diploma/Degree obtained, If any			
HS DIPLOMA			
School Name			**From - To (MM/YY – MM/YY)**
Northeastern University			01/80-09/83
Address	**City**	**State**	**Zip**
Boston, MA			
Diploma/Degree obtained, If any			
BS, Business Administration, Concentration Accounting			
School Name			**From - To (MM/YY – MM/YY)**
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			
School Name			**From - To (MM/YY – MM/YY)**
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			
School Name			**From - To (MM/YY – MM/YY**
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/99-CURRENT	[redacted] Lake Ave	Scotch Plains	NJ	07076
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Daiichi Sankyo, Inc.			2004 - Present
Business Address	**City**	**State**	**Zip**
211 Mount Airy Road	Basking Ridge	NJ	07920
Phone	**Title**	**Number of Employed Hours**	
862-344-0516	Associate Director Distribution & Customer Operations	40+ hours / week	
Description of Duties			
Distribution operations for DSI branded products, oversee operations at 3PL			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
		40+ hours / week	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
		40+ hours / week	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
		40+ hours / week	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Applicant's initials _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials

I, Richard A. Muskus, **certify that as the designated representative for**

Daiichi Sankyo, Inc.,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Richard A. Muskus
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/31/2023
Date

Applicant's initials

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard A. Muskus
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/31/2023
Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Somerset

I, Richard A. Muskus, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/31/2023
Date

Subscribed and Sworn to before me this 31st day of January, 2023

Notary Public Signature

THEODORA M. BONELLI
NOTARY PUBLIC OF NEW JERSEY
Comm. # 2202992
My Commission Expires 6/20/2023

(Seal)

Applicant's initials

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107759684

Application/License No. _____

Daiichi Sankyo, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 211 Mt. Airy Road, Basking Ridge, NJ 07920 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1 Tower Sq 2MS Hartford, CT, 06183-0001 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 18th, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of January, 20 23.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

Daiichi Sankyo, Inc.

SURETY

Surety Company's Representative
Travelers Casualty and Surety Company of America

Thomas M. Niland, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

ACKNOWLEDGEMENT OF CONTRACTOR, IF A CORPORATION

STATE OF NEW JERSEY
COUNTY OF SOMERSET

ON THE 31ST DAY OF JANUARY **2023** BEFORE ME PERSONALLY CAME MILA TARTAKOVSKY
TO ME KNOWN, WHO BEING BY ME DULY SWORN, DID DEPOSE AND SAY THAT (S)HE RESIDES AT SEA BRIGHT, NEW JERSEY
THAT (S)HE IS THE V.P. FINANCE AND TREASURER
OF **DAIICHI SANKYO, INC.** A CORPORATION DESCRIBED IN AND WHICH EXECUTED THE ABOVE INSTRUMENT; AND THAT (S)HE SIGNED HIS/HER NAME THERETO BY ORDER OF THE BOARD OF DIRECTORS OF SAID CORPORATION

Notary Public

THEODORA M. BONELLI
NOTARY PUBLIC OF NEW JERSEY
Comm. # 2202992
My Commission Expires 8/20/2023

ACKNOWLEDGEMENT OF SURETY

STATE OF **NEW JERSEY**
COUNTY OF **BERGEN**

ON THE **18TH DAY** OF **JANUARY 2023**, BEFORE ME PERSONALLY CAME **THOMAS M. NILAND** TO ME KNOWN, WHO, BEING BY ME DULY SWORN, DID DEPOSE AND SAY THAT (S)HE RESIDES AT **LIDO BEACH, NY** THAT (S)HE IS THE ATTORNEY IN FACT OF **TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA** THE CORPORATION DESCRIBED IN AND WHICH EXECUTED THE ABOVE INSTRUMENT; THAT (S)HE KNOWS THE SEAL OF SAID CORPORATION; THAT ONE OF THE SEALS AFFIXED TO THE FOREGOING INSTRUMENT IS SUCH SEAL; THAT IT WAS SO AFFIXED BY ORDER OF THE BOARD OF DIRECTORS OF SAID CORPORATION; AND THAT (S)HE SIGNED HIS/HER NAME THERETO BY LIKE ORDER

Notary Public

Anne Milnes
A Notary Public of New Jersey
My Commission Expires February 18, 2027

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint Thomas M Niland of Melville New York , their true and lawful Attorney-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this 3rd day of February, 2017.

State of Connecticut

City of Hartford ss.

By: Robert L. Raney, Senior Vice President

On this the 3rd day of February, 2017, before me personally appeared Robert L. Raney, who acknowledged himself to be the Senior Vice President of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

In Witness Whereof, I hereunto set my hand and official seal.

My Commission expires the 30th day of June, 2021

Marie C. Tetreault, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, Kevin E. Hughes, the undersigned, Assistant Secretary of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 18th day of January, 2023

Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney-in-Fact and the details of the bond to which the power is attached.

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

HARTFORD, CONNECTICUT 06183

FINANCIAL STATEMENT AS OF DECEMBER 31, 2021

AS FILED IN THE STATE OF NEW YORK

CAPITAL STOCK $ 6,460,000

ASSETS		LIABILITIES & SURPLUS	
BONDS	$ 4,427,068,873	LOSSES	$ 1,224,258,147
STOCKS	90,892,083	LOSS ADJUSTMENT EXPENSES	157,266,812
CASH AND INVESTED CASH	3,976,380	COMMISSIONS	49,977,844
OTHER INVESTED ASSETS	4,609,133	OTHER EXPENSES	46,607,590
SECURITIES LENDING REINVESTED COLLATERAL ASSETS	7,433,066	TAXES, LICENSES AND FEES	16,655,025
INVESTMENT INCOME DUE AND ACCRUED	37,877,324	CURRENT FEDERAL AND FOREIGN INCOME TAXES	1,972,277
PREMIUM BALANCES	294,061,729	UNEARNED PREMIUMS	1,212,347,629
REINSURANCE RECOVERABLE	70,677,646	ADVANCE PREMIUM	1,824,313
NET DEFERRED TAX ASSET	60,158,960	POLICYHOLDER DIVIDENDS	14,256,052
OTHER ASSETS	3,266,703	CEDED REINSURANCE NET PREMIUMS PAYABLE	47,473,619
		AMOUNTS WITHHELD / RETAINED BY COMPANY FOR OTHERS	42,097,036
		REMITTANCES AND ITEMS NOT ALLOCATED	10,579,448
		PROVISION FOR REINSURANCE	6,873,132
		PAYABLE TO PARENT, SUBSIDIARIES AND AFFILIATES	40,373,235
		PAYABLE FOR SECURITIES LENDING	7,433,066
		ESCHEAT LIABILITY	537,132
		RETROACTIVE REINSURANCE RESERVE ASSUMED	616,092
		OTHER ACCRUED EXPENSES AND LIABILITIES	250,005
		TOTAL LIABILITIES	$ 2,861,596,277
		CAPITAL STOCK	$ 6,460,000
		PAID IN SURPLUS	433,803,760
		OTHER SURPLUS	1,678,177,878
		TOTAL SURPLUS TO POLICYHOLDERS	$ 2,118,461,638
TOTAL ASSETS	$ 5,000,059,915	TOTAL LIABILITIES & SURPLUS	$ 5,000,059,915

STATE OF CONNECTICUT)

COUNTY OF HARTFORD) SS

CITY OF HARTFORD)

MICHAEL J. DOODY, BEING DULY SWORN, SAYS THAT HE IS VICE PRESIDENT – FINANCE, OF TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA, AND THAT TO THE BEST OF HIS KNOWLEDGE AND BELIEF, THE FOREGOING IS A TRUE AND CORRECT STATEMENT OF THE FINANCIAL CONDITION OF SAID COMPANY AS OF THE 31ST DAY OF DECEMBER, 2021.

Michael J. Doody

VICE PRESIDENT – FINANCE

SUBSCRIBED AND SWORN TO BEFORE ME THIS
17TH DAY OF MARCH, 2022

SUSAN M. WEISSLEDER NOTARY PUBLIC CONNECTICUT

NOTARY PUBLIC

SUSAN M. WEISSLEDER
Notary Public
My Commission Expires November 30, 2022

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Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Daiichi Sankyo, Inc.
211 Mount Airy Road
Basking Ridge, NJ 07920 · USA
Phone +1 908 992 6400
www.dsi.com

CONFIDENTIAL

May 24, 2023

Via UPS Overnight Service
Maria Herrera, Licensing Specialist
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy., Suite 206
Reno, NV 89521

Re: Wholesaler Application-Daiichi Sankyo, Inc.

Dear Ms. Herrera:

We are writing in reply to your March 23, 2023 email requesting supporting documentation regarding Daiichi Sankyo, Inc.'s ("DSI") response to Question No. 3 of the Nevada State Board of Pharmacy Wholesaler Application, to which DSI responded in the affirmative with the following responses:

> "In January 2020, the Nevada Department of Health & Human Services (DHHS) imposed a penalty in the amount of $31,350 on Daiichi Sankyo, Inc. for its failure to timely submit certain information required by the Nevada Revised Statutes (NRS) 439B.600 through 439B.695 concerning transparency in the pricing of certain diabetes medications.
>
> In January 2015, DSI entered into a settlement agreement with various agencies of the United States government related to allegations that DSI submitted false claims to federal healthcare programs by inducing physicians to prescribe certain DSI products (Benicar, Benicar HCT, Azor, Tribenzor and Welchol) in the form of honoraria payments and meals related to certain speaker programs. The resolution resulted in DSI paying a settlement amount of $39 million in 2015 (to settle federal and state Medicaid matters, including Nevada) and entering into a Corporate Integrity Agreement with the Office of Inspector General for a period of five years. DSI was released from the Corporate Integrity Agreement in 2020, having fulfilled the obligations therein. (See U.S. ex rel. Fragoules v. Daiichi Sankyo, Inc., Civil Action No. 10-10420 (D. Mass.))."

Nevada DHHS matter

By way of brief background, at the time of the issue, NRS 439B.635-640 required manufacturers of prescription drugs that appeared on the 2019 list compiled by DHHS pursuant to NRS439B.630 to submit an annual report on or before April 1, 2019. The relevant list was comprised of diabetes medicines. DSI submitted its initial report to the Nevada Department of Health & Human Services (DHHS) on January 9, 2019. DSI missed filing the second report (due on April 1, 2019) despite having previously submitted the initial report. The missed filing was the result of a

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Daiichi-Sankyo

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misinterpretation by one of DSI's former in-house attorneys that the second report would be due in each subsequent calendar year. This misinterpretation was based on the impact to filing deadlines for the reports due to the delay in enforcement of the regulation agreed to by DHHS. The misinterpretation by DSI was inadvertent.

DSI was initially notified of the missing filing by a reporter for *The Nevada Independent* on Wednesday, August 21, 2019. There was no follow up by DHHS about the missing report and in fact, DHHS learned through DSI's contact. DSI contacted DHHS via telephone on Thursday, August 22, 2019, to identify the error and discuss how to remedy. During that call, DSI was informed to submit the report as soon as possible. DSI also submitted a summary email (with a link of the article from the reporter since DHHS had not been aware of the article being prepared) to DHHS that day. DSI filed the missing report on Monday, August 26, 2019 – five days after learning about the missing report for the first time. DHHS advised DSI was notified on August 26, 2019 about the missing report, but DSI had already on that date submitted the report based on its verbal communications with DHHS.

DSI received notice of the administrative penalty imposed on DSI by DHHS in the amount of $735,000 on October 4, 2019. There were subsequent communications between DSI and DHHS including DSI's request for an informal dispute resolution meeting. On January 3, 2020, DSI attended an informal dispute resolution meeting via teleconference with the Nevada Department of Health & Human Services (DHHS). Based upon information provided in support of DSI's position for the elimination of or significant reduction of the penalty that DHHS was seeking to impose on DSI, DSI received a response from DHHS that it had imposed a penalty in the amount of $31,350, which was an amount similar to the figure suggested by DSI to reflect the maximum penalty for the 5 days between the time DSI became aware of the omission and August 26, 2019. The penalty was timely paid. Thereafter, the DSI subject prescription drug was removed from Nevada's 2020 Essential Diabetes and Asthma Drug List, which meant that DSI was not required to file any further reports. The subject prescription drug has since been divested by DSI.

Please see the enclosed copies of the following documents regarding the Nevada DHHS matter:

1. September 30, 2019 Notice of Administrative Penalty from DHHS to DSI;
2. October 10, 2019 email from Albert McCormick, Esq. of DSI to DHHS requesting an informal dispute resolution meeting; and
3. October 23, 2019 email from DHHS to DSI scheduling the information dispute resolution meeting on January 3, 2020.

Corporate Integrity Agreement with the Office of Inspector General ("CIA")

In addition, please find the following documents regarding the settlement of federal and state Medicaid matters (including Nevada) and CIA with the Office of Inspector General of the United States Department of Health and Human Services ("OIG"):

1. January 7, 2015 CIA between the OIG and DSI;

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Daiichi-Sankyo

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2. January 8, 2015 Settlement Agreement among the OIG, the Defense Healthcare Agency, DSI and Relator (as defined therein);
3. January 9, 2015 Department of Justice Press Release titled "Daiichi Sankyo Inc. Agrees to Pay $39 Million to Settle Kickback Allegations Under the False Claims Act";
4. January 9, 2015 DSI Press Release titled "Daiichi Sankyo, Inc. Announced Civil Settlement";
5. March 5, 2015 State Settlement Agreement between the State of Nevada and DSI; and
6. September 18, 2020 letter from OIG to DSI titled "Re: Completion of Corporate Integrity Agreement Requirements."

If you have any questions, please contact Theodora Bonelli, Sr. Paralegal, at statelicensing@dsi.com. Thank you.

Very truly yours,

DocuSigned by:
Patricia A. Barbieri
4FC21C0B1B9C4B7...

Patricia A. Barbieri, Esq.
SVP, General Counsel and Secretary
Legal and Corporate Affairs

Enclosures

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Nevada DHHS Matter

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STEVE SISOLAK
Governor

RICHARD WHITLEY, MS
Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIRECTOR'S OFFICE
4126 Technology Way, Suite 100
Carson City, NV 89706
Telephone (775) 684-4000 • Fax (775) 684-4010
http://dhhs.nv.gov

September 30, 2019

CERTIFIED MAIL: 9171 9690 0935 0218 7060 12

Daiichi Sankyo, Inc.
211 Mt. Airy Road
Basking Ridge, NJ 07920-2311

NOTICE OF ADMINISTRATIVE PENALTY

YOU ARE HEREBY NOTIFIED that the Department of Health and Human Services (DHHS) is imposing upon your organization an administrative penalty of $735,000 for violation of Nevada Revised Statutes (NRS) 439B.635-640.

Statutory Authority

DHHS is imposing a penalty in accordance with NRS 439B.695(2), that states:

> If a manufacturer fails to provide to the Department the information required by NRS 439B.635, 439B.640 or 439B.660, a pharmacy benefit manager fails to provide to the Department the information required by NRS 439B.645, a nonprofit organization fails to post or provide to the Department, as applicable, the information required by NRS 439B.665 or a manufacturer, pharmacy benefit manager or nonprofit organization fails to post or provide, as applicable, such information on a timely basis, and the failure was not caused by excusable neglect, technical problems or other extenuating circumstances, the Department may impose against the manufacturer, pharmacy benefit manager or nonprofit organization, as applicable, an administrative penalty of not more than $5,000 for each day of such failure.

Facts Supporting the Administrative Penalty

As mandated by NRS 439B.635-640, manufacturers of prescription drugs that appear on the 2019 list compiled by DHHS pursuant to NRS 439B.630 were required to prepare and submit an annual report on or before April 1, 2019. By the required submission date, DHHS did not receive a report from your organization even though Daiichi Sankyo manufactured drugs that appeared on the beforementioned list. Additionally, DHHS verified that your company's essential diabetes drugs were purchased by Medicaid patients in Nevada in 2018. Your organization was notified on 8/26/2019 of noncompliance with pharmaceutical drug manufacturer reporting requirements outlined in Nevada Revised Statutes (NRS) 439B.635-640. Your organization responded to DHHS and submitted a completed report by 8/26/2019. The Department received documentation sent by your organization outlining

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your justification for late reporting. This information was useful for the state to preliminarily review your position, but an informal dispute resolution meeting will need to be scheduled as outlined below to further clarify your position. Your organization was out of compliance with the statutory requirements for 147 days.

Payment Instructions for Penalty

Payment is due to DHHS by October 24, 2019. Payment should be submitted to the following address and the check can be made out to "Department of Health and Human Services".

Department of Health and Human Services
Director's Office
4126 Technology Way, Suite 100
Carson City, NV 89706

If the penalty is not received by October 24, 2019, DHHS will refer the case to the State of Nevada Attorney General's Office to produce a court order to obtain the penalty.

Informal Dispute Resolution

If your organization would like to request an informal dispute resolution meeting, please submit a request to DHHS by email to drugtransparency@dhhs.nv.gov within 10 days of receipt of this notice. Within 10 days of receipt of your request, DHHS will notify you of the date of the meeting.

Any questions regarding this notice can be directed to drugtransparency@dhhs.nv.gov.

Sincerely,

Richard Whitley, MS
Director

Cc: Linda Anderson, Chief Deputy Attorney General
Scott Jones, Division of Public and Behavioral Health

From: McCormick, Albert
To: "drugtransparency@dhhs.nv.gov"
Subject: Nevada Notice of Administrative Penalty - Request for Informal Dispute Resolution
Date: Thursday, October 10, 2019 9:08:00 AM
Attachments: Scanned from a Xerox Multifunction Printer.pdf

Dear Mr. Whitley,
We received the attached Notice of Administrative Penalty on Thursday, October 3. The purpose of this email is to officially request an informal dispute resolution meeting. As mentioned in my August 22nd email to your department, we submitted our first report on January 1, 2019. After communicating with a reporter from *The Nevada Independent* on August 21st and reviewing our internal records, it became clear that we did not file the April 1, 2019 report; this was the result of a misinterpretation of the regulation due to the delay in enforcement of the regulation by your department. We submitted the second report on August 26th.
We attempted to contact you to address certain questions related to this request; however, we were advised to include those questions in this email. Our questions are as follows:

- We would like to provide additional facts and explanation to supplement our August 22nd email; would we be allowed to submit that prior to our informal meeting or would we have to submit at the meeting? If prior, may we have until October 23, 2019 to submit the supplement?
- Will the informal dispute resolution meeting be held in person or via teleconference?
- Will we be required to pay the penalty imposed prior to the deadline of October 24, 2019? If so, what happens if there is an elimination or (at a minimum) reduction in the amount currently assessed?
- Would additional penalties, administrative costs or fees be likely imposed given our request for an informal meeting whether or not there is an elimination or (at a minimum) reduction in the current penalty?

Sincerely,
Albert McCormick, Esq.
Associate General Counsel, Commercial & Corporate Business Functions
Legal Affairs Department
Daiichi Sankyo, Inc.
211 Mt. Airy Road
Basking Ridge, NJ 07920 • USA
Phone +908 992 6641
amccormick@dsi.com
www.dsi.com

This message is being sent by or on behalf of a lawyer. This message, together with any attachments contains information intended for the specific addressee(s) named above, and may be a privileged attorney-client communication or may contain other privileged, confidential or proprietary information that is protected from disclosure. Dissemination, distribution or copying of this message or the information herein to anyone other than the intended addressee(s) is strictly prohibited. If you have received this message in error, you are not to review, use, disseminate, distribute or copy this message, any attachments thereto, or their contents. Please immediately notify Daiichi Sankyo at the above telephone number and by return e-mail message, and delete and destroy the original message and all copies. Thank you for your cooperation.

From: DHHS DO Drug Transparency
To: McCormick, Albert
Cc: Tawny Chapman; Shannon Litz; Richard Whitley; DHHS DO Drug Transparency
Subject: Informal Dispute Resolution Meeting Date - Daiichi Sankyo, Inc
Date: Wednesday, October 23, 2019 10:51:09 AM
Attachments: image001.png

In response to Daiichi Sankyo's request for an informal dispute resolution meeting regarding the penalty letter submitted to your organization by the Nevada Department of Health and Human Services (DHHS), DHHS has schedule a meeting from 1:00PM to 2:00PM PST on 01/03/2020. The meeting will be held via teleconference using the following dial-in information:
(775) 687-0999
Access Code: 44008#
Enforcement of the collection of penalties will take place after the scheduled date of the informal dispute resolution meeting. Any materials that your organization wants the Department to review in advance of the meeting must be submitted to drugtransparency@dhhs.nv.gov at least 10 business days in advance of the meeting. Please direct any questions to drugtransparency@dhhs.nv.gov.

Drug Transparency - Nevada
Department of Health and Human Services
Division of Public and Behavioral Health
4150 Technology Way, Suite 300 | Carson City, NV 89706
(775) 684-4255 | drugtransparency@dhhs.nv.gov
www.dhhs.nv.gov | http://dhhs.nv.gov/HCPWD/DRUG_TRANSPARENCY/

NOTICE: This message and accompanying documents are covered by the electronic Communications Privacy Act, 18 U.S.C. §§ 2510-2521, may be covered by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and may contain confidential information or Protected Health Information intended for the specified individual(s) only. If you are not the intended recipient or an agent responsible for delivering it to the intended recipient, you are hereby notified that you have received this document in error and that any review, dissemination, copying, or the taking of any action based on the contents of this information is strictly prohibited. Violations may result in administrative, civil, or criminal penalties. If you have received this communication in error, please notify sender immediately by e-mail, and delete the message.

Corporate Integrity Agreement with the Office of Inspector General

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CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND DAIICHI SANKYO, INC.

I. PREAMBLE

Daiichi Sankyo, Inc. (Daiichi) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

Contemporaneously with this CIA, Daiichi is entering into a Settlement Agreement with the United States. Daiichi is also entering into settlement agreements with various states (State Settlement Agreements) and Daiichi's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA, Daiichi established a Compliance Program. Daiichi shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Daiichi may modify its Compliance Program as appropriate, but, at a minimum, Daiichi shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The compliance obligations assumed by Daiichi under this CIA shall commence on the Effective Date of this CIA and endure for five (5) Reporting Periods, as described in this paragraph. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. The first "Reporting Period" shall be the period beginning on the Effective Date of this CIA and ending on March 31, 2016. Each one-year period subsequent to the first Reporting Period, beginning with the one-year period commencing April 1, 2016, shall be referred to as a "Reporting Period."

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B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Daiichi's final Annual Report; or (2) any additional materials submitted by Daiichi pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all owners of Daiichi who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading) and all officers and directors of Daiichi;

b. all employees of Daiichi who are engaged in or who supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.6); and

c. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Daiichi, and in that capacity either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), or consumers; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Daiichi employee who is a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the Reporting Period.

2. "Relevant Covered Persons" includes all Covered Persons who engage in any of the Covered Functions and all individuals who supervise Covered Persons who engage in any of the Covered Functions.

3. "Government Reimbursed Products" refers to all Daiichi products that are: (a) marketed or sold by Daiichi in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

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4. The term "Promotional Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to Daiichi's review and approval processes for promotional materials and any applicable review committee(s).

5. The term "Product Related Functions" includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs, HCIs, and Payors, as defined below in Section II.C.10, about Government Reimbursed Products, including those functions relating to any applicable review committees and those functions relating to medical affairs services or involved in scientific exchange; (b) contracting with HCPs licensed in the United States or with HCIs to conduct post-marketing clinical trials, Investigator-Sponsored Studies (ISSs), and any other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as Drugdex or other CMS-recognized compendia of information about Government Reimbursed Products).

6. The term "Covered Functions" refers to "Promotional Functions," and/or "Product Related Functions," collectively.

7. The term "Third Party Educational Activity" shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by Daiichi, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

8. The term "Third Party Personnel" shall mean personnel who perform Promotional Functions or Product Related Functions who are employees of entities with which Daiichi has or may in the future (during the term of this CIA) enter into agreements to co-promote a Government Reimbursed Product in the United States or to engage in joint promotional activities in the United States relating to such a product. Daiichi has represented that: (a) Third Party Personnel are employed by entities other than Daiichi; (b) Daiichi does not control the Third Party Personnel; and (c) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Daiichi agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.6. Provided that Daiichi complies with the requirements of Sections III.B.2, V.A.7, and V.B.6, Daiichi

shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

9. (a) The term "Daiichi Affiliate(s)" shall mean any entity, other than Daiichi Sankyo, Inc., that is owned or controlled directly or indirectly, by Daiichi Sankyo Co., Ltd. and whose employees or contractors perform any Covered Functions. All obligations set forth in Section III below apply to the Covered Functions performed by the Daiichi Affiliate(s) and all references to "Daiichi" in the defined terms set forth in this Section II shall mean Daiichi and Daiichi Affiliate(s). In addition, the notice requirements in Section IV and the certification obligations set forth in Section V.C. below shall apply to both Daiichi and any Daiichi Affiliate(s).

(b) Notwithstanding the requirements of Section II.C.9(a) above, for a period of 120 days following the Effective Date, the obligations of this CIA applicable to Daiichi Affiliates shall not apply to Luitpold Pharmaceuticals, Inc. and its operating subsidiaries (Luitpold), based on Daiichi's representations that: (i) Luitpold is not controlled directly or indirectly by Daiichi; (ii) Luitpold operates pursuant to its own separate compliance program; and (iii) given the foregoing, it is impracticable to obtain Luitpold's compliance with the applicable Daiichi Affiliate CIA obligations on or before the Effective Date.

10. The term "Payors" shall mean entities that provide a drug health benefit program for Government Reimbursed Products, including but not limited to government payors (*e.g.*, Medicaid and Medicare) or individuals or entities under contract with or acting on behalf of government payors and commercial health plans.

III. CORPORATE INTEGRITY OBLIGATIONS

Daiichi shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Responsibilities of Certain Daiichi Employees and the Board of Directors.

1. *Compliance Officer.* Since prior to the Effective Date, Daiichi has had in place an individual to serve as its Chief Compliance Officer. Daiichi shall maintain a Compliance Officer for the term of the CIA who fulfills, at a minimum, the obligations set forth in this CIA. The Compliance Officer is and shall continue to be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Compliance Officer is and shall remain a

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member of senior management of Daiichi; reports and shall continue to report directly to the Executive Chairman and President of Daiichi; shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Daiichi; and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request. The Compliance Officer is not and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Daiichi. The Compliance Officer is and shall remain responsible for monitoring the day-to-day compliance activities engaged in by Daiichi as well as for any reporting obligations created under this CIA. Any job responsibilities of the Compliance Officer unrelated to compliance shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Daiichi shall report to OIG, in writing, any change in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Since prior to the Effective Date, Daiichi has had in place a Compliance Committee that assists the Compliance Officer in the implementation and enhancement of Daiichi's Compliance Program. Daiichi shall maintain the Compliance Committee during the term of this CIA, and at a minimum, the Compliance Committee shall meet the Compliance Committee obligations set forth in this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, medical affairs, regulatory affairs, research and development, human resources, audit, and finance). The Compliance Officer shall chair the Compliance Committee. The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Daiichi's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Daiichi shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

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3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of Daiichi (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board must include an independent (i.e., non-executive) member.

The Board shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee Daiichi's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee; and

b. for each Reporting Period of the CIA, adopting a resolution, signed by each individual member of the Board, summarizing its review and oversight of Daiichi's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors has made a reasonable inquiry into the operations of Daiichi's Compliance Program during the preceding twelve-month period including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Daiichi has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Daiichi.

Daiichi shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Accountability and Certifications*: In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Daiichi officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable

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Daiichi business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Executive Chairman and President of Daiichi; President, U.S. Commercial; Vice President Marketing and Access Strategy; Vice President Managed Markets and Key Account Management; Vice President Sales; Vice President Medical Affairs; Vice President Business Development and New Product Planning; Vice President Supply Chain and Technical Operations; Senior Vice President External Scientific Affairs; Executive Vice President Global Head of Development ; and, to the extent that a Daiichi business unit performs Covered Functions and is not covered by the certifications of one of the above-listed individuals, such other Daiichi executives, vice-presidents, or leaders of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit engaged in Covered Functions.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Daiichi policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of Daiichi is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Code of Conduct.* To the extent not already accomplished, and within 90 days after the Effective Date, Daiichi shall update, implement, and distribute a written Code of Conduct that meets the requirements of this paragraph III.B.1 to all Covered Persons. Daiichi shall make the performance of job responsibilities in a manner

consistent with the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct shall include, at a minimum, the following:

a. Daiichi's commitment to full compliance with all Federal health care program requirements and FDA requirements, including its commitment to comply with all requirements relating to the Covered Functions;

b. Daiichi's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements and FDA requirements, and with Daiichi's own Policies and Procedures;

c. Daiichi's requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Daiichi, suspected violations of any Federal health care program requirements, FDA requirements, or of Daiichi's own Policies and Procedures; and

d. the right of all individuals to use the Disclosure Program described in Section III.F, and Daiichi's commitment to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Daiichi's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Daiichi shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. Third Party Personnel. Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Daiichi shall send, electronically or in hard copy format, a letter to each entity employing Third Party Personnel. The letter shall outline Daiichi's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Daiichi's Compliance Program.

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Daiichi shall include with the letter a copy of its Code of Conduct and shall request the entity employing Third Party Personnel to either: (a) make a copy of Daiichi's Code of Conduct and a description of Daiichi's Compliance Program available to its Third Party Personnel; or (b) represent to Daiichi that it has and enforces a substantively comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* To the extent not already accomplished, and within 90 days after the Effective Date, Daiichi shall implement written policies and procedures regarding the operation of its Compliance Program, including the compliance program requirements outlined in this CIA and Daiichi's compliance with Federal health care program and FDA requirements (Policies and Procedures). At a minimum, the Policies and Procedures shall address the following:

a. the subjects relating to the Code of Conduct identified in Section III.B.1;

b. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;

c. appropriate ways to conduct Product Related Functions in compliance with: (i) all applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;

d. the materials and information that may be distributed by Daiichi sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Daiichi sales representatives respond to requests for information about unapproved uses of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives: (i) not engage (directly or indirectly) in improper promotion of Government Reimbursed Products (i.e., sales representatives shall not promote the products for usages, dosages, length of treatment, or patient populations other than those in, or consistent with, the FDA-approved label); (ii) use only materials that have been reviewed and

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approved by Daiichi; and (iii) refer all requests for information about unapproved uses of Government Reimbursed Products to Medical Affairs;

e. the materials and information that may be distributed by Medical Affairs and the mechanisms through, and manner in which, Medical Affairs receives and responds to requests for information from an HCP, HCI, or another individual or entity about unapproved uses of Government Reimbursed Products; the form and content of information disseminated by Daiichi in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Daiichi develop a database for use by Medical Affairs (Inquiries Database) to track all requests for information about Government Reimbursed Products made to Medical Affairs. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Government Reimbursed Products: (i) date of Inquiry; (ii) form of Inquiry (e.g., fax, phone, etc.); (iii) name of the requesting HCP, HCI, or other individual or entity; (iv) nature and topic of request (including exact language of the Inquiry if made in writing); (v) an evaluation of whether the Inquiry relates to information about an unapproved use for the product; (vi) nature/form of the response from Daiichi (including a record of the materials provided to the HCP, HCI, or other individual or entity in response to the request); and (vii) the name of the Daiichi representative who called on or interacted with the HCP, HCI, or other individual or entity, if known;

f. the manner and circumstances under which Medical Affairs personnel interact with or participate in meetings or events with HCPs, HCIs, or Payors (either alone or with Daiichi sales representatives) and the role of the Medical Affairs personnel at such meetings or events, as well as how they handle responses to requests for information about unapproved uses of Government Reimbursed Products. These Policies and Procedures shall require that Medical Affairs personnel not engage (directly or indirectly) in the promotion of Government Reimbursed Products for unapproved uses;

g. the materials and information that may be distributed or made available by Daiichi through social media and/or direct-to-consumer

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PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

advertising. These Policies and Procedures shall be designed to ensure that Daiichi's activities in this area and the information distributed or made available comply with all applicable Federal health care program and FDA requirements, and have been reviewed and approved by the applicable Daiichi personnel before they are posted or disseminated;

h. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other Daiichi representatives who promote and sell Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that Daiichi review the call plans for the product and the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Daiichi modify the call plans as necessary to ensure that Daiichi is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

i. the development, implementation, and review of all plans for the distribution of samples of, or coupons or vouchers for, Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons, or vouchers from Daiichi (including, separately, from sales representatives, from Medical Affairs, or through other channels). The Policies and Procedures shall also require that Daiichi modify the Sample Distribution Plans as necessary to ensure that Daiichi is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;

j. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, and any other

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PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;

k. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

l. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Daiichi's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;

m. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.7 above. These Policies and Procedures shall be designed to ensure that Daiichi's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: (1) Daiichi disclose its financial support of the Third Party Educational Activity and, to the extent feasible with Section III.B.3.m.5 below, disclose any financial relationships with faculty, speakers, or organizers at such Activity; (2) as a condition of funding, the third party agree to disclose Daiichi's financial support of the Third Party Educational Activity and any financial relationships that Daiichi might have with faculty, speakers, or organizers at such Activity; (3) as a condition of funding, the third party require faculty, speakers, or organizers at the Third Party Educational Activity to disclose any financial relationship with Daiichi; (4) the Third Party Educational Activity

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

have an educational focus; (5) the content, organization, and operation of the Third Party Educational Activity (including the faculty, educational methods, materials, and venue) be independent of Daiichi's control; (6) Daiichi support only Third Party Educational Activity that is non-promotional in tone/nature; and (7) Daiichi's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

n. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside Daiichi by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and/or medical concerns are properly addressed during Daiichi's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: (i) applicable review committees review all promotional materials prior to the distribution or use of such materials; (ii) the copy review and approval process ensure that FDA communications relevant to the product are considered and appropriately reflected in promotional materials and in a file or summary of information maintained for each product; and (iii) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

o. compensation (including through salaries, bonuses, or other means) for Relevant Covered Persons who are sales representatives and their field based managers. These Policies and Procedures shall: (i) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Daiichi's Government Reimbursed Products; and (ii) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate improper promotion of Government Reimbursed Products;

p. the submission of information about any Government Reimbursed Product to any CMS-recognized compendia such as

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PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any changes based on Daiichi's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results.) The Policies and Procedures shall include a requirement that Daiichi conduct: (i) a review at the time of submission of information to Compendia, to verify that the information submitted to the Compendia (including information about clinical studies and other research) is complete and accurate; (ii) an annual review of all Daiichi product listings and monographs within the Compendia designed to identify errors and ensure the information is complete and accurate; and (iii) an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by Daiichi to any Compendia. Daiichi's legal or compliance personnel shall be involved in this review; and

q. disciplinary policies and procedures for violations of Daiichi's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

Within 90 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Daiichi shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education.

1. *General Training*. Within 90 days after the Effective Date, Daiichi shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Daiichi's:

a. CIA requirements; and

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PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

b. Compliance Program (including the Code of Conduct).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training*. Within 120 days after the Effective Date, each Relevant Covered Person engaged in Promotional Functions and/or Product Related Functions shall receive at least four hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

a. applicable Federal health care program requirements relating to Promotional Functions and/or Product Related Functions;

b. applicable FDA requirements relating to Promotional Functions and/or Product Related Functions;

c. Daiichi Policies and Procedures and other requirements applicable to Promotional Functions and/or Product Related Functions;

d. the personal obligation of each individual involved in Promotional Functions and/or Product Related Functions to comply with applicable Federal health care program and FDA requirements and other applicable legal requirements;

e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and

f. examples of proper and improper practices related Promotional Functions and Product Related Functions.

New Relevant Covered Persons shall receive their Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

3. *Board Member Training.* Within 90 days after the Effective Date, Daiichi shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a board member or within 90 days after the Effective Date, whichever is later.

4. *Certification.* Each Covered Person who is required to complete training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain these certifications, along with all course materials.

5. *Qualifications of Trainer.* Persons responsible for providing training shall be knowledgeable about the subject area of the training, including about applicable Federal health care program and FDA requirements.

6. *Update of Training.* Daiichi shall review its training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any significant issues discovered during internal audits or the IRO Reviews, and any other relevant information.

7. *Computer-based Training.* Daiichi may provide the training required under this CIA through appropriate computer-based training approaches. If Daiichi chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Risk Assessment and Mitigation Process. Within 120 days after the Effective Date, Daiichi shall implement a standardized, centralized annual risk assessment and mitigation process (RAMP) as further described in this Section III.D and Appendix B. The RAMP shall require compliance, legal and business unit leaders, at least annually, to evaluate and identify risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products. Based on the outcomes of the risk-identification component of the RAMP, Daiichi legal, compliance and other personnel shall centrally develop and implement specific plans designed to mitigate or reduce the identified risks. The risk mitigation plans shall be developed annually and a plan shall be developed for each

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PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

Government Reimbursed Product. Daiichi shall implement the risk mitigation plans and shall track the implementation of the mitigation plans. The RAMP shall be reviewed by the IRO, and the IRO review of the process is described in more detail in Appendix B. Daiichi shall maintain the RAMP for the duration of the CIA.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Daiichi shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Daiichi in assessing and evaluating its Covered Functions and its RAMP. More specifically, the IRO(s) shall conduct reviews that assess Daiichi's systems, processes, policies, procedures, and practices relating to the Covered Functions and the RAMP (collectively, "IRO Reviews"). The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records.* The IRO and Daiichi shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Daiichi) related to the IRO Reviews.

2. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components: Systems Reviews and Transactions Reviews relating to the Covered Functions and the RAMP. The Systems Reviews shall assess Daiichi's systems, processes, policies, and procedures relating to the Covered Functions and the RAMP. If there are no material changes in Daiichi's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the second and fourth Reporting Periods. If Daiichi materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the second and fourth Reporting Periods, as set forth more fully in Appendix B.

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

The Transactions Reviews shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

In addition, as set forth in Appendix B, each Transactions Review shall also include a review of up to three additional areas or practices of Daiichi identified by the OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Daiichi and may consider internal audit and monitoring work conducted by Daiichi, the Government Reimbursed Product portfolio, the nature and scope of Daiichi's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, Daiichi may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Daiichi's internal audit and monitoring work to be substituted for any portion of the Additional Items review conducted by the IRO.

The OIG shall notify Daiichi of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Daiichi shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

3. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices A-B.

4. *Validation Review.* In the event OIG has reason to believe that: (a) any of Daiichi's IRO Reviews fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Daiichi shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Daiichi's final Annual Report shall be initiated no later than one year after Daiichi's final submission (as described in Section II) is received by OIG.

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

Prior to initiating a Validation Review, OIG shall notify Daiichi of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Daiichi may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. Daiichi agrees to provide any additional information as may be requested by OIG under this Section III.E.4 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with Daiichi prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Daiichi a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

F. Disclosure Program.

Prior to the Effective Date, Daiichi established and shall maintain a Disclosure Program throughout the term of the CIA that includes a mechanism (e.g., a toll free compliance telephone line and web-based reporting system) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Daiichi's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Daiichi publicizes and shall continue to appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasizes and shall continue to emphasize a nonretribution, nonretaliation policy and includes and shall continue to include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the

appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Daiichi shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

Daiichi maintains and shall continue to maintain a disclosure log which includes a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's System for Award Management (SAM) (available through the Internet at http://www.sam.gov).

2. *Screening Requirements.* Daiichi shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

a. Daiichi shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Daiichi shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and thereafter shall screen against theExclusion Lists on an annual basis .

c. Daiichi shall maintain a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section III.G affects Daiichi's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Daiichi understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Daiichi may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Daiichi meets the requirements of Section III.G.

3. *Removal Requirement.* If Daiichi has actual notice that a Covered Person has become an Ineligible Person, Daiichi shall remove such Covered Person from responsibility for, or involvement with, Daiichi's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by Federal health care programs at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Daiichi has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Daiichi shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Daiichi shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Daiichi conducted or brought by a

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

governmental entity or its agents involving an allegation that Daiichi has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Daiichi shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

I. Reportable Events.

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by Daiichi.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Daiichi determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Daiichi shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.I.1.a – III.I.1.c.* For Reportable Events under Sections III.I.1.a through III.I.1.c, the report to OIG shall include:

a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

b. a description of Daiichi's actions taken to correct the Reportable Event; and

c. any further steps Daiichi plans to take to address the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.I.1.d.* For Reportable Events under Section III.I.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

J. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between Daiichi and the FDA that materially discusses Daiichi's or a Covered Person's actual or potential unlawful or improper promotion of Daiichi's products, Daiichi shall provide a copy of the report, correspondence, or communication to the OIG. Daiichi shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed improper promotional matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

K. Sales Force Monitoring and Review Efforts.

Within 120 days after the Effective Date, Daiichi shall establish a comprehensive Sales Force Monitoring Program (SFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The SFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential improper promotional activities or other improper conduct. As described in more detail below, the SFMP shall include: (1) a Speaker Monitoring Program; (2) direct field observations (Observations) of sales personnel; and (3) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* With regard to speaker programs, Daiichi has implemented a process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of Daiichi approved materials and requirements that speakers may not directly or indirectly promote the product for unapproved uses.) Daiichi shall establish a centralized, electronic system(s) to initiate and track all speaker programs that includes

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

controls designed to ensure that speaker programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements. The controls shall also be designed to ensure that there is a legitimate need for the speaker programs.

Daiichi shall ensure that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by Daiichi (or a qualified third-party vendor on behalf of Daiichi). Daiichi shall maintain a comprehensive list of speaker program attendees through its centralized electronic system(s). In addition, Daiichi shall use its centralized electronic system(s) to handle all logistics and spending associated with speaker programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs. Daiichi shall require certifications by sales representatives or other Daiichi personnel that a speaker program complied with Daiichi requirements, or in the event of non-compliance, Daiichi shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

Daiichi shall institute a Speaker Monitoring Program under which Daiichi compliance or other appropriately trained personnel who are independent from the functional area being monitored (Monitoring Personnel) shall attend 75 speaker programs during each Reporting Period and conduct live audits of the programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected using a risk-based targeting approach or a random sampling approach. For each program reviewed, Monitoring Personnel shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Daiichi sales representative activities during the program to assess whether the programs were conducted in a manner consistent with Daiichi's Policies and Procedures. Daiichi shall maintain the controls around speaker programs as described above and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations*. As a component of the SFMP, Monitoring Personnel shall conduct observations of field sales representatives (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with Daiichi's Policies and Procedures. These observations shall be full day ride-alongs with field sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the Reporting Period, judgmentally selected by Monitoring Personnel, include a review of each therapeutic area and actively promoted product, and be conducted across the United States.

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

At the completion of each Observation, Monitoring Personnel shall prepare an Observation report which includes:

1) the identity of the sales representative;
2) the identity of the Monitoring Personnel who conducted the Observation;
3) the date and duration of the Observation;
4) the product(s) promoted during the Observation;
5) an overall assessment of compliance with Daiichi Policies and Procedures; and
6) the identification of any potential improper promotional activity or other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least 30 Observations during each Reporting Period.

3. *Records Reviews.* As a component of the SFMP, Daiichi shall also review various types of records to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. For each Reporting Period, Daiichi shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate region who promoted the products under review.

These Records Reviews shall include the monitoring and review of: (1) records and systems associated with field sales representatives' interactions with HCPs and HCIs (including records relating to speaker program activities, samples, travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers); (2) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of representatives interactions with HCPs and HCIs; (3) records relating to requests for medical information about or Inquiries relating to, the Government Reimbursed Products under review; (4) call notes, or if Daiichi does not require and/or utilize call notes, the information in Daiichi's sales force automation tool that captures information about sales representatives' interactions with HCPs and HCIs and related information; (5) field sales representatives' e-mails and other electronic records; and (6) recorded results of the Observations of field sales force representatives, coaching guides, if coaching guides are required and/or used, and applicable notes or information from the sales representatives' managers.

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

For each sales representative reviewed, Monitoring Personnel shall complete a Records Review report that includes:

1) the identity of the sales representative;
2) the identity(ies) of the the Monitoring Personnel who conducted the records review;
3) the time period covered by the records review;
4) the Government Reimbursed Product(s) promoted by the sales representative during the records review period;
5) an inventory of the records from the lists above reviewed during the records review for the sales representative and the reason that any records were not reviewed (if applicable);
6) an assessment of compliance with Daiichi Policies and Procedures; and
7) the identification of any potential improper promotional activity or other improper conduct by the field sales representative.

4. *Reporting and Follow-up.* Monitoring Personnel shall have access to all relevant records and information necessary to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. Results from the SFMP shall be compiled and reported to the Compliance Officer (or designee) for review and remediation as appropriate. Potential violations related to improper promotion of a Government Reimbursed Product or potential violations of Federal health care program or FDA requirements shall be reported to the Compliance Officer for appropriate follow-up activity. In the event that a compliance issue, including but not limited to any potential improper promotion or noncompliance with Daiichi's Policies and Procedures or legal or compliance requirements, is identified during any portion of the SFMP, Daiichi shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the investigative procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.I above, as applicable. Any compliance issues identified during the SFMP and any corrective action shall be recorded in the files of the Compliance Department.

Daiichi shall include a summary of the SFMP and the results of the SFMP as part of each Annual Report. As part of each Annual Report, Daiichi also shall provide the OIG with copies of the Observation report or Records Review Report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Daiichi took as a result of such determinations. Daiichi shall make all other Observation reports and Records Review reports available to the OIG upon request.

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PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

L. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 90 days after the Effective Date, Daiichi shall develop and implement a monitoring program for the following types of activities: (1) consultant arrangement activities; and (2) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program (NPMP).

1. *Consulting Arrangement Activities.* To the extent that Daiichi engages U.S.-based U.S.-licensed HCPs for services other than for speaker programs, research-related activities, or publication activities that relate to Promotional Functions or to Product Related Functions (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs shall be referred to herein as Consultants. Daiichi shall require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Daiichi (or a qualified third-party vendor on behalf of Daiichi).

To the extent not already accomplished and within 90 days after the Effective Date, Daiichi shall establish a process to develop an annual engagement plan that identifies the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year. The annual Consultant engagement plan shall also identify the budgeted amounts to be spent on Consultant-related activities. Daiichi compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Daiichi Policies and Procedures.

To the extent not already accomplished and within 90 days after the Effective Date, Daiichi shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Daiichi compliance personnel.

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PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

Within 90 days after the Effective Date, Daiichi shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Daiichi received the work product generated by the Consultant.

Within 90 days after the Effective Date, Daiichi shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Program Audits) of at least 30 consultant programs with HCPs during each Reporting Period. The Consultant Program Audits shall include at least 10 advisory boards and 20 professional services arrangements with HCPs. The Consultant Monitoring Program shall select Consultant arrangements for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review needs assessment documents, Consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Daiichi's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of Daiichi policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow up as appropriate.

2. *Medical Education Grant Activities.* Prior to the Effective Date, Daiichi established a grants management system that is the exclusive mechanism though which requestors may request or be awarded grants for independent medical education grants, other grant activities, and charitable contributions supported by Daiichi. Daiichi's sales and marketing personnel do not and shall continue to have no involvement in, or influence over, the review and approval of medical education grants or charitable contribution requests. Grant and charitable contribution requests shall be submitted through a centralized grants management system and processed in accordance with standardized, objective criteria developed by Daiichi (such as based upon the qualifications of the requestor, or the quality of the program funded by the grant.) In addition, the grants or charitable contributions shall be provided only pursuant to a written agreement with the funding recipient, and if payments to the funding recipient are consistent with the written agreement. Daiichi shall continue the grant and charitable contribution process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

To the extent not already accomplished and within 90 days after the Effective Date, Daiichi shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 medical education grants. The Grants Monitoring Program shall select grants for review on a risk-based targeting approach or a

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

random sampling approach. Monitoring Personnel shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant management system's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with Daiichi's Policies and Procedures. Results from the Grants Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

3. *Follow Up Reviews and Reporting.* In the event that a potential violation of Daiichi's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the NPMP, Daiichi shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.I above, if applicable.

Daiichi shall include a summary of the NPMP and the results of the NPMP as part of each Annual Report. As part of each Annual Report, Daiichi also shall provide the OIG with descriptions of any instances identified through the NPMP in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Daiichi's Policies and Procedures, and a description of the action(s) that Daiichi took as a result of such determinations. Daiichi shall make the documents relating to the NPMP available to the OIG upon request.

M. Reporting of Physician Payments.

1. *Reporting of Payment Information.* On or before March 31, 2015, and 90 days after the end of each subsequent calendar year during the term of the CIA, Daiichi shall post on its website a report of the cumulative value of the Payments provided to all Physician Covered Recipients from Daiichi during the prior applicable calendar year. Each annual report shall be easily accessible and readily searchable.

Each report posted pursuant to this Section III.M shall include a complete list of all Physician Covered Recipients to whom Daiichi made Payments in the preceding year. Each report shall be arranged alphabetically according to the Physician Covered Recipient's last name. The Payment amounts in the reports shall be reported in the actual amount paid for all Physician Covered Recipients on the report. For each Physician Covered Recipient, the applicable report shall include the following information: (i)

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PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

physician's full name; (ii) city and state that the physician has provided to Daiichi for contact purposes; and (iii) the aggregate value of the Payment(s) in the preceding year.

2. *Definitions and Miscellaneous Provisions.*

a. Daiichi shall make each annual report of Payments available on its website during the term of the CIA. Daiichi shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual report of Payments. Nothing in this Section III.M affects the responsibility of Daiichi to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to Physician Covered Recipients.

b. For purposes of Section III.M.1, "Payments" is defined to include all "direct or indirect payments or other transfers of value" as that term is defined in 42 U.S.C. § 1320a-7h and applicable regulations and guidance (including FAQs) published by CMS. The term Payments includes the types of payments or other transfers of value enumerated in 42 U.S.C. § 1320a-7h(a)(1)(A)(vi) and applicable regulations. The term includes all indirect payments or other transfers of value made to a Physician Covered Recipient through a third party where Daiichi requires, instructs, directs, or otherwise causes the third party to provide the Payment to the Physician Covered Recipient. The term also includes direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the Daiichi on behalf of a Physician Covered Recipient.

c. For purposes of its annual website postings as described above, and only with regard to Payments made pursuant to product research or development agreements and clinical investigations as set forth in 42 U.S.C. § 1320a-7h(c)(1)(E), Daiichi may delay the inclusion of such Payments on its website listings consistent with 42 U.S.C. § 1320a-7h(c)(1)(E) and any regulations promulgated thereunder.

d. The term "Payments" does not include direct or indirect payments or others transfers of value or other items that are not included in or are excluded from the definition of "payment" or

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

otherwise excluded from reporting under 42 U.S.C. § 1320a-7h and applicable regulations and guidance (including FAQs) published by CMS.

e. For purposes of this Section III.M, the term "Physician Covered Recipient" is defined to include any physician, except for a physician who is a bona fide employee of Daiichi, as that term is defined in 42 U.S.C. § 1320a-7h(e)(6) and applicable regulations.

N. Other Transparency/Disclosure Initiatives.

1. *Medical Education Grants.* Within 90 days after the Effective Date, Daiichi shall begin posting on its company website the following information with respect to all medical education grants and charitable contributions: (i) the name of the recipient; (ii) the program name and a brief description of the program; and (iii) the amount of the grant or contribution. Daiichi shall post (and provide updates to) the above-described information about grants and charitable contributions on at least an annual basis throughout the term of this CIA. Daiichi shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of grants and healthcare donations or posting of the above-referenced information relating to such funding.

2. *Consultant Disclosure Obligations.* To the extent not already accomplished and within 90 days after the Effective Date, Daiichi shall require all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Daiichi that may be externally imposed on the Consultants based on their affiliation with formulary or Pharmacy & Therapeutics (P&T) committees or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. Within 90 days after the Effective Date, to the extent not already accomplished, Daiichi shall amend its policies relating to Consultants to explicitly state that Daiichi requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Daiichi that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 90 days following the Effective Date, Daiichi shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

in this paragraph. Daiichi shall continue these disclosure requirements throughout the term of this CIA.

3. *Authors*. To the extent not already accomplished and within 90 days following the Effective Date, Daiichi shall implement a requirement that all Authors of biomedical manuscripts must fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with Daiichi and disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Within 90 days after the Effective Date, to the extent not already accomplished, Daiichi shall amend its policies to explicitly state Daiichi's requirement about full disclosure by Authors consistent with ICMJE criteria and the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts and/or engagement letters with Authors and in any contracts and/or engagement letters with Authors entered into after 90 days following the Effective Date, Daiichi shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with Daiichi, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

4. *Post-Marketing Commitments*. Within 90 days after the Effective Date, Daiichi shall post or make available information on its company website about post-marketing commitments (PMCs). The Daiichi website or links included therein shall provide access to general information about the PMC process, descriptions of ongoing Daiichi studies related to PMCs, and information about the nature and status of FDA PMCs. Daiichi shall continue to post or make available the above-described information about PMCs on its website or links included therein throughout the term of this CIA.

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Daiichi changes locations or closes a business, business unit or location related to or engaged in any of the Covered Functions, Daiichi shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the business, business unit, or location.

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Daiichi purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, Daiichi shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or location. This notification shall include the address of the new business, business unit or location, phone number, and fax number. Each new business, business unit or location and all Covered Persons at each new business, business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Daiichi proposes to sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA, Daiichi shall notify OIG no later than five days after the date on which the sale of its business, business unit, or location is publicly disclosed by Daiichi. This notification shall include a description of the business, business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Daiichi shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names of the members of the Board of Directors who are responsible for satisfying the obligations referenced in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4;

5. a copy of Daiichi's Code of Conduct required by Section III.B.1;

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

6. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

7. (a) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to Daiichi's letter;

8. a summary of all Policies and Procedures required by Section III.B.3 (copies of such Policies and Procedures shall be made available to OIG upon request);

9. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information (including training certifications) shall be made available to OIG, upon request.

10. a description of the RAMP required by Section III.D;

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; (d) a summary and description of any and all current and prior engagements and agreements between Daiichi and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Daiichi;

12. a description of the Disclosure Program required by Section III.F;

13. a description of the process by which Daiichi fulfills the requirements of Section III.G regarding Ineligible Persons;

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

14. (if applicable) a certification from the Compliance Officer that to the best of his/her knowledge, information regarding Payments has been posted on Daiichi's website as required by Section III.M;

15. a list of all of Daiichi's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers;

16. a description of Daiichi's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. Daiichi shall submit to OIG annually a report with respect to the status of, and findings regarding, Daiichi's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, or the group of Certifying Employees described in Sections III.A.1-III.A.4;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available upon request);

3. a copy of the Board resolution required by Section III.A.3;

4. a summary of any changes or amendments to Daiichi's Code of Conduct required by Section III.B.1 and the reasons for such changes, along with a copy of the revised Code of Conduct;

5. the number of Covered Persons required to review Daiichi's Code of Conduct and complete the certifications required by Section III.B.1, the percentage of Covered Persons who have completed such certifications, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

6. (a) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.2 sent to each party employing Third Party Personnel; (b) a list

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to Daiichi's letter;

7. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);

8. the following information regarding each type of training required by Section III.C:

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete the initial and annual training, percentage of individuals who completed the training, and an explanation of any exceptions.

A copy of all training materials and the documentation (including training certifications) supporting this information shall be available to OIG, upon request;

9. a description of the RAMP required by Section III.D, a summary of any changes to the process, and a description of the reasons for such changes;

10. a complete copy of all reports prepared pursuant to Section III.E and Appendix B along with a copy of the IRO's engagement letter;

11. Daiichi's response to the reports prepared pursuant to the reviews outlined in Section III.E and Appendix B, along with corrective action plan(s) related to any issues raised by the reports;

12. a summary and description of any and all current and prior engagements and agreements between Daiichi and the IRO (if different from what was submitted as part of the Implementation Report);

13. a certification from the IRO regarding its professional independence and objectivity with respect to Daiichi;

14. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

Government Reimbursed Products (the complete disclosure log shall be made available to OIG upon request);

15. any changes to the process by which Daiichi fulfills the requirements of Section III.G regarding Ineligible Persons;

16. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

17. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

18. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.J. This summary shall include a description of each matter and the status of each matter;

19. a summary of the SFMP and the results of the SFMP required by Section III.K, including copies of the Observations for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Daiichi took as a result of such determinations;

20. a summary of the NPMP and the results of the program described in Section III.L, including detailed description of any identified instances in which it was determined that the activities violated Daiichi's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Daiichi took as a result of such determinations;

21. a certification from the Compliance Officer that information regarding Payments has been posted on Daiichi's website as required by Section III.M;

22. a description of all changes to the most recently provided list of Daiichi's locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers;

23. a description of: (i) any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.3.p; (ii) Daiichi's review of information submitted to the Compendia and Daiichi's conclusion

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

as to whether information submitted to the Compendia and product listings and monographs contained in the Compendia about Government Reimbursed Products are accurate and complete and do not contain any errors; and (iii) all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia that were evaluated during the annual review described in Section III.B.3.p; and

24. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. *Certifying Employees.* In each Annual Report, Daiichi shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer.* In each Implementation Report and Annual Report, Daiichi shall include the following individual certifications by the Compliance Officer:

a. to the best of his or her knowledge, except as otherwise described in the report, Daiichi is in compliance with the requirements of this CIA;

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;

c. Daiichi's: (i) Policies and Procedures as referenced in Section III.B.3 above; (ii) templates for standardized contracts and other similar documents; and (iii) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Daiichi's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Daiichi have been reviewed by competent regulatory, medical, and/or, as appropriate, legal counsel in accordance with applicable Policies and Procedures

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

to ensure that legal, medical, and regulatory concerns have been addressed by Daiichi and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

d. Daiichi's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.h) and, for each product the call plans were found to be consistent with Daiichi's Policies and Procedures referenced above in Section III.B.3.h.

D. Designation of Information. Daiichi shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Daiichi shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

Facsimile: 202.205.0604

Daiichi:

Matt Allegrucci
Vice President
Ethics & Compliance Officer
Daiichi Sankyo, Inc.
2 Hilton Court
Parsippany, NJ 07054
Telephone: 973.944.2787
Facsimile: 973.205.2808

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Daiichi may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine and/or request copies of Daiichi's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Daiichi's locations for the purpose of verifying and evaluating: (a) Daiichi's compliance with the terms of this CIA; and (b) Daiichi's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Daiichi to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Daiichi's Covered Persons who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Daiichi shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Daiichi's Covered Persons may elect to be interviewed with or without a representative of Daiichi present.

CONFIDENTIAL – FOIA EXEMPT
PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

VIII. DOCUMENT AND RECORD RETENTION

Daiichi shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Daiichi prior to any release by OIG of information submitted by Daiichi pursuant to its obligations under this CIA and identified upon submission by Daiichi as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Daiichi shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Daiichi is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Daiichi and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Daiichi fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. the Board's compliance obligations, including the resolution from the Board;

d. the management accountability and certification obligations;

e. a written Code of Conduct;

f. written Policies and Procedures;

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g. the training of Covered Persons, Relevant Covered Persons, and Board Members;

h. a RAMP as required in Section III.D and Appendix B;

i. a Disclosure Program;

j. Ineligible Persons screening and removal requirements;

k. notification of Government investigations or legal proceedings;

l. reporting of Reportable Events;

m. notification of written communications with FDA as required by Section III.J;

n. the SFMP required by Section III.K;

o. the NPMP required by Section III.L;

p. posting of any Payment-related information as required by Section III.M; and

q. implementation of the other transparency/disclosure requirements described in Section III.N.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Daiichi fails to engage and use an IRO as required in Section III.E and Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Daiichi fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Daiichi fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

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5. A Stipulated Penalty of $1,500 for each day Daiichi fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Daiichi fails to grant access.)

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Daiichi as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Daiichi fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Daiichi stating the specific grounds for its determination that Daiichi has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Daiichi shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Daiichi receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions. Daiichi may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Daiichi fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after Daiichi receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Daiichi has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Daiichi of: (a) Daiichi's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

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2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Daiichi shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Daiichi elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Daiichi cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Daiichi has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

a. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by Daiichi to report a Reportable Event and take corrective action as required in Section III.I;

c. a failure to engage and use an IRO in accordance with Section III.E and Appendices A and B;

d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Daiichi constitutes an independent basis for

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Daiichi's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Daiichi has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Daiichi of: (a) Daiichi's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Daiichi shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Daiichi is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30 day period, but that: (i) Daiichi has begun to take action to cure the material breach; (ii) Daiichi is pursuing such action with due diligence; and (iii) Daiichi has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Daiichi fails to satisfy the requirements of Section X.D.3, OIG may exclude Daiichi from participation in the Federal health care programs. OIG shall notify Daiichi in writing of its determination to exclude Daiichi (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Daiichi's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Daiichi may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Daiichi of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Daiichi shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an

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appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Daiichi was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Daiichi shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Daiichi to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Daiichi requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether Daiichi was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Daiichi had begun to take action to cure the material breach within that period; (ii) Daiichi has pursued and is pursuing such action with due diligence; and (iii) Daiichi provided to OIG within that period a reasonable timetable for curing the material breach and Daiichi has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Daiichi, only after a DAB decision in favor of OIG. Daiichi's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Daiichi upon the issuance of an ALJ's decision in

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favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Daiichi may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Daiichi shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Daiichi, Daiichi shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Daiichi and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. The undersigned Daiichi signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

D. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

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ON BEHALF OF DAIICHI

/Joseph Kenneth Keller/	1-6-15
JOSEPH KENNETH KELLER PRESIDENT, U.S. COMMERCIAL DAIICHI SANKYO, INC.	DATE
/Wendy Goldstein/	1-7-15
WENDY GOLDSTEIN Cooley LLP Counsel for Daiichi	DATE

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ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Robert K. DeConti/ — 1/7/15

ROBERT K. DECONTI — DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

/Keshia B. Thompson/ — 1/7/15

KESHIA B. THOMPSON — DATE
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

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APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement

1. Daiichi shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.11 of the CIA or any additional information submitted by Daiichi in response to a request by OIG, whichever is later, OIG will notify Daiichi if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Daiichi may continue to engage the IRO.

2. If Daiichi engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Daiichi shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Daiichi at the request of OIG, whichever is later, OIG will notify Daiichi if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Daiichi may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and have expertise in all applicable Federal health care program and FDA requirements relating to Covered Functions and the RAMP, including but not limited to expertise relating to marketing and promotional activities associated with pharmaceutical products. The assigned individuals shall also be experienced in risk identification and mitigation in relation to pharmaceutical product marketing and promotion. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Government Reimbursed Products are reimbursed;

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2. assign individuals to design and select the sample for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy or regulation, request clarification from the appropriate authority (*e.g.*, CMS or FDA);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform each IRO Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Daiichi.

E. IRO Removal/Termination

1. *Provider and IRO.* If Daiichi terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Daiichi must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Daiichi must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

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2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Daiichi to engage a new IRO in accordance with Paragraph A of this Appendix. Daiichi must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Daiichi to engage a new IRO, OIG shall notify Daiichi of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Daiichi may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Daiichi prior to requiring Daiichi to terminate the IRO. However, the final determination as to whether or not to require Daiichi to engage a new IRO shall be made at the sole discretion of OIG.

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Appendix B to CIA
for
Daiichi Sankyo, Inc.
IRO Reviews

I. IRO Engagement, General Description

As specified more fully below, Daiichi shall retain an Independent Review Organization(s) (IRO) to perform engagements to assist Daiichi in assessing and evaluating certain of its systems, processes, policies, and procedures related to Daiichi's Covered Functions and RAMP (IRO Review). The IRO Review shall consist of two components - a systems review (the Covered Functions and RAMP Review) and a transactions review (the IRO Transactions Review), as described more fully below. Daiichi may engage, at its discretion, a single entity to perform both components of the IRO Review, provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Daiichi's systems, processes, policies, and procedures relating to Covered Functions or its RAMP, the IRO shall perform the Systems Review for the second and fourth Reporting Periods. If Daiichi materially changes its systems, processes, policies, and procedures relating to Covered Functions or its RAMP, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the second and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. IRO Systems Review

The Covered Functions and RAMP Systems Review shall be a review of Daiichi's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Covered Functions and its RAMP. Where practical, Daiichi personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Daiichi pursuant to the preceding sentence. Specifically, the IRO shall review Daiichi's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

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1) Daiichi's systems, processes, polices, and procedures relating to incentive compensation for Relevant Covered Persons who are sales representatives and field-based managers of sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Daiichi's products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Daiichi establishes different systems, processes, policies, or procedures relating to compensation for different products, the IRO shall review each type of compensation arrangement separately;

2) Daiichi's systems, processes, policies, and procedures relating to the development and review of call plans (as described in Section III.B.3.h of the CIA). This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on, among other factors, expected utilization of products for FDA-approved uses or non-FDA-approved uses;

3) Daiichi's systems, processes, policies, and procedures relating to sample distribution. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Daiichi (including, separately, from Daiichi sales representatives, from Medical Affairs, or through other channels). It shall also include a review of whether samples of Government Reimbursed Products are distributed by Daiichi through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

4) Daiichi's systems (including any centralized electronic system), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

5) Daiichi's systems, processes, policies, and procedures relating to non-speaker related consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, presentations, consultant task force meetings, advisory boards, preceptorships, mentorships (if any), and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;

6) Daiichi's systems, processes, policies and procedures relating to the submission of information about any product to any CMS-recognized compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the Product ("Compendia"). This includes

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any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information, (*e.g.*, any changes based on Daiichi's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The review shall also assess Daiichi's processes relating to its annual review of all arrangements with, and processing fees or other payments or financial support (if any) provided by the company to any Compendia;

7) Daiichi's systems, processes, policies and procedures relating to the RAMP, including but not limited to, a review of the: (i) the sources and types of information used in connection with the risk assessment (*e.g.*, the individual personnel, departments or functional areas, and/or any data and systems involved); (ii) the timing for development of the risk assessment and risk mitigation plans;

8) An assessment of whether, in developing the risk assessment or risk mitigation plans: (i) additional or different sources of information should be utilized; (ii) additional or different types of data or information should be utilized; and (iii) additional or different timing cycles should be utilized;

9) A review of the experience and background of personnel responsible for the development of the risk assessment and risk mitigation plans; and an assessment of the completeness and appropriateness of the relevant training, policies, procedures, standard operating procedures, and guidance each such individual receives;

10) An assessment of whether risk monitoring and audit activities related to RAMP: (i) adequately identify potential risks; (ii) adequately monitor all relevant identified risks; (iii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iv) prevent reoccurrence of any problems associated with an identified risk;

11) An assessment of whether risk monitoring and audit activities related to Daiichi's RAMP should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; and/or (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific Daiichi products reviewed; and

12) A review of the systems, policies, procedures, and processes by which Daiichi tracks and manages RAMP activities and an assessment of whether the systems, policies, procedures and processes ensure that risk mitigations plans are appropriately implemented (including by identifying individuals responsible for the follow-up action items).

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III. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II. above, the report shall include the following items:

1) description of the documentation (including policies) reviewed and any personnel interviewed;

2) a detailed description of Daiichi's systems, policies, processes, and procedures relating to the items identified in Sections II.1-12 above, including a general description of Daiichi's control and accountability systems (*e.g.*, documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.1-12 above are made known or disseminated within Daiichi;

4) a detailed description of Daiichi's incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Daiichi may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

5) findings and supporting rationale regarding any weaknesses in Daiichi's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any;

6) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any;

7) whether the risk monitoring and risk mitigation action associated with RAMP identify relevant risks and address identified risks;

8) whether sufficient controls exist to ensure that all monitoring and auditing activities and risk mitigation action items are tracked appropriately;

9) whether the RAMP (including the options for risk mitigation activities) potentially mitigates identified risks; and

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PROPRIETARY AND CONFIDENTIAL TO DAIICHI SANKYO, INC.

10) whether sufficient controls exist to ensure that all agreed-upon risk monitoring and audit activities and risk mitigation action items are completed as planned pursuant to the RAMP.

IV. IRO Transactions Review

As described more fully below in Sections IV.A-C, the Transactions Review shall include: (1) a review of records relating to a sample of the Payments that are reported by Daiichi pursuant to Section III.M of the CIA; and (2) a review of up to three additional items identified by the OIG in accordance with Section III.E. of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. IRO Review of Physician Payment Listings

1. Information Contained in Physician Payment Listings

As set forth in Section III.M of the CIA, Daiichi shall post annual reports of Physician Covered Recipients who received Payments, as defined in the CIA, directly or indirectly from Daiichi. For each Physician Covered Recipient, each report shall include the following information: (i) physician's full name; (ii) city and state of the physician's practice; and (iii) the aggregate value of the Payment(s) in the preceding calendar year.

For purposes of this IRO review, the term "Control Documents" shall include all documents or electronic records associated with each Payment reflected in the report for the sampled Physician Covered Recipient. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the report; contracts relating to the Payment(s) reflected in the report; documents relating to the occurrence of Payment(s) reflected in the report; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify up to 50 Physician Covered Recipients from the applicable report that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the Physician Covered Recipients subject to the IRO review.

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If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 Physician Covered Recipients to be included in the review. For each selected Physician Covered Recipient, the IRO shall review the entry in the report and the Control Documents relating to Payments reflected in the report identified by the IRO as necessary and sufficient to validate the Payment information in the report.

3. IRO Review of Control Documents for Sampled Physician Covered Recipients

For each Physician Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the report to evaluate the following:

a) Whether Control Documents are available relating to each Payment reflected in the report for the sampled Physician Covered Recipient;

b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Daiichi's policies;

c) Whether the aggregate value of the Payment(s) as reflected in the report for the sampled Physician Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents; and

d) Whether the Control Documents reflect that Daiichi's policies were followed in connection with Payment(s) reflected in the report (*e.g.*, all required written approvals for the activity were obtained in accordance with Daiichi's policies.)

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

a) A situation in which all required Control Documents relating to Payments reflected in the report for the sampled Physician Covered Recipient do not exist and:

   i. no corrective action was initiated prior to the selection of the sampled Physician Covered Recipients; or

   ii. the IRO cannot confirm that Daiichi otherwise followed its policies and procedures relating to the entry in the report for the sampled Physician Covered Recipient, including its policies and procedures relating to any Payment(s) reflected in the report; or

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b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Daiichi's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Daiichi has initiated corrective action prior to the selection of the sampled Physician Covered Recipient, or if a Control Document does not exist but the IRO can determine that Daiichi otherwise followed its policies and procedures with regard to each entry in the report for a sampled Physician Covered Recipient, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

B. IRO Review of Additional Items

As set forth in Section III.E. of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items".) No later than 150 days prior to the end of the applicable Reporting Period, the OIG shall notify Daiichi of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Daiichi shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Daiichi's systems, processes, policies, and procedures based on its review of each Additional Item.)

Daiichi may propose to the OIG that its internal audit(s) and/or reviews conducted as part of the Sales Force Monitoring Program (SFMP) described in Section III.K of the CIA or the Non-Promotional Monitoring Program (NPMP) described in Section III.L of the CIA be substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Daiichi's internal audit work and monitoring

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activities to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Daiichi's planned monitoring activities and internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Daiichi's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Daiichi's request to permit its monitoring activities or internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Daiichi shall engage the IRO to perform the Review as outlined in this Section IV.

If the OIG agrees to permit certain of Daiichi's monitoring activities or internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Daiichi in its internal audits.

C. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Reviews. The report shall include the following:

1) General Elements to Be Included in Report

a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Transactions Review Report:

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(Relating to the Physician Covered Recipient Payment Reports)

a) a description of the entries in the report for each Physician Covered Recipient sampled and a description of Control Documents reviewed in connection with each selected Physician Covered Recipient;

b) for each sampled Physician Covered Recipient, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Daiichi policy; (iii) the aggregate value of the Payment(s) as reflected in the report for the sampled Physician Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Daiichi's policies were followed in connection with the underlying activity reflected in the document (*e.g.*, all required approvals were obtained); and (v) any corrective action or disciplinary action was undertaken in those instances in which Daiichi policies were not followed;

c) for each sampled Physician Covered Recipient, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled Physician Covered Recipient, including a description of the circumstances requiring corrective action and the nature of the corrective action; and

d) if any Material Errors are discovered, a description of each error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Additional Items)

e) for each Additional Item reviewed, a description of the review conducted;

f) for each Additional Item reviewed, the IRO's findings based on its review;

g) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Daiichi's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and

h) for each Additional Item reviewed, recommendations, if any, for changes in Daiichi's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

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SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice, the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), and the Defense Healthcare Agency ("DHA"), acting on behalf of the TRICARE program (collectively the "United States"), Daiichi Sankyo, Inc. ("Daiichi"), and Kathy Fragoules ("Relator") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Daiichi is a Delaware Corporation with headquarters in Parsippany, New Jersey, that develops and markets pharmaceuticals, including Benicar and Benicar HCT, Welchol, Azor, and Tribenzor (collectively the "Drugs").

B. On March 10, 2010, Kathy Fragoules filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States, et al., ex rel. Fragoules v. Daiichi Sankyo, Inc., et al.*, Civil Action No. 10.10420-NG , pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action"). In her complaint, Relator alleges, among other things, that Daiichi caused false claims to be submitted to federal healthcare programs by providing inducements to physicians to prescribe the Drugs in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

C. The United States contends that Daiichi submitted or caused to be submitted claims for payment to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk; the Medicaid Program ("Medicaid"), 42 U.S.C. §§ 1396-1396w-5; and the TRICARE Program, 10 U.S.C. §§ 1071-1110a; and

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caused purchases by the Veterans Affairs Program, 38 U.S.C. §§ 1701-1743 (collectively the "Federal Healthcare Programs").

D. The United States contends that it has certain civil claims against Daiichi arising from Daiichi having caused false claims to be submitted to Federal Healthcare Programs by paying kickbacks to induce physicians to prescribe the Drugs. Specifically, the United States contends that the kickbacks took the form of honoraria payments, meals and other remuneration to physicians who participated, or supposedly participated, in Physician Opinion & Discussion programs ("PODs") during the period from January 1, 2005, through March 31, 2011, and other speaker programs during the period from January 1, 2004, through February 4, 2011 (collectively, the "Speaker Programs"). The United States contends that the honoraria, meals and other remuneration were kickbacks, because Daiichi paid physicians who participated in the Speaker Programs even if, among other things: (1) the honoraria recipient spoke only to members of his or her own staff in his or her own office; (2) the physician participants in PODs took turns accepting a "speaker" honoraria for duplicative discussions; (3) the audience included the honoraria recipient's spouse; (4) the honoraria recipient did not speak at all because the event was cancelled beforehand; and/or (5) the associated dinners were lavish and at times even exceeded Daiichi's own internal cost limitations of $140 per person. Daiichi's Speaker Programs during the time periods specified in this Paragraph D are referred to in the Agreement as the "Covered Conduct."

E. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

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F. Daiichi has entered or will be entering into separate settlement agreements, described in Paragraph 1.b below (the "Medicaid State Settlement Agreements"), with certain states (the "Medicaid Participating States") in settlement of the Covered Conduct.

To settle, compromise, and resolve the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Daiichi shall pay to the United States and the Medicaid Participating States $39,015,770, plus interest at an annual rate of 2.125% from September 16, 2014, and continuing until and including the day of payment (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States as follows:

a. Daiichi shall pay to the United States the sum of $34,015,770 plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States. Daiichi shall make this electronic funds transfer no later than seven business days after the Effective Date of this Agreement.

b. Daiichi shall pay the sum of $5,000,000 plus accrued interest as set forth above ("Medicaid State Settlement Amount") to the Medicaid Participating States pursuant to the terms of the Medicaid State Settlement Agreements that Daiichi has entered or will enter into with the Medicaid Participating States.

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2. Conditioned upon the United States receiving the Federal Settlement Amount from Daiichi and as soon as feasible after receipt, the United States shall pay $6,122,838.60 plus a pro rata share of the accrued interest at the rate set forth above to Relator by electronic funds transfer.

3. Daiichi agrees to pay Relator's attorneys' fees and costs, as contemplated by 31 U.S.C. § 3730(d), in accordance with the terms set forth in a separate agreement being entered into simultaneously with the execution of this Settlement Agreement.

4. Subject to the exceptions in Paragraph 7 (concerning excluded claims) below, and conditioned upon Daiichi's full payment of the Settlement Amount, the United States releases Daiichi, together with its current and former parent corporations, the direct and indirect subsidiaries of Daiichi and its parent, and each of their brother or sister corporations, divisions, current or former owners, officers, directors, agents, and employees, and the successors and assigns of any of them from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. In consideration of the obligations of Daiichi in this Agreement and the Corporate Integrity Agreement ("CIA"), entered into between OIG-HHS and Daiichi, conditioned upon Daiichi's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Daiichi under 42 U.S.C. § 1320a-7a or 42

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U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Daiichi from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

6. In consideration of the obligations of Daiichi set forth in this Agreement, conditioned upon Daiichi's full payment of the Settlement Amount, DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Daiichi under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims), below, and as reserved in this Paragraph. DHA expressly reserves authority to exclude Daiichi from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding the releases given in Paragraphs 4, 5, and 6 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

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b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

g. Any liability for failure to deliver goods or services due; and

h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

8. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

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9. Relator, for herself, and for her heirs, successors, attorneys, agents, and assigns, releases Daiichi, together with its current and former parent corporations, direct and indirect subsidiaries, brother or sister corporations, affiliates, divisions, current or former owners, officers, agents, insurers and employees, and the successors and assigns of any of them, from any liability to Relator arising from the filing of the Civil Action.

10. Daiichi waives and shall not assert any defenses Daiichi may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

11. Daiichi fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Daiichi has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

12. Daiichi fully and finally releases the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Daiichi has asserted, could have asserted, or may assert in the future against the Relator, related

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to the allegations in the *qui tam* complaint filed in the Civil Action and the Relator's investigation and prosecution thereof.

13. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, carrier), Medicaid contractor, TRICARE payer or any state payer, related to the Covered Conduct; and Daiichi agrees not to resubmit to any Medicare contractor, Medicaid contractor, TRICARE payer or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

14. Daiichi agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Daiichi, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s) and civil or criminal investigation(s) of the matters covered by this Agreement;

(3) Daiichi's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil or criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

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(4) the negotiation and performance of this Agreement;

(5) the payment Daiichi makes to the United States pursuant to this Agreement and any payments that Daiichi may make to Relator, including costs and attorneys' fees; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to:

(i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and

(ii) prepare and submit reports to the OIG-HHS

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP") (hereinafter referred to as Unallowable Costs). However, nothing in Paragraph 14.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Daiichi.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Daiichi, and Daiichi shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Daiichi or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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c. Treatment of Unallowable Costs Previously Submitted for Payment: Daiichi further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Daiichi or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Daiichi agrees that the United States, at a minimum, shall be entitled to recoup from Daiichi any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Daiichi or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Daiichi or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Daiichi's books and records to

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determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

15. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 16 (waiver for beneficiaries paragraph), below.

16. Daiichi agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

17. Upon the United States' receipt of the Federal Settlement Amount, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1), (a) dismissing with prejudice all claims concerning the Covered Conduct asserted on behalf of the United States against Daiichi in the Civil Action and (b) dismissing with prejudice to Relator and without prejudice to the United States all remaining claims against Daiichi in the Civil Action.

18. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

19. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

20. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this

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Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

21. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

22. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

23. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

24. This Agreement is binding on Daiichi's successors, transferees, heirs, and assigns.

25. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

26. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

27. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

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THE UNITED STATES OF AMERICA

DATED: 1/8/15 BY: _____

DOUGLAS ROSENTHAL
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 1/8/15 BY: _____

GREGG SHAPIRO
LISA ASIAF
GISELLE J. JOFFRE
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

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DATED: 1/21/15

BY: Robert K. DeConti

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____

PAUL J. HUTTER
General Counsel
Defense Health Agency
United States Department of Defense

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DATED: _____

BY: _____
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: 1/8/2015

BY: _____, Deputy, by Proxy
for PAUL J. HUTTER
General Counsel
Defense Health Agency
United States Department of Defense

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DAIICHI SANKYO, INC.

DATED: 1-6-15

BY: Joseph K Keller
JOSEPH KENNETH KELLER
President, U.S. Commercial
Daiichi Sankyo, Inc.

DATED: 1-7-15

BY: Wendy C. Goldstein
WENDY C. GOLDSTEIN
SARAH K. DIFRANCESCA
Cooley LLP
Counsel for Daiichi Sankyo, Inc.

KATHY FRAGOULES

DATED: _____

BY: _____
KATHY FRAGOULES

DATED: _____

BY: _____
KEN NOLAN
MARCELLA AUERBACH
JEB WHITE
Nolan Auerbach & White P.L.
Counsel for Kathy Fragoules

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DAIICHI SANKYO, INC.

DATED: _____ BY: _____
JOSEPH KENNETH KELLER
President, U.S. Commercial
Daiichi Sankyo, Inc.

DATED: _____ BY: _____
WENDY C. GOLDSTEIN
SARAH K. DIFRANCESCA
Cooley LLP
Counsel for Daiichi Sankyo, Inc.

KATHY FRAGOULES

DATED: 1/7/2015 BY: Kathy Fragoules
KATHY FRAGOULES

DATED: 1/7/15 BY: Ken Nolan
KEN NOLAN
MARCELLA AUERBACH
JEB WHITE
Nolan Auerbach & White P.L.
Counsel for Kathy Fragoules

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, January 9, 2015

Daiichi Sankyo Inc. Agrees to Pay $39 Million to Settle Kickback Allegations Under the False Claims Act

Daiichi Sankyo Inc., a global pharmaceutical company with its U.S. headquarters in New Jersey, has agreed to pay the United States and state Medicaid programs $39 million to resolve allegations that it violated the False Claims Act by paying kickbacks to induce physicians to prescribe Daiichi drugs, including Azor, Benicar, Tribenzor and Welchol, the Justice Department announced today.

"The Anti-Kickback Statute prohibits payments intended to influence a physician's ordering or prescribing decisions," said Acting Assistant Attorney General Joyce R. Branda for the Civil Division. "The Department of Justice is committed to preserving the independence and objectivity of those decisions, which are cornerstones of our public health programs."

The Anti-Kickback Statute was enacted to ensure that physicians' medical judgment is not compromised by improper payments and gifts by other health care providers. The statute generally prohibits anyone from offering, paying, soliciting or receiving remuneration to induce referrals of items or services covered by federal health care programs, including Medicare and Medicaid.

In this case, the government alleged that Daiichi paid physicians improper kickbacks in the form of speaker fees as part of Daiichi's Physician Organization and Discussion programs, known as "PODs," which were run from Jan. 1, 2005, through March 31, 2011, as well as other speaker programs that were run from Jan. 1, 2004, through Feb. 4, 2011. Allegedly, payments were made to physicians even when physician participants in PODs took turns "speaking" on duplicative topics over Daiichi-paid dinners, the recipient spoke only to members of his or her own staff in his or her own office, or the associated dinner was so lavish that its cost exceeded Daiichi's own internal cost limitation of $140 per person.

"Drug companies are prohibited from using lavish entertainment and padded speaker program payments to induce physicians to prescribe their drugs for beneficiaries of federal health care programs," said U.S. Attorney Carmen Ortiz for the District of Massachusetts. "Settlements like this one show that the government will continue to pursue health care companies that use kickbacks to promote their products."

As part of the settlement, Daiichi has agreed to enter into a corporate integrity agreement with the Department of Health and Human Services-Office of Inspector General (HHS-OIG), which obligates the defendants to undertake substantial internal compliance reforms for the next five years.

"Schemes such as this are particularly abhorrent," said Inspector General Daniel R. Levinson for the U.S. Department of Health and Human Services. "Manufacturers and physicians who engage in them are cheating Medicare and Medicaid out of millions of dollars and threatening programs upon which many elderly and disabled Americans rely. My office will take whatever steps necessary to guard against improper alliances between manufacturers of drugs and those who prescribe them. Through our corporate integrity agreement we will be closely monitoring Daiichi."

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The settlement announced today stems from a complaint filed by Kathy Fragoules, a former Daiichi sales representative, under the whistleblower provisions of the False Claims Act, which authorize private parties to sue on behalf of the United States, and to receive a portion of any recovery. Fragoules will receive $6.1 million of the federal recovery.

This settlement illustrates the government's emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than $23.3 billion through False Claims Act cases, with more than $14.9 billion of that amount recovered in cases involving fraud against federal health care programs.

The investigation and litigation was conducted by the Civil Division, the U.S. Attorney's Office for the District of Massachusetts, the U.S. Department of Veterans Affairs, the Department of Defense Criminal Investigative Service, HHS-OIG and the FBI. The claims settled by this agreement are allegations only and there has been no determination of liability.

The case is captioned *U.S. ex rel. Fragoules v. Daiichi Sankyo, Inc.*, Civil Action No. 10-10420 (D. Mass.).

Topic(s):
False Claims Act
Health Care Fraud

Component(s):
Civil Division

Press Release Number:
15-017

Updated May 1, 2017

Daiichi Sankyo, Inc. Announces Civil Settlement

Parsippany, NJ – January 9, 2015 – Daiichi Sankyo, Inc. ("the Company") announced today that it has reached a civil settlement with the U.S. Government, as well as participating states to conclude a Federal investigation related to certain types of speaker programs related to Azor, Benicar, Benicar HCT, Welchol and Tribenzor.

Under the agreement, the Company has agreed to pay approximately $39 million, plus fees and costs, and has entered into a Corporate Integrity Agreement with the Office of Inspector General for the U.S. Department of Health and Human Services.

The settlement involves claims regarding Physician Opinion & Discussion programs during the period from January 1, 2005, through March 31, 2011, and other speaker programs during the period from January 1, 2004, through February 4, 2011.

"We are pleased to have finalized these agreements and remain focused on our core mission of helping people live healthy and meaningful lives," said Ken Keller, President, U.S. Commercial, Daiichi Sankyo, Inc. "We are committed to being an ethical, trusted and respected company, and constantly improving how we operate is part of our culture. As part of our compliance program, we continue to review and strengthen our policies, procedures and processes to ensure compliance with applicable laws, regulations and industry standards, and to meet our own high ethical standards."

Daiichi Sankyo, Inc. cooperated with investigators at all times throughout the investigative process.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit: www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit www.dsi.com.

Kimberly Wix
Daiichi Sankyo, Inc.
kwix@dsi.com
(973) 944-2338

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STATE SETTLEMENT AGREEMENT

PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of Nevada ("the State") and Daiichi Sankyo, Inc. ("DSI"), hereinafter collectively referred to as "the Parties."

RECITALS

The Parties agree as follows:

A. At all relevant times, DSI, a Delaware corporation with its principal place of business in Parsippany, New Jersey, distributed, marketed and/or sold pharmaceutical products in the United States, including the drugs Azor, Benicar/Benicar HCT, Tribenzor and Welchol (collectively, the "Subject Drugs").

B. On March 10, 2010, Kathleen Fragoules ("Relator") filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States of America, et al., ex. rel Fragoules* v. *Daiichi Sankyo, Inc., et. al,* Civil Action No. 10.10420-NG. The following four related *qui tams* actions were subsequently filed and thereafter transferred to the District of Massachusetts and administratively consolidated under the caption *United States ex. rel Fragoules v. Daiichi Sankyo, Inc.*, Civil Action No. 10-10420-FDS:

(i) *United States of America, et al., ex. rel Gramig and Andreozzi, v. Daiichi Sankyo, Inc., et. al* (Civil Action No. 10-cv-01599, USDC D.D.C.);

(ii) *United States of America, et al., ex. rel Reilly v. Daiichi-Sankyo, Inc.* (Civil Action No. 11-cv-0082, USDC W.D. Mich.);

(iii) *United States of America, et al., ex. rel Tun v. Daiichi Sankyo Co., Ltd., et. al*

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(Civil Action No. 11-cv-10831, USDC D.Ma.); and

(iv) *United States of America, et al., ex. rel Bozeman v. Daiichi-Sankyo Co., et. al* (Civil Action No. 2:13-cv-02781, USDC W.D. Tenn.).

These five consolidated cases will be collectively referred to as the "Civil Actions." The complaints filed in the Civil Actions alleged, *inter alia*, that DSI caused false claims to be submitted to government healthcare programs by providing inducements to physicians to prescribe the Subject Drugs in violation of the federal Anti-Kickback Statute (42 U.S.C. §§ 1320a-7b(b)) and analogous state statutes.

C. DSI has entered or will be entering into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States of America (as that term is defined in the Federal Settlement Agreement), hereinafter referred to as the "United States."

D. The State contends DSI caused claims for payment to be submitted to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396(v)).

E. The State contends that it has certain civil claims against DSI arising from DSI having caused false claims to be submitted to state Medicaid programs by paying kickbacks to induce physicians to prescribe the Subject Drugs. Specifically, the State contends that the kickbacks took the form of honoraria payments, meals and other remuneration to physicians who participated, or supposedly participated, in Physician Opinion & Discussion programs ("PODs") during the period from January 1, 2005, through March 31, 2011, and other speaker programs during the period from January 1, 2004, through February 4, 2011 (collectively, the "Speaker Programs"). The State contends that the honoraria, meals and other remuneration were kickbacks because DSI

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paid physicians who participated in the Speaker Programs even if, among other things: (1) the honoraria recipient spoke only to members of his or her own staff in his or her own office; (2) the physician participants in PODs took turns accepting a "speaker" honoraria for duplicative discussions; (3) the audience included the honoraria recipient's spouse; (4) the honoraria recipient did not speak at all because the event was cancelled beforehand; and/or (5) the associated dinner was so lavish that its cost exceeded DSI's own internal cost limitation of $140 per person. DSI's Programs and alleged conduct described in this Paragraph E are referred to in the Agreement as the "Covered Conduct."

F. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of liability by DSI nor a concession by the State its claims are not well founded.

G. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the Civil Actions and the above-cited claims, the Parties mutually desire to reach a full and final settlement as set forth below.

TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. DSI agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of $39,015,770, plus

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interest at an annual rate of 2.125% from September 16, 2014, and continuing until and including the day of payment (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of the Federal Settlement Agreement and subject to the terms of this Agreement. The debt shall be discharged by payments to the United States and the Medicaid Participating States under the following terms and conditions:

(a) DSI shall pay to the United States the principal sum of $34,015,770, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) DSI shall pay to the Medicaid Participating States the sum of FIVE MILLION DOLLARS ($5,000,000) plus accrued interest ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the sixty (60) day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the State Negotiating Team ("State Team"), such written instructions to be delivered to counsel for DSI.

(c) DSI shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which DSI and the State Team have agreed,

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or in a form otherwise agreed to by DSI and an individual State. The State shall constitute a Medicaid Participating State provided the Agreement is fully executed by the State and delivered to DSI's attorneys within sixty (60) days of receiving this Agreement. If this condition is not satisfied within sixty (60) days, DSI's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for DSI and the State Team to extend the sixty (60) day period.

(d) The total portion of the amount paid by DSI in settlement for the Covered Conduct for the State is $9,295.34 consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of $4,336.32, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within sixty (60) days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by DSI absent written agreement between counsel for DSI and the State Team to extend the time period for executing this Agreement.

2. The State agrees to promptly dismiss with prejudice all state law claims which the State has the authority to dismiss currently pending against DSI in State or Federal Courts for the Covered Conduct including any supplemental state law claims asserted in the Civil Actions.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of DSI set forth in this Agreement, and conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State agrees to release DSI, together with its current and former parent corporations, direct and indirect subsidiaries,

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brother or sister corporations, affiliates, divisions, current and former owners, directors, officers, agents, insurers and employees, and the predecessors, successors, transferees, heirs, and assigns of any of them, individually and collectively (collectively, the "DSI Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State Medicaid Program as a result of the Covered Conduct.

4. Notwithstanding any term of this Agreement, the State specifically does not release any person or entity from any of the following liabilities:

(a) any criminal, civil, or administrative liability arising under state revenue codes;

(b) any criminal liability not specifically released by this Agreement;

(c) any civil or administrative liability that any person or entity, including any DSI Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation or rule not expressly covered by the release in Paragraph 3 above, including but not limited to, any and all of the following claims: (i) State or federal antitrust violations; (ii) Claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability which may be asserted on behalf of any other payors or insurers, including those that are paid by the State's Medicaid program on a capitated basis;

(f) any liability based upon obligations created by this Agreement;

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(g) any administrative liability, including mandatory exclusions from the State's Medicaid program, unless explicitly stated in this Agreement;

(h) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services provided by DSI;

(i) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or

(j) any liability based on a failure to deliver goods or services due.

5. In consideration of the obligations of DSI set forth in this Agreement, and the Corporate Integrity Agreement ("CIA") that DSI has entered or will be entering into with the Office of the Inspector General of the United States Department of Health and Human Services ("HHS-OIG") in connection with this matter, and conditioned upon receipt by the State of its share of the State Medicaid Settlement Amount, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid program against DSI for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against DSI in the event that DSI is excluded by the federal government, or for conduct and practices other than the Covered Conduct as reserved in Paragraph 4 above.

6. DSI waives and shall not assert any defenses it may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or the Excessive Fines Clause of the Eighth Amendment

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of the Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. In consideration of the obligations of the State set forth in this Agreement, DSI waives and discharges the State, its agencies, political subdivisions, employees, servants, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which DSI has asserted, could have asserted, or may assert in the future against the State, its agencies, political subdivisions, employees, servants, and agents, arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that DSI must pay to the State pursuant to Paragraph 1(d) above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the State's Medicaid program, or any other state payor, for the Covered Conduct; and DSI agrees not to resubmit to the State's Medicaid program or any other state payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal or cause the appeal of any such denials of claims.

9. DSI shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

10. DSI expressly warrants that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount and compliance with this Agreement.

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11. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

12. DSI agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice, DSI shall facilitate, and agree not to impair, the cooperation of its directors, officers, employees or agents, for interviews and testimony, consistent with the rights and privileges of such individuals and of DSI. Upon request, DSI agrees to furnish to the State complete and unredacted copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in their possession, custody or control, concerning the Covered Conduct. DSI shall be responsible for all costs it may incur in complying with this paragraph.

13. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

14. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any liability against any other person or entity.

15. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

16. In addition to all other payments and responsibilities under this Agreement, DSI agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. DSI will pay this amount by separate

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check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

17. This terms of this Agreement are governed by the laws of the State, except disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

18. The undersigned DSI signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

19. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

20. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

21. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

22. This Agreement may be executed in counterparts, each of which shall constitute an original, and all of which shall constitute one and the same Agreement.

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State of Nevada

By: Mark Kemberling Dated 02/18/15

[Name] Mark Kemberling
[Title] MFCU-Director // Chief Deputy Attorney General
OFFICE OF THE ATTORNEY GENERAL

By: [signature] Dated 2/13/15

[Name] Lorraine Spurlock
[Title] Division Administrator, MCFP
Medicaid Program

[illegible]

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DAIICHI SANKYO, INC.

By: Joseph K Keller Dated: 3/4/2015

JOSEPH KENNETH KELLER
President, U.S. Commercial
Daiichi Sankyo, Inc.

By: Wendy C. Goldstein Dated: 3/5/2015

WENDY C. GOLDSTEIN
SARAH K. DIFRANCESCA
Cooley LLP
Counsel to Daiichi Sankyo, Inc.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

September 18, 2020

VIA E-MAIL

Matthew Allegrucci
Vice President, Chief Ethics & Compliance Officer
Daiichi Sankyo, Inc.
American Regent, Inc.
c/o Daiichi Sankyo, Inc.
211 Mount Airy Road
Basking Ridge, NJ 07920

Re: Completion of Corporate Integrity Agreement Requirements

Dear Mr. Allegrucci:

We are writing in response to the Daiichi Sankyo, Inc. (DSI) e-mails dated September 9, 2020 and September 16, 2020 which provide additional information requested concerning the Fifth Annual Report submitted by DSI. Based on our review of this additional information and the information provided in DSI's Fifth Annual Report, it appears that DSI was in compliance with the terms of the Corporate Integrity Agreement (CIA) between the Office of Inspector General (OIG) of the Department of Health and Human Services and DSI during the fifth annual reporting period.

The 5-year term of DSI's CIA has now concluded. During the term of the CIA, DSI submitted reports on the status of its compliance activities for each of the 5 reporting periods. DSI otherwise communicated with OIG to provide CIA-related information, including information requested by OIG.

This acknowledgement that DSI has satisfied its CIA requirements is not a determination by the OIG that DSI has implemented an effective compliance program. It is DSI's responsibility to develop and implement a compliance program that is effective for ensuring compliance with all applicable Federal health care program and FDA requirements. The OIG makes no representations in this letter as to DSI's practices or conduct that may be the subject of ongoing investigations, if any. Also, our comments do

not reflect our assessment of any legal claims that may be made against DSI in connection with any ongoing or future investigation.

We recommend that DSI continue to incorporate into its operations the compliance program elements that were implemented by DSI during the term of its CIA. We also suggest that DSI regularly consult the OIG's website in the future for information regarding the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers.

At the next update, the Daiichi Sankyo, Inc. CIA will be moved to the closed Corporate Integrity Agreements listing on the OIG's website.

If you have any questions regarding this letter, please contact me at (202) 539-6270.

Sincerely,

Keshia B. Thompson
Senior Counsel

13

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician IN TRAINING (PTT) Application

Non-Refundable $50 fee

Rev (03/16/2023)

Y

Section 1: General Information

First: JOSHUA Middle: SANTIAGO Last: SATSATIN

Date of Birth: 04/07/1984 SSN or ITIN: 621-30-8410 Sex: ☑ M ☐ F ☐ X

Mailing Address: 2501 WIGWAM PKWY. APT 618

City: HENDERSON State: NV Zip: 89074

Telephone: (702) 417-3488 Email: JOSH.SATSATIN@GMAIL.COM

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258

Program/School Name:

Address:

City: State: Zip:

Name of Program Director:

Signature of Program Director:

Section 3: Employment Information

Pharmacy Name: TOTAL INFUSION CARE License #: PHC02936

Address: 3041 W. HORIZON RIDGE PKWY #100

City: HENDERSON State: NV Zip: 89052

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	✓	
2. Are you a high school graduate or the equivalent?	✓	

High School Name: BETHEL ACADEMY Graduation Date OR Date GED obtained (mm/yy): 04/06

Address:

City: PHILIPPINES State: Zip:

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 7: Personal and Professional History		
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: WARNING You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.	**Initials** JS	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state even if the case or charge has been dismissed, sealed, acquitted, or expunged?	✓	
3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
9/9/21	3/14/22	NV	HENDERSON	CLARK
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21CRH001070-0000		HENDERSON JUSTICE COURT		
Reason/Charge				
MISDEMEANOR - BATTERY				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

SEE ATTACHED LETTER FROM ATTORNEY AND CASE FILES

Original Signature (electronic, copies or stamps not accepted)

7/21/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

JOSHUA SATSATIN

Print Name

Original Signature (electronic, copies or stamps not accepted)

7/21/23

Date

Board Use Only	Date Received: 7/25/23	Amount: 50-CC

FLANGAS LAW FIRM, LTD. 3496

LEO P. FLANGAS, ESQ
leo@flangaslawfirm.com

KENNETH G. FRIZZELL III, ESQ
ken@flangaslawfirm.com

LICENSED ALSO IN UTAH

STATEMENT OF EXPLANATION

Thursday, July 20th, 2023

Ref: PAGE 4

Attn: NEVADA BOARD OF PHARMACY
Re: SATSATIN, JOSHUA SANTIAGO

To Whom It May Concern:

I, Kenneth G. Frizzell III, Esq., was retained to represent Mr. Satsatin for his criminal case (#21CRH001070-0000) that was filed on September 14th, 2021.

Mr. Satsatin was arrested on or about September 9th, 2021, for the following charges: Battery By Use of Strangulation (Category C Felony – NRS 200.481 – NOC 54735); and two counts of Battery (Misdemeanor – NRS 200.481 – NOC 50212). I have attached the original criminal complaint as Exhibit "1". It should be noted that the events transcribed in the Declaration of Arrest are not entirely accurate and are only told from one side of the story. My client and the alleged victim were cooks employed at Fiesta Filipina Cuisine at the time of the incident. On September 1st, 2021, my client and the alleged victim were involved in a contention surrounding a customer's food order. The conflict escalated when my client felt his safety was at risk. While it can be agreed upon that the means my client engaged in to physically restrain the initiator were not ideal, he de-escalated the dispute and apologized to the alleged victim after emotions settled. Both individuals finished their shift in peace and went about their night. In the following days, the individuals had no conflicts or negative interactions. The alleged victim filed a report almost a week after the incident with their version of the narrative, and my client was subsequently arrested on September 9th, 2021.

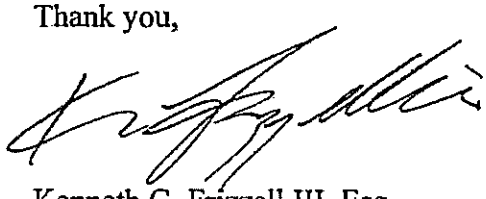
Through the ordinary course of this case, Mr. Satsatin's charges were dropped except one count of Battery, which is a misdemeanor in the state of Nevada. Mr. Satsatin completed counseling per his negotiations and completed other requirements such as fine payments and to

"stay out of trouble" for six months to resolve the case. On June 16th, 2022, Mr. Satsatin's case was officially closed with the final disposition being a misdemeanor charge. I attached the final court docket of the case as Exhibit "2."

My client has no record to this day besides this instant matter. Due to a variety of factors, I ask that Mr. Satsatin's admission decision not be influenced by this case as it is not representative of my client's character. The minor incident occurred years ago, and my client has been a prosocial member of the community since then and always.

If you have any questions or need any further information, please feel free to contact me at my office number (702) 384-1990. Alternatively, you can email me at ken@flangaslawfirm.com. I appreciate your time and consideration in this matter.

Thank you,



Kenneth G. Frizzell III, Esq.

cc: client
3498

JUSTICE COURT, HENDERSON TOWNSHIP
CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

JOSHUA SANTIAGO SATSATIN #2752468,

Defendant.

DA CASE NO: 202143337C

CRIMINAL COMPLAINT

The Defendant above named having committed the crimes of BATTERY BY STRANGULATION (Category C Felony - NRS 200.481 - NOC 54735) and BATTERY (Misdemeanor - NRS 200.481 - NOC 50212), in the manner following, to wit: That the said Defendant, on or about the 1st day of September, 2021, at and within the County of Clark, State of Nevada,

COUNT 1 - BATTERY BY STRANGULATION

did then and there willfully, unlawfully, and feloniously use force or violence upon the person of another, to wit: RONNIELENE ROMANO, by strangulation.

COUNT 2 - BATTERY

did willfully and unlawfully use force or violence upon the person of another, to wit: RONNIELENE ROMANO, by twisting the said RONNIELENE ROMANO's arm.

COUNT 3 - BATTERY

did willfully and unlawfully use force or violence upon the person of another, to wit: RONNIELENE ROMANO, by pushing the said RONNIELENE ROMANO's head.

///

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///

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All of which is contrary to the form, force and effect of Statutes in such cases made and provided and against the peace and dignity of the State of Nevada. Said Complainant makes this declaration subject to the penalty of perjury.

09/10/21

/js
HPD EV# 2116486
(TK)

Henderson Police Department
223 Lead Henderson, NV 89015
Booking Custody Record

0750

DR NUMBER	PRE BOOKING NUMBER:		SCOPE	ARRESTED DATE AND TIME
21-16488	B1002117349	NVHPS1551983C	2752468	09/09/2021 07:27:20

LOCATION OF CRIME	LOCATION OF ARREST
2980 St Rose Pkwy #120, Henderson, NV 89052	2501 Wigwam Pkwy, Henderson, NV, 89074

MIRANDA GIVEN	DATE AND TIME	GIVEN BY
No		

ARRESTING OFFICER	TRANSPORT OFFICER
1330 - Guess, N	1330 - Guess, N

PERSON 1	PERSON NAME (LAST, FIRST, MID, SUFFIX)	SSN	DOB	AGE
	Salsalin, Joshua, Santiago	[redacted]	[redacted]	32

HEIGHT	WEIGHT	HAIR	EYES	RACE	GENDER	STATE OF BIRTH	COUNTRY OF BIRTH
5' 9"	330	BLK - Black	BRO - Brown	A - Asian	M - Male	California	United States of America

PERSON ADDRESS

[redacted] Wigwam Pkwy #618, Hen, NV 89074 (H)

PHONE TYPE	PHONE NUMBER	ALIAS:
M - Mobile		

VIOLATIONS	SEQUENCE	STATUTE	CLASS	NOC CODE	COUNT	WARRANT NUMBER	COURT
	001	200.481.1A	M	50212	1		JC
		M-50212-Battery					

VIOLATIONS	SEQUENCE	STATUTE	CLASS	NOC CODE	COUNT	WARRANT NUMBER	COURT
	002	200.481.2b	C	54735	1		JC
		C-54735-BATTERY BY STRANGULATION					

PROBABLE CAUSE REVIEW

The undersigned Magistrate has reviewed the Affidavit and Declaration of Probable Cause for the arrest of the above-named defendant without warrant for the charge(s) shown.

FINDING

I find there is sufficient probable cause, for the purpose of continued incarceration, to believe that charged crime(s) have been committed and that said defendant has committed such crime(s). THEREFORE, IT IS ORDERED that the defendant may be held in custody until bail is posted.

☐ BAIL: STANDARD ☐ OTHER: $

I find there is NOT sufficient probable cause shown to allow the defendant to be held in custody. THEREFORE, IT IS ORDERED that the defendant be immediately release from custody as to the charge(s). This order is without prejudice to the City or State to proceed with the charge(s) based upon additional evidence sufficient to establish probable cause.

☐ OPCH ☐ OR RELEASE ☐ COR RELEASE ☐ IAD RELEASE

COMMENT:

RETIURN DATE: NORMAL SCHEDUL ☐ FIRST AVAILABLE ☐ ☐ OTHER DATE:

Signature of Magistrate: _____ Justice Court ☐ Municipal Court ☐ Date/Time: _____

Henderson Police Department
223 Lead Street, Henderson, Nevada 89015
Declaration of Arrest

Arrestee's Name: Satsatin, Joshua, Santiago **DR#:** 21-16486
Date and time of Arrest: 09/09/2021 07:27:20

Charge(s)	Degree	NRS\HMC
Battery	M	200.481.1A
BATTERY BY STRANGULATION	C	200.481.2b

THE UNDERSIGNED MAKE THE FOLLOWING DECLARATIONS SUBJECT TO THE PENALTY OF PERJURY AND SAYS: That I Guess, N am a Peace Officer with the Henderson PD, Clark County Nevada. I learned the following facts and circumstances which led me to believe that the above-named subject committed (or was committing) the above offense/offenses at the location of 2501 Wigwam Pkwy and that the offense approximately occurred at 9/9/2021 7:27:20 AM.

Details of Probable Cause

On 9/7/2021 at approximately 1000 hours, I Officer N. Guess #1330 was notified of a Battery with Strangulation that occurred on 9/1/2021 at Fiesta Filipino Cuisine, located at 2980 St. Rose Parkway #120 in Henderson, NV.

Ronnielene Romano (DOB [redacted] came into the HPD West Desk. Ronnielene speaks fluent Tagalog and very broken English, so I had HPD Dispatch initiate Language Link, who provided translator Mona, #13287 to assist me with the investigation.

Through Mona, Ronnielene advised that she works at Fiesta Filipino Cuisine. Ronnielene works as a server for the morning shift, and switches to dish washer in the afternoon. Ronnielene said that around 1630 hours, she was washing (dishes or cloths), and the cook, Joshua, grabbed her left arm and twisted it behind her back. Joshua pulled Ronnielene to a casserole of papaitan he was cooking and threatened to shove her face in it, putting his right arm around her neck in a headlock motion, which Ronnielene demonstrated. Joshua pushed Ronnielene's face to the papaitan, but it did not touch. Then Joshua strangled Ronnielene, and she passed out.

Ronnielene was woken up by manager Rey Castro, who pulled Ronnielene up by her arm. Ronnielene said that she was laying flat on the floor of the kitchen with her arms slightly spread out by her sides. Ronnielene said that her clothing was not disturbed, and remembered she was wearing a black shirt, but could not remember other clothing she was wearing. Ronnielene said she believed the whole encounter lasted approximately 20 minutes, and was unconscious about five minutes. Ronnielene said she did not defecate or urinate on herself, advised her throat did not hurt, either immediately after the incident or later that night, did not have any marks or noticeable injuries. Ronnielene said that her arm was hurting worse in the time since the incident, and was going to get medical attention.

On 9/8/2021, I Officer N. Guess #1330 responded to Fiesta Filipina Cuisine, located at 2980 St. Rose Parkway #120 in Henderson, NV.

I contacted Rey Castro (DOB [redacted] the manager of Fiesta Filipina and witness to this incident. Rey identified Joshua, the suspect as Joshua Satsatin (DOB [redacted] as the suspect from his employee personnel information and personal knowledge.

Rey and I watched the surveillance video together.

There are two videos, one beginning on 9/1/2021 at 1641 hours, and the other beginning at 1648 hours. We watched the 1648 video first, and Rey identified a large Asian male in the back of house as Joshua Satsatin, cooking on the left side of the video, facing the left. In the foreground, closer to the camera, Ronnielene is seen moving left to right, with a blue and white colored cap on her head, wearing a white chef's coat and grey pants. Ronnielene goes through a door on the right to clock out. Moments later, Ronnielene comes in the door at the far side of the kitchen, and walks past Joshua, who has his back turned, cooking on the stove. Ronnielene tries to move as far away from Joshua as possible, and Joshua spins around grabs

Ronnielene around the neck. Joshua's back is to the camera view. Ronnielene is seen dropping, limp, and Rey comes in the same door Ronnielene had just entered through, and seems to be attempting to remove Joshua's hands and arms from Ronnielene's neck. Rey then drops to Ronnielene's right side and shakes her, seeming to wake her up, and assists her to her feet.

Next, Rey played the 1641 hour video, where Ronnielene is seen in a different part of the back of house, washing something in a sink. Joshua is seen coming up on Ronnielene's left side, then punches her forcefully on the left arm, and she rocks from the blow.

Due to the fact Joshua punched Ronnielene on the left shoulder with his right fist, causing Ronnielene to rock visibly in the 1641 hour surveillance video, I have probable cause to believe Joshua committed Battery upon Ronnielene, a violation of NRS 200.481.1A.

Due to the fact Joshua grabbed Ronnielene in the 1648 hour surveillance video, that she visibly dropped in his arms, going limp, and slumped to the floor; that Rey advised he had to tell Joshua to stop strangling Ronnielene, that Rey advised he had to wake Ronnielene up and assist her to her feet; that Ronnielene advised she was strangled by Joshua and "lost her mind" (meaning lost consciousness), I have probable cause to believe Joshua committed Battery by Strangulation, a violation of NRS 200.481.2B.

I contacted Joshua on 9/9/2021 at his residence at approximately 0715 hours. Joshua said he would speak with me voluntarily, and I asked him if he could tell me his side of the story about the incident in the kitchen last week with Ronnielene. Joshua made the comment, "It was a misjudgement...whatever I did or didn't, it wasn't justified by whatever I did." Joshua then asked me what the gravity or situation was. I advised him that the greater charge was Battery by Strangulation, and Joshua said he wanted to speak to his lawyer first, and did not want to complete a voluntary written statement.

I took Joshua into custody and transported him to the Henderson Detention Center, where he was booked accordingly.

Wherefore, Declarant prays that a finding be made by a magistrate that probable cause exists to hold said person for preliminary hearing (if charges are a felony or gross misdemeanor) or for trial (if charges are a misdemeanor).

Guess, N

Declarant's Name

HENDERSON POLICE DEPARTMENT

WITNESS STATEMENT

HPD 0155

PAGE 1 OF 1

DR# 21-16486

DATE: 09/02/21

TIME: 10:36AM

STATE OF NEVADA)
)
COUNTY OF CLARK)

SS: HENDERSON

I, RONNIELENE E. ROMANO, date of birth [redacted]

Social Security Number _____ Occupation Stay at Home

Home Address [redacted] Crusoe Creek Court LAS VEGAS NV 89141, Email Address _____

Business Address _____

Phone #'s: (H) [redacted] (W) _____ (C) _____

do hereby make the following true statements to: Nicole Guess #1330
of the Henderson Police Department, of my own free will. There have been no threats, or promises of immunity or reward made to me to make this statement. It is further understood that this statement may be used either wholly or in part as evidence in a Court of Law.
I can read this and write the English language.

First I was washing the towel once when I came out he called me then he dipped my face in the pot and I went out again when I entered again I passed behind him then he choked me once I sat on the floor I was stunned by what I was going to happen then I was built by me to calm down he said I was taken out from behind the door of the place where we work that's it.

Officer

Witness Signature

Information collected per NRS 179A.075.

RONNIELENE ROMANO 21-16486

1/2

INUTASAN LANG AKO NI JOSH
ILANG TINUTULUNGAN
SALIT PA DUNGAN LANG AKO
SA HARAPAN NIYA SABAY
SI NAKAL AKO KAHIT
KIJIEWHIN PA ANG CAMERA
MAY IVIDENCIA LAHAT SAKIN
NDS HINDI NILA AKO KAHUHULIP
PANG AABUSO
NILA LAHAT NA GINAGAWA
SA KIN PAGGAGAWA
PORKET HINDI AKO NAIMIK KUNG
NUSUTASAN NILA AKO SILANG BOSS
MANAGER NGA HINDI AKO INUUTUSAN
PARE PARETAS LANG KAMI DAPAT PANTAS PANTAS
LAHAT AKO HULOS PAGOD NA PAGOD AKO
ARAW-ARAW!!!

Affm #1330

VICTIM - RONNIELENE CASTRO

21.66486
2/2

NAGLALAGAY AKO NUNG TIME
NAY[illegible] [illegible] SABAY SINUBSUB NIYA DAUKHA
KO SA KALDERO THEN pag daan KO SA
HARAP NIYA BIGLA NALANG AKONG SIPAK

Alfie #1330

9/6/21
21-16486

Nagtatalo sila sa hugasan kanne iil sa naglaba si Rm sa hugasan ng arne. Nagpa ulan na papaitan na alagyan ng bula ng sabon.

Rmanagbas

Agustin #1330

Ronald Managbas
PREP

Ley Castro (MANAGER)

9/1/21
21-16486

Nangyari ang insidente sa loob ng cooking area. bandang hapon 5pm, Sep 1, 2021. Noong araw na iyon maraming pila sa tindahan at kaming dalawa lang ni Rose ang server. Habang ako ay nag serve, nilapitan ako ni Rose na may sigawan sa banclang kitchen, sinabi ko kay Rose na "tapusin ko lang itong sini-serve ko at puntahan ko sila. Pero ng matapos ako mag serve ay wala na ang dalawa sa kitchen kaya nagpatuloy ako mag serve at nang may marinig ako sigaw sa bandang cooking area ay doon ko nakita si Josh na sakal ng braso niya si Ron. at ng matanggal ni Josh ung braso niya ay tinanong ko si Ron "kung okay ba" at dinala ko siya sa may labas para maka hinga ng fresh Air. Tatanong ko din sya kung kailangan ko [redacted] tumawag ng "911" pero okay na daw sya. Tapos bigla dumating si Rose at tinawag ako dahil may problema sa kanya. At nagpatuloy na ko mag serve. . . 1330

Roselyn Aroc
Fiesta Filipina
(Server / Cashier acsitant)

Witnesses.
21-16486

This is my statement on the scenes that i witnessed on the day that Josh and Ron had a fight at work. When i went into the kitchen to order palabok i heard Josh yelling so loud about why his pot had some bubbles on it (accidentally bubble soap got into the pot) and Ron replied back to him but it (voice) was too low for me to hear. Then, i saw Josh attempted to punch her while yelling at her. Then, i went back outside (counter) to serve the customers. After a minute, i approached Rey that something is happening in the kitchen that he must check them out. Since people were lined up at the counter, Rey wasn't able to check them out right away. After a while, i saw Ron came out from the kitchen, and later after we heard some noises ~~again~~ in the kitchen where nearby the exit and so Rey and i went quickly and i saw Josh kneeling down while arm wrapped around Ron's neck while Ron was struggling on the floor. She was red faced, red-eyes as if struggling for her breath and heard Josh telling her not to fight back. calm the situation down.

1330

21CRH001070-0000 STATE OF NEVADA VS SATSATIN, JOSHUA SANTIAGO CLOSED

- Case Type:
- CRIMINAL COMPLAINT HND
- Case Status:
- CLOSED
- File Date:
- 09/14/2021
- DCM Track:
- Action:
- BATTERY
- Status Date:
- 09/14/2021
- Case Judge:
- GEORGE, STEPHEN L
- Next Event:

All Information | Party | Charge | Ticket/Citation # | Event | Docket | Linked Case | Disposition

Party Information

SATSATIN, JOSHUA SANTIAGO
- DEFENDANT CR/TR

- Disposition
- Disp Date
- Scope ID Number
- 2752468

Alias

Party Attorney
- Attorney
- FLANGAS, LEO
- Bar Code
- 005637
- Address
- 600 S THIRD ST
  LAS VEGAS, NV 89101
- Phone

More Party Information

Pending Cases

Party Charge Information

SATSATIN, JOSHUA SANTIAGO
- DEFENDANT CR/TR

Charge # 1:
50212 - MISDEMEANOR BATTERY

- Original Charge
- 54735 BATTERY BY STRANGULATION (FELONY)
- Indicted Charge
- Amended Charge
- 50212 BATTERY (MISDEMEANOR)
- DV Related?
- Modifiers
- Stage Date
- PCN
- NVHP5155183C
- PCN Sequence
- 002

Party Charge Disposition
Disposition Date
Disposition
03/14/2022
GUILTY PLEA W/SENT BEFORE PRELIM

- Ticket #
- ATN #
- Tracking #
- Place of Offense
- HENDERSON TOWNSHIP
- Offense Location
- Date of Offense
- 09/09/2021
- Complainant

Sentencing Information

- SATSATIN, JOSHUA SANTIAGO
- - DEFENDANT CR/TR
  Charge # 2:
  50212 - MISDEMEANOR BATTERY

- Original Charge
  - 50212 BATTERY (MISDEMEANOR)
- Indicted Charge
- Amended Charge
- DV Related?
- Modifiers
- Stage Date
- PCN
  - NVHP5155183C
- PCN Sequence
  - 001
- Ticket #
- ATN #
- Tracking #
- Place of Offense
  - HENDERSON TOWNSHIP
- Offense Location
- Date of Offense
  - 09/09/2021
- Complainant

Party Charge Disposition
Disposition Date
Disposition
03/14/2022
DISMISSED BEFORE TRIAL

Sentencing Information

- SATSATIN, JOSHUA SANTIAGO
- - DEFENDANT CR/TR
  Charge # 3:
  50212 - MISDEMEANOR BATTERY

- Original Charge
  - 50212 BATTERY (MISDEMEANOR)
- Indicted Charge
- Amended Charge
- DV Related?
- Modifiers
- Stage Date
- PCN
  - NVHP5155183C
- PCN Sequence
  - 3
- Ticket #
- ATN #
- Tracking #
- Place of Offense
  - HENDERSON TOWNSHIP
- Offense Location
- Date of Offense
  - 09/09/2021
- Complainant

Party Charge Disposition
Disposition Date
Disposition
03/14/2022
DISMISSED BEFORE TRIAL

Sentencing Information

Ticket/Citation #

Citation # : - HENDERSON TOWNSHIP

- Offense Date
  - 09/09/2021

- Agency
  - HENDERSON POLICE DEPARTMENT
- Officer
- Second Officer
- Complainant
- Speed Cited
- Speed Limit
- Location
- Insured/Proof
- Accident
  - N
- Work Zone
- Haz Mat
- Points
- Priors
- License Taken

- N
- BAC

- Plate
- State
- Year
- Type
- Style
- Color

Events

Date/Time	Location	Type	Result	Event Judge
10/14/2021 09:00 AM	DEPARTMENT 2	FELONY ARRAIGNMENT HND	ARRAIGNMENT HEARING HELD	GEORGE, STEPHEN L
03/14/2022 09:30 AM	DEPARTMENT 2	PRELIMINARY HEARING HND	CRIMINAL HEARING HELD	GEORGE, STEPHEN L
06/16/2022 09:00 AM	DEPARTMENT 2	STATUS CHECK HND	CRIMINAL HEARING HELD	GEORGE, STEPHEN L

Docket Information

Date	*Docket Text*	Amount Owed
09/09/2021	$6000.00 SURETY BOND POSTED Charge #1: BATTERY	
09/09/2021	PROBABLE CAUSE FORWARDED TO CHAMBERS FOR 48 HOUR REVIEW - DEPT. 1	
09/14/2021	COMPLAINT FILED CONTINUED FOR BAIL RETURN DATE	
09/14/2021	SET FOR COURT APPEARANCE Event: FELONY ARRAIGNMENT HND Date: 10/14/2021 Time: 9:00 am Judge: GEORGE, STEPHEN L Location: DEPARTMENT 2 Result: ARRAIGNMENT HEARING HELD	
10/04/2021	EMAILED LETTER OF REPRESENTATION RECEIVED FROM L. FLANGAS, ESQ	
10/14/2021	S.L. GEORGE, JP, M. SCHIEBLE, DDA K. FRIZZELL, ESQ FOR L. FLANGAS, ESQ J. NESCI, CLK S. GRAHAM, CR	
10/14/2021	INITIAL ARRAIGNMENT: DEFENDANT NOT PRESENT DEFENSE COUNSEL ACKNOWLEDGES, WAIVED READING OF THE COMPLAINT BY AND THROUGH HIS ATTORNEY, DEFENDANT ASKED FOR DATE CERTAIN FOR HEARING WAIVED 15 DAY RULE PRELIMINARY HEARING DATE SET SURETY BOND CONTINUES	
10/14/2021	ARRAIGNMENT HEARING HELD The following event: FELONY ARRAIGNMENT HND scheduled for 10/14/2021 at 9:00 am has been resulted as follows: Result: ARRAIGNMENT HEARING HELD Judge: GEORGE, STEPHEN L Location: DEPARTMENT 2	
10/14/2021	SET FOR COURT APPEARANCE Event: PRELIMINARY HEARING HND Date: 03/14/2022 Time: 9:30 am Judge: GEORGE, STEPHEN L Location: DEPARTMENT 2	
03/14/2022	CHARGE AMENDED 50212 Charge #1: BATTERY	
03/14/2022	S.L. GEORGE, JP C. PANDELIS, DDA A. PURSER, ESQ FOR L. FLANGAS, ESQ	

Date	Docket Text	Amount Owed
	D. LOPEZ, CLK L. BRENSKE, CR	
03/14/2022	PRELIMINARY HEARING: DEFENDANT PRESENT PER NEGOTIATIONS: COUNT 1: AMENDED TO MISDEMEANOR "BATTERY" NOLO CONTENDERE ENTERED AND ACCEPTED PAY $1,000 FINE COMPLETE ANGER MANAGEMENT OR IMPULSE CONTROL COUNSELING STAY AWAY FROM VICTIM STAY OUT OF TROUBLE FOR PENDENCY OF CASE 6 MONTHS CLARK COUNTY JAIL, SUSPENDED COUNTS 2 & 3: DISMISSED SURETY BOND EXONERATED	
03/14/2022	HEARING HELD The following event: PRELIMINARY HEARING HND scheduled for 03/14/2022 at 9:30 am has been resulted as follows: Result: CRIMINAL HEARING HELD Judge: GEORGE, STEPHEN L Location: DEPARTMENT 2	
03/14/2022	SET FOR COURT APPEARANCE Event: STATUS CHECK HND Date: 06/16/2022 Time: 9:00 am Judge: GEORGE, STEPHEN L Location: DEPARTMENT 2	
06/16/2022	E. LEE THOMSON PROTEM FOR S.L. GEORGE, JP C. PANDELIS, DDA A. PURSER, ESQ FOR L. FLANGAS, ESQ A. DALFONZO, CLK L. BRENSKE, CR	
06/16/2022	STATUS CHECK: DEFENDANT NOT PRESENT FINE PAID IN FULL ANGER MANAGEMENT/IMPULSE CONTROL COUNSELING DONE CASE CLOSED	
06/16/2022	HEARING HELD The following event: STATUS CHECK HND scheduled for 06/16/2022 at 9:00 am has been resulted as follows: Result: CRIMINAL HEARING HELD Judge: GEORGE, STEPHEN L Location: DEPARTMENT 2	
06/16/2022	CASE CLOSED	

Linked Cases

Link Group	Case #	File Date
21CRH001070-0000	21PCH001062-0000	09/09/2021

Case Disposition

Disposition	Date	Case Judge
CLOSED	06/16/2022	GEORGE, STEPHEN L

14

14A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist Application
Non-Refundable $250 fee

Rev (06/28/2022)

y

Section 1: Select how will you be obtaining your Nevada Pharmacist Registration

☐ **Examination**

☐ **Score Transfer** (Transfer your NAPLEX SCORE to Nevada within 89 days after taking your exam at https://nabp.pharmacy/ before completing this application.)

☑ **Reciprocation** (Complete NABP's Electronic Licensure Transfer Program (e-LTP) application at https://nabp.pharmacy/ before completing this application.)

Are you submitting this application to RETAKE the NAPLEX and/or MPJE? ☐ Yes ☑ No

Section 2: General Information

First: Matthew Middle: William Last: Dulin

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Ridge RD

City: Pine Grove State: CA Zip: 95665

Telephone: [redacted] Email: [redacted]

Section 3: Employment Information

Pharmacy Name: Not employed NV Pharmacy License # (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 4: College of Pharmacy Information

School Name: South University School of Pharmacy

Address: 709 Mall Blvd

City: Savannah State: GA Zip: 31406

Country/Territory/Province: United States

Graduation Date: 2013 Degree: ☑ PharmD ☐ BS in Pharmacy ☐ Other

Section 5: ONLY COMPLETE this section if you are applying for a Nevada Pharmacist Registration by RECIPROCATION.

Original State of licensure/registration you are reciprocating from must be active and issued by exam (passing the NAPLEX and that state's MPJE).

State: FL License #: PS 52833 Date of Issuance: ~~4/28/2023~~ 11/5/2014 NWD Expiry Date: 9/30/2023

Section 6: List all pharmacist license/registration you have/had in other states. Use another sheet if additional space is needed.

State	License/ Registration #	Issued Date	Expiry Date	License/Registration Status (check applicable box)				
				Active	Inactive	Expired	Revoked	Surrendered
FL	PS 52833	11/5/2014	9/30/2023	X				
SC	36987	2/10/2017	4/30/2024	X				
GA	RPH 029504	9/16/2016	Pending		X			

Section 7: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 8: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 9: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		✓
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 9 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/1/2019	12/13/2021	GA	Savannah	Chatham

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
4:19 CR 00171-1	DEA / CNT

Reason/Charge	
Conspiracy to Posses with intent to distribute Marijuana and Maintaining a Drug-involved premises	
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**
Name of Business/Industry/Entity	

Provide explanation below:

See attached. I have attached The Judgment in the Criminal Case, I have attached a letter I have written to the board stating what I did and how I am on the road to recovery. I have attached Character witness letters and my criminal Background Check. Also, I have attached the licenses of South Carolina and Florida along with good standing certificates from their states. I have went through all the Boards protocols in each state and got my licenses reinstated I will have an answer from Georgia on 7/19/2013. Finally I did attach all the certificates of rehabilitation programs I have taken to help with my rehabilitation as well. Thank you again for the opportunity to apply to the California Board of Pharmacy

God Bless

Mark Oli

Original Signature (electronic, copies or stamps not accepted)

7/19/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Matthew William Dulin

Print Name

Original Signature, no copies or stamps accepted

7/19/2023

Date

Board Use Only	Date Received: 7/25/23	Amount: 125-CK-188
	NAPLEX:	MPJE:

20

CAUTION: NOT TO BE USED FOR IDENTIFICATION PURPOSES | THIS IS AN IMPORTANT RECORD. SAFEGUARD IT. | ANY ALTERATIONS IN SHADED AREAS RENDER FORM VOID

CERTIFICATE OF RELEASE OR DISCHARGE FROM ACTIVE DUTY

1. NAME (Last, First, Middle)	2. DEPARTMENT, COMPONENT AND BRANCH	3. SOCIAL SECURITY NUMBER
DULIN, MATTHEW WILLIAM	ARMY/RA	[redacted]

4a. GRADE, RATE OR RANK	4b. PAY GRADE	5. DATE OF BIRTH (YYYYMMDD)	6. RESERVE OBLIGATION TERMINATION DATE (YYYYMMDD)
PV2	E02	[redacted]	20100510

7a. PLACE OF ENTRY INTO ACTIVE DUTY	7b. HOME OF RECORD AT TIME OF ENTRY (City and state, or complete address if known)
WEST DES MOINES, IOWA	[redacted] LYNWOOD AVE GENESEO ILLINOIS 61254

8a. LAST DUTY ASSIGNMENT AND MAJOR COMMAND	8b. STATION WHERE SEPARATED
010041FABTRY A FC	FORT STEWART, GA 31314

9. COMMAND TO WHICH TRANSFERRED	10. SGLI COVERAGE
USAR CON GP (REINF) 1 RESERVE WAY, ST LOUIS, MO 63132	[ ] NONE AMOUNT: $400,000.00

11. PRIMARY SPECIALTY (List number, title and years and months in specialty. List additional specialty numbers and titles involving periods of one or more years.)

13B10 CANNON CREWMEMBER - 3 YRS 5 MOS//NOTHING FOLLOWS

12. RECORD OF SERVICE	YEAR(S)	MONTH(S)	DAY(S)
a. DATE ENTERED AD THIS PERIOD	2002	05	28
b. SEPARATION DATE THIS PERIOD	2006	05	27
c. NET ACTIVE SERVICE THIS PERIOD	0004	00	00
d. TOTAL PRIOR ACTIVE SERVICE	0000	00	00
e. TOTAL PRIOR INACTIVE SERVICE	0000	00	00
f. FOREIGN SERVICE	0001	06	02
g. SEA SERVICE	0000	00	00
h. EFFECTIVE DATE OF PAY GRADE	2005	10	01

13. DECORATIONS, MEDALS, BADGES, CITATIONS AND CAMPAIGN RIBBONS AWARDED OR AUTHORIZED (All periods of service)

ARMY COMMENDATION MEDAL//USA/USAF PRES UNIT CITATION//NATIONAL DEFENSE SERVICE MEDAL//IRAQ CAMPAIGN MEDAL//GLOBAL WAR ON TERRORISM EXPEDITIONARY MEDAL//GLOBAL WAR ON TERRORISM SERVICE MEDAL//ARMY SERVICE RIBBON//NOTHING FOLLOWS

14. MILITARY EDUCATION (Course title, number of weeks, and month and year completed)

NONE//NOTHING FOLLOWS

15a. MEMBER CONTRIBUTED TO POST-VIETNAM ERA VETERANS' EDUCATIONAL ASSISTANCE PROGRAM		YES	X	NO
b. HIGH SCHOOL GRADUATE OR EQUIVALENT	X	YES		NO
16. DAYS ACCRUED LEAVE PAID 24.5	17. MEMBER WAS PROVIDED COMPLETE DENTAL EXAMINATION AND ALL APPROPRIATE DENTAL SERVICES AND TREATMENT WITHIN 90 DAYS PRIOR TO SEPARATION	YES		NO
			X	

18. REMARKS

SUBJECT TO ACTIVE DUTY RECALL, MUSTER DUTY AND/OR ANNUAL SCREENING//BLOCK 6, PERIOD OF DELAYED ENTRY PROGRAM: 20020511-20020528//SERVED IN A DESIGNATED IMMINENT DANGER PAY AREA//SERVICE IN KUWAIT/IRAQI 20030121-20030721//SERVICE IN KUWAIT/IRAQI 20050105-20060105//MEMBER HAS COMPLETED FIRST FULL TERM OF SERVICE//NOTHING FOLLOWS

The information contained herein is subject to computer matching within the Department of Defense or with any other affected Federal or non-Federal agency for verification purposes and to determine eligibility for, and/or continued compliance with, the requirements of a Federal benefit program.

19a. MAILING ADDRESS AFTER SEPARATION (Include ZIP Code)	19b. NEAREST RELATIVE (Name and address – Include ZIP Code)
[redacted] FALLIGANT AVE SAVANNAH GEORGIA 31310	RICHARD DULIN [redacted] COLONA ILLINOIS 61241

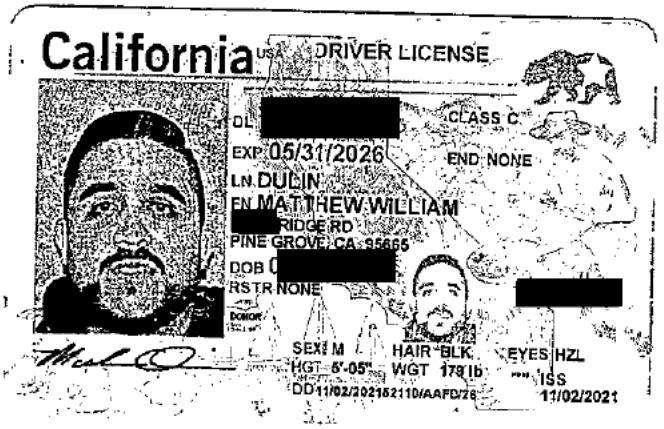
20. MEMBER REQUESTS COPY 6 BE SENT TO IL DIRECTOR OF VETERANS AFFAIRS [X] YES [ ] NO

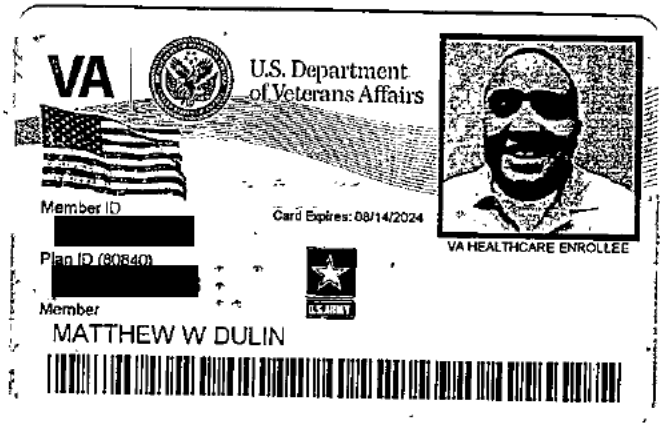
21. SIGNATURE OF MEMBER BEING SEPARATED	22. OFFICIAL AUTHORIZED TO SIGN (Typed name, grade, title and signature)
[signature]	M L DOUGHERTY, GS09, CHIEF, TRANSITION CENTER

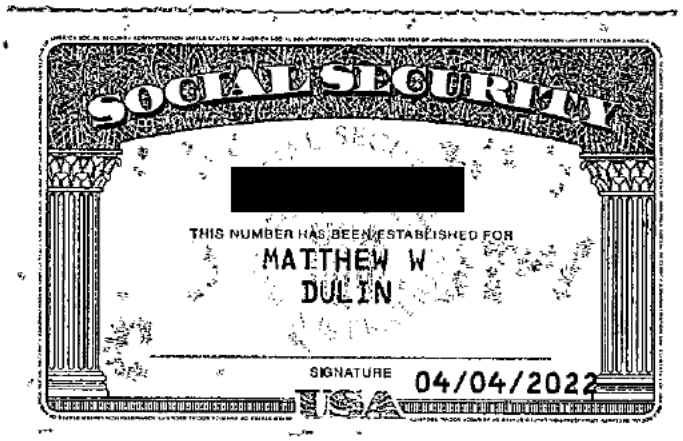
SPECIAL ADDITIONAL INFORMATION (For use by authorized agencies only)

23. TYPE OF SEPARATION	24. CHARACTER OF SERVICE (Include upgrades)	
RELEASE FROM ACTIVE DUTY	HONORABLE	
25. SEPARATION AUTHORITY	**26. SEPARATION CODE**	**27. REENTRY CODE**
AR 635-200, CHAP 4	MBK	1
28. NARRATIVE REASON FOR SEPARATION		
COMPLETION OF REQUIRED ACTIVE SERVICE		
29. DATES OF TIME LOST DURING THIS PERIOD (YYYYMMDD)	**30. MEMBER REQUESTS COPY 4** (Initials) MWD	
NONE		

DD FORM 214-AUTOMATED, FEB 2000 | PREVIOUS EDITION IS OBSOLETE GENERATED BY TRANSPROC | SERVICE-2


California DRIVER LICENSE
DL [redacted] CLASS C
EXP 05/31/2026 END NONE
LN DULIN
FN MATTHEW WILLIAM
[redacted] RIDGE RD
PINE GROVE CA 95665
DOB [redacted]
RSTR NONE
DONOR
SEX M HAIR BLK EYES HZL
HGT 5'-05" WGT 178 lb ISS
DD 11/02/202152110/AAFD/28 11/02/2021


VA
U.S. Department of Veterans Affairs
Member ID [redacted]
Card Expires: 08/14/2024
Plan ID (80840) [redacted]
VA HEALTHCARE ENROLLEE
Member
MATTHEW W DULIN


SOCIAL SECURITY
[redacted]
THIS NUMBER HAS BEEN ESTABLISHED FOR
MATTHEW W
DULIN
SIGNATURE
04/04/2022
USA

CERTIFICATION OF VITAL RECORD

STATE OF TEXAS
COUNTY OF BAILEY

COPY VOID COPY VOID COPY VOID COPY VOID COPY VOID COPY VOID

STATE OF T... CERTIF...E OF BIRTH BIRTH NO.

Texas Department of Health — BUREAU OF VITAL STATISTICS

CHILD

1. NAME [Type or print] [a] First	[b] Middle	[c] Last	2. DATE
Matthew	William	Dulin	[redacted]

3. SEX	4a. PLACE OF BIRTH — COUNTY	4b. CITY OR TOWN [If outside city limits, give precinct no.]
male	Bailey	Muleshoe, Tx 79347

4c. NAME OF HOSPITAL [If not in hospital, give street address]	4d. INSIDE CITY LIMITS?	5a. THIS BIRTH-SINGLE, TWIN, TRIPLET, ETC. [Specify]	5b. IF TWIN OR TRIPLET, WAS CHILD BORN 1st, 2nd, 3rd [Specify]
West Plains Medical Center	yes	single	

FATHER

6. NAME [a] First	[b] Middle	[c] Last
Richard	Arlin	Dulin

7. RACE	8a. IS FATHER OF SPANISH ORIGIN?	8b. IF YES, SPECIFY MEXICAN, CUBAN, PUERTO RICAN, ETC.
cauc.	no	

9. AGE [At time of this birth]	10. BIRTHPLACE [State or foreign country]	11a. USUAL OCCUPATION	11b. KIND OF BUSINESS OR INDUSTRY
28	Ohio	laborer	Meat packing plant

MOTHER

12. MAIDEN NAME [a] First	[b] Middle	[c] Last
Carolina		Espinoza

13. RACE	14a. IS MOTHER OF SPANISH ORIGIN?	14b. IF YES, SPECIFY MEXICAN, CUBAN, PUERTO RICAN, ETC.
cauc.	yes	Mexican

15. AGE [At time of this birth]	16. BIRTHPLACE [State or foreign country]	17a. USUAL OCCUPATION	17b. KIND OF BUSINESS OR INDUSTRY
25	Texas	h/w	

18a. RESIDENCE — STATE	18b. COUNTY	18c. CITY OR TOWN [If outside city limits, show rural] ZIP CODE	18d. STREET ADDRESS [If rural, give location]	18e. INSIDE CITY LIMITS?
New Mexico	Curry	Clovis, NM 88101	104 Gary	yes

19. Children previously born to this mother [Do NOT include this birth]	a. How many other children are now living?	b. How many other children were born alive but are now dead?	c. How many children were born dead after 20 weeks pregnancy?	20. INFORMANT
	1	0	0	Carolina Dulin

21. I hereby certify that this child was born alive on the date stated above	22a. ATTENDANT'S SIGNATURE	22b. ATTENDANT AT BIRTH M.D., D.O., C.N.M., MIDWIFE, OTHER [Specify]
at 9:41 P.M.	Dr Jerry Dr Gregory	D.O.
	22c. ATTENDANT'S ADDRESS Jerry D. Gregory, D.O. 708 South First Muleshoe, Tx 79347	22d. DATE SIGNED 6-01-83

23a. REGISTRAR'S FILE NO.	23b. DATE REC'D BY LOCAL REGISTRAR	23c. SIGNATURE OF LOCAL REGISTRAR
65	6-13-83	Jack Bates J.P.

VOID COPY VOID COPY VOID COPY VOID COPY VOID COPY VOID

S2681

STATE OF TEXAS
COUNTY OF BAILEY

This is to certify that this is a true and correct copy of the Original record recorded in the office of the Vital Statistic Registrar.

DATE ISSUED June 12, 2006

Paula Benton
COUNTY CLERK AND REGISTRAR
BAILEY COUNTY, TEXAS

By: Paula Benton
Deputy

GAS 245B (Rev. 04/20) Judgment in a Criminal Case
DC Custody TSR

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF GEORGIA
SAVANNAH DIVISION

UNITED STATES OF AMERICA
v.
Matthew Dulin

JUDGMENT IN A CRIMINAL CASE

Case Number: 4:19CR00171-1

USM Number: 23321-021

William Dow Bonds
Defendant's Attorney

THE DEFENDANT:

☒ pleaded guilty to Counts 1 and 3

☐ pleaded nolo contendere to Count(s) _____ which was accepted by the court.

☐ was found guilty on Count(s) _____ after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
21 U.S.C. §846, 21 U.S.C. §§ 841(a)(1) and (b)(1)(C), and 18 U.S.C. § 2	Conspiracy to possess with intent to distribute, and to distribute, marihuana	October 1, 2019	1
21 U.S.C. §856(a)(1), 21 U.S.C. § 856(b), and 18 U.S.C. § 2	Maintaining a drug-involved premises	October 1, 2019	3

The defendant is sentenced as provided in pages 2 through 7 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

☐ The defendant has been found not guilty on Count(s) _____

☒ Counts 2 and 4 of the Indictment are dismissed as to this defendant on the motion of the United States.

It is ordered that the defendant must notify the United States Attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the Court and United States Attorney of material changes in economic circumstances.

December 13, 2021
Date of Imposition of Judgment

Signature of Judge

R. Stan Baker
United States District Judge
Southern District of Georgia
Name and Title of Judge

December 17, 2021
Date

IMPRISONMENT

The defendant is hereby committed to the custody of the Federal Bureau of Prisons to be imprisoned for a total term of: 20 months as to each of Counts 1 and 3, to be served concurrently.

☒ The Court makes the following recommendations to the Bureau of Prisons:
It is recommended that the defendant be given credit toward this federal sentence for all time served in custody from August 19, 2019, until August 21, 2019, and from October 16, 2019, until October 24, 2019, that is not credited toward another sentence. It is recommended that the defendant be evaluated by Bureau of Prisons officials to establish bis participation in an appropriate program of substance abuse treatment and counseling, including the Residential Drug Abuse Program (RDAP), during his term of incarceration. Finally, it is recommended that the defendant be designated to one of the following facilities: FCI Terminal Island in San Pedro, California; FCI Lompac in Lompac, California; or FCI Mendota in Mendota, California.

☐ The defendant is remanded to the custody of the United States Marshal.

☐ The defendant shall surrender to the United States Marshal for this district:

☐ at _____ ☐ a.m. ☐ p.m. on _____.

☐ as notified by the United States Marshal.

☒ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

☒ before 2 p.m. on February 11, 2022.

☒ as notified by the United States Marshal.

☐ as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to _____

at _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

By _____
DEPUTY UNITED STATES MARSHAL

DEFENDANT: Matthew Dulin
CASE NUMBER: 4:19CR00171-1

SUPERVISED RELEASE

Upon release from imprisonment, you will be on supervised release for a term of: 3 years as to each of Counts 1 and 3, to be served concurrently.

MANDATORY CONDITIONS

1. You must not commit another federal, state, or local crime.
2. You must not unlawfully possess a controlled substance.
3. You must refrain from any unlawful use of a controlled substance. You must submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court.

   ☐ The above drug testing condition is suspended, based on the court's determination that you pose a low risk of future substance abuse. *(Check, if applicable.)*
4. ☐ You must make restitution in accordance with 18 U.S.C. §§ 3663 and 3663A or any other statute authorizing a sentence of restitution. *(Check, if applicable.)*
5. ☒ You must cooperate in the collection of DNA as directed by the probation officer. *(Check, if applicable.)*
6. ☐ You must comply with the requirements of the Sex Offender Registration and Notification Act (34 U.S.C. § 20901, et seq.) as directed by the probation officer, the Bureau of Prisons, or any state sex offender registration agency in the location where you reside, work, are a student, or were convicted of a qualifying offense. *(Check, if applicable.)*
7. ☐ You must participate in an approved program for domestic violence. *(Check, if applicable.)*

You must comply with the standard conditions that have been adopted by this court as well as with any other conditions on the attached page.

DEFENDANT: Matthew Dulin
CASE NUMBER: 4:19CR00171-1

STANDARD CONDITIONS OF SUPERVISION

As part of your supervised release, you must comply with the following standard conditions of supervision. These conditions are imposed because they establish the basic expectations for your behavior while on supervision and identify the minimum tools needed by probation officers to keep informed, report to the court about, and bring about improvements in your conduct and condition.

1. You must report to the probation office in the federal judicial district where you are authorized to reside within 72 hours of your release from imprisonment, unless the probation officer instructs you to report to a different probation office or within a different time frame.
2. After initially reporting to the probation office, you will receive instructions from the court or the probation officer about how and when you must report to the probation officer, and you must report to the probation officer as instructed.
3. You must not knowingly leave the federal judicial district where you are authorized to reside without first getting permission from the court or the probation officer.
4. You must answer truthfully the questions asked by your probation officer.
5. You must live at a place approved by the probation officer. If you plan to change where you live or anything about your living arrangements (such as the people you live with), you must notify the probation officer at least 10 days before the change. If notifying the probation officer in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
6. You must allow the probation officer to visit you at any time at your home or elsewhere, and you must permit the probation officer to take any items prohibited by the conditions of your supervision that he or she observes in plain view.
7. You must work full time (at least 30 hours per week) at a lawful type of employment, unless the probation officer excuses you from doing so. If you do not have full-time employment you must try to find full-time employment, unless the probation officer excuses you from doing so. If you plan to change where you work or anything about your work (such as your position or your job responsibilities), you must notify the probation officer at least 10 days before the change. If notifying the probation officer at least 10 days in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
8. You must not communicate or interact with someone you know is engaged in criminal activity. If you know someone has been convicted of a felony, you must not knowingly communicate or interact with that person without first getting the permission of the probation officer.
9. If you are arrested or questioned by a law enforcement officer, you must notify the probation officer within 72 hours.
10. You must not own, possess, or have access to a firearm, ammunition, destructive device, or dangerous weapon (i.e. anything that was designed, or was modified for, the specific purpose of causing bodily injury or death to another person such as a nunchakus or tasers).
11. You must not act or make any agreement with a law enforcement agency to act as a confidential human source or informant without first getting permission from the court.
12. If the probation officer determines that you pose a risk to another person (including an organization), the probation officer may require you to notify the person about the risk and you must comply with that instruction. The probation officer may contact the person and confirm that you have notified that person about the risk.
13. You must follow the instructions of the probation officer related to the conditions of supervision.

U.S. Probation Office Use Only

A U.S. probation officer has instructed me on the conditions specified by the court and has provide me with a written copy of this judgment containing these conditions. For further information regarding these conditions, see *Overview of Probation and Supervised Release Conditions*, available at: www.uscourts.gov.

Defendant's Signature _____ Date _____

SPECIAL CONDITIONS OF SUPERVISION

1. You must participate in a substance abuse treatment program and follow the rules and regulations of that program. The probation officer will supervise your participation in the program. You must pay the costs of treatment in an amount to be determined by the probation officer, based on your ability to pay or availability of third-party payment.

2. You must submit to substance abuse testing to determine if you have used a prohibited substance. You must not attempt to obstruct or tamper with the testing methods.

3. You must submit your person, property, house, residence, office, vehicle, papers, computers (as defined in 18 U.S.C. § 1030(e)(1)), other electronic communications or data storage devices or media, to a search conducted by a United States probation officer. Failure to submit to a search may be grounds for revocation of release. You must warn any other occupants that the premises may be subject to searches pursuant to this condition. The probation officer may conduct a search under this condition only when reasonable suspicion exists that you have violated a condition of supervision and that the areas to be searched contain evidence of this violation. Any search must be conducted at a reasonable time and in a reasonable manner.

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments.

	Assessments	Restitution	Fine	AVAA Assessment*	JVTA Assessment **
TOTALS	$200	N/A	None	N/A	N/A

☐ The determination of restitution is deferred until . An *Amended Judgment in a Criminal Case (AO 245C)* will be entered after such determination.

☐ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss***	Restitution Ordered	Priority or Percentage

TOTALS	$ _____	$ _____

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Amy, Vicky, and Andy Child Pornography Victim Assistance Act of 2018, Pub. L. No. 115-299.
** Justice for Victims of Trafficking Act of 2015, Pub. L. No. 114-22.
*** Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties is due as follows:

A ☒ Lump sum payment of $ 200 due immediately.

☐ not later than _____, or
☐ in accordance ☐ C, ☐ D, ☐ E, or ☐ F below; or

B ☐ Payment to begin immediately (may be combined with ☐ C, ☐ D, or ☐ F below); or

C ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after the date of this judgment; or

D ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after release from imprisonment to a term of supervision; or

E ☐ Payment during the term of supervised release will commence within _____ *(e.g., 30 or 60 days)* after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

F ☐ Special instructions regarding the payment of criminal monetary penalties:

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several
Defendant and Co-Defendant Names and Case Numbers *(including defendant number)*, Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

☒ The defendant shall forfeit the defendant's interest in the following property to the United States:
Pursuant to the plea agreement, the defendant shall forfeit his interest in $68,700 in safe deposit box 363 at Bank of America, a 2013 Chevrolet Silverado C1500 (VIN 3GCPCSEA8DG109231), and a 2018 Toyota Highlander Limited (VIN 5TDYZRFH5JS283164).

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) JVTA Assessment, (8) penalties, and (9) costs, including cost of prosecution and court costs.

U.S. District Court | Eastern District of California
U.S. Probation Office

ACKNOWLEDGMENT OF CONDITIONS PROBATION OR SUPERVISED RELEASE AND RECEIPT OF ☒ CRIMINAL JUDGMENT ☐ PROB12B-PETITION

Docket Number: **113J/4:19CR00171-01**

I have received a copy of the ☒ Criminal Judgment ☐ Prob12B-Petition Modification, which includes all the standard, mandatory and special conditions as ordered by the Court.

Mandatory Revocation Issues:

☐ **Original offenses committed before 09/13/1994:** 18 USC 3565 (probation) instructs that supervision be revoked upon a finding of: 1) possession of a firearm; or, 2) possession of a controlled substance ("use" may constitute "possession"); 18 USC 3583 (supervised release) instructs that supervision be revoked upon a finding of: 1) possession of a controlled substance ("use" may constitute "possession").

☒ **Original offenses committed after 09/13/1994:** 18 USC 3565 (probation) and 18 USC 3583 (supervised release) instruct that supervision be revoked upon a finding of: 1) possession of a firearm; 2) possession of a controlled substance ("use" may constitute "possession"); or 3) refusal to comply with the drug testing.

Positive/Failed Drug Tests after 11/02/2002: 18 USC 3565 (probation) and 18 USC 3583 (supervised release) requires that supervision be revoked for: testing positive for illegal controlled substances more than three times over the course of one year.

Upon a finding of a violation of probation or supervised release, I understand that the Court may (1) revoke supervision, (2) extend the term of supervision, and/or modify the conditions of supervision.

The conditions of supervision, including mandatory revocation issues, have been read and explained to me. I fully understand the conditions and my requirements, and have been provided a copy of them.

Matthew Dulin
Defendant — Date

United States Probation Officer / Designated Witness — Date

CC: Case File (PDIM)

Matthew Dulin

South University School of Pharmacy

Graduation Class of 2013

PharmD

To: The Nevada Board of Pharmacy

To Whom This May Concern,

My name is Matthew Dulin I am registered Pharmacist in Florida, Georgia, and South Carolina. I am writing this letter for my application for admission to the Nevada Board of Pharmacy. In the application section about Criminal History, I must provide an explanation to my criminal conviction that occurred in the state of Georgia. On October 1, 2019, I was arrested and charged with a Conspiracy to Distribute Marijuana (21 USC 846, 21 USC 841 (a) (1) and (b) (1) (C), and USC 2 and Maintaining a Drug-involved Premises 21 USC 856 (a)(1), 21 USC 856 (b), and 18 USC 2. Case Number 4:19CR00171-1. At the time I was working for Publix Pharmacy in South Carolina. On January 27, 2021, I voluntarily surrendered my Georgia Pharmacist License to J. David Stubbons Senior Assistant Attorney General. I was on Pre-trial bond from October 2019 to February 2022. During this time, I had no infractions and followed everything directed by my Probation Officers. I was sentenced on December 13, 2021, to 20 months in prison at FCI Lompoc. During my incarceration I enrolled and completed several programs which include, Drug Education (12-hour program), Non-residential Drug Abuse Program (48-Hour Program), Kiaros Christian Family Program (40-Hour Program), Parenting program (24-hour program), Money Smart Program (36-hour program), Financial Peace Program (12-hour program), Brain Health Program (6-hour program), Talking to your Doctor Program (6-hour program), Walk With Ease Program (6-hour program), Disabilities Education Program (10-hour program for my PTSD), Trauma and Resilience Program (12-hour program), and Combat Vet Support Program (10-hour Program). These programs that I completed in prison helped with my re-entry back into society from prison. At the time of my arrest, I was motivated to do things for myself, at the cost of others, mainly my family. My time in prison has humbled me tremendously. Since, my arrest I have recommitted my life to the Lord, I am heavily involved in my church. I go to Men's bible studies, and I also go to Counseling sessions with my wife with Pastor Lopez from The Call Church (Contact Info: email brianl@calvaryamador.org) every week. I have phone counseling with my Care Pastor from Savannah Georgia Craig Fennell (Contact info: email cfennell@cbcsavannah.com), who has been counseling my wife and I since the day we got arrested and is currently still counseling us every week. I have been taking the proper steps to reinstate my license in Georgia. While I was in prison, the Georgia Board of Pharmacy sent me a letter in prison stating that they would be willing to reconsider reinstating my license. I have already got my licenses reinstated in Florida and South Carolina and I currently waiting for the Georgia Board of Pharmacy's decision on July19th. My life has changed for the better and I know I will never do anything like this again. Thank you for giving me a chance to apply to the Nevada Board of Pharmacy and no matter the outcome my life has changed for the better, and I thank my Lord and Savior Jesus Christ for that. If you have any questions involving the case you can contact myself Matthew Dulin (email [redacted] or by Phone [redacted] or my Attorney Dow Bonds (email dowbonds@yahoo.com or by Phone 912-660-1528. Thank you again for the opportunity to apply to your state board and look forward to hearing from you.

Regards,

Matthew Dulin

To whom it may concern,

The Call CHURCH

I'm writing this letter on behalf
of Matt Dulin as a character
reference. I have had the privilege to get well acquainted with Matt over the past two years when he and his wife Trinh began attending The Call Church where I serve as the lead pastor. From the day he arrived, Matt has proven himself to be a faithful and regular attender of the church. He has been very transparent with me regarding his past and was quick to take responsibility for his decisions and his past choices.
I have watched Matt grow as a man, as a husband and in his relationship with God. I have met weekly with he and his wife for counseling appointments and he has been a part of a weekly men's study that I lead. I have also served alongside Matt in several different ministry events at the church. In all of these environments, Matt has demonstrated authenticity, growth, loyalty, dependability, and tremendous character. I know he is working hard to get back on his feet and live a life of integrity that honors God. I also know that part of the journey for Matt is getting his pharmacy license reinstated, which I am hopeful will take place. I believe he is truly repentant of his past, his actions have demonstrated it, and would be a well deserving candidate for a second chance.
If I can be of any further assistance, please feel free to contact me at brianl@calvaryamador.org or by phone at (530) 409-2505.

Sincerely,
Brian Lopez
Brian Lopez
Lead Pastor
The Call Church

The Call Church ❑ 18400 Ridge Rd. Pine Grove, CA 95665
209.296.5961 ❑ thecallchurch.com

To: Amit Navare <attorneynavare@gmail.com>, Dow Bonds <dowbonds@yahoo.com>
Subject: Fwd: To the Honorable Judge Stan Baker

Sent from my iPhone

Begin forwarded message:

From: Trinh K <[redacted]>
Date: June 12, 2020 at 3:09:56 PM EDT
To: Dow Bonds <dowbonds@yahoo.com>, Amit Navare <attorneynavare@gmail.com>
Subject: Fwd: To the Honorable Judge Stan Baker

Sent from my iPhone

Begin forwarded message:

From: Andrew Keenan <[redacted]>
Date: June 12, 2020 at 3:05:40 PM EDT
To: [redacted]
Subject: To the Honorable Judge Stan Baker

To the Honorable Judge Stan Baker,

My name is Andrew Keenan. I have lived in Savannah for 10 years after moving here in 2010 to begin pharmacy school at South University. It was in that same summer of 2010 that I had the privilege of meeting Matt Dulin and subsequently his wife,Trinh, and her 3 boys that Matt was helping to raise. I am writing to you today on behalf of Matt, trinh, and their entire family to relay the kindhearted and genuine people that they are.

Matt was one of the first people that befriended me when I moved to Savannah. He was quick to show me around, introduce me to his friends as well as his family. He frequently invited me and other classmates into their home, to meet and spend time with Trinh and the boys, enjoy time on their deck, in their pool, enjoy a meal with them. They are incredibly giving and loving people, and I believe that is still true today.

Matt, trinh, and the boys are all good people, of good character and good morals. The type of

people who would take you into their home if you needed a place to stay or a meal to eat. I hold them in very high regard and always will. They may have had a momentary lapse in judgment, but they are good, Christian people.

I know how remorseful they are and I hope that you can find mercy on them for a second chance.

Sincerely,
Andrew Keenan

From: Trinh K [redacted]
Subject: Character letter from Craig fennell our care pastor
Date: Apr 17, 2023 at 10:04:18 AM
To: stephanie.calhoun@llr.sc.gov

June 8th, 2020
Re: Matt Dulin & Trinh Kapu

To Whom it May Concern,

My name is Craig Fennell, and I'm the Care Pastor at Community Bible Church in Savannah. My role is to serve others within the church who are suffering from various problems by using biblical counseling. We believe God has answers in the Scriptures to every aspect of life, so it is a joy and privilege to come along side hurting people with the hope of the Gospel, and the truths and promises of God.

I began meeting with Matt & Trinh in September of 2019, this after Matt had initially contacted me for help after visiting our church. We began meeting on a weekly basis for approximately one to two hours. Our initial meetings consisted of getting to know one another, listening to the details about their lives, and gathering information about why they were seeking biblical counsel at our church. I found them to be very transparent and honest about the actions that led to their arrest. They were both dealing with a strong sense of conviction and guilt about decisions and actions they made that affected their family members, specifically, their children, and the family business. I appreciated that they did not use excuses and took responsibility for what they did. Since our initial meetings, we have continued meeting weekly, even via zoom during the pandemic. We have developed a great friendship during our time of counseling, which is always a desire of mine. Our time has consisted of reading through and discussing various passages of Scripture and how they apply to life in this season. As with all of us, we have also worked through trusting God in this season of unknowns, whether it be their sentencing, this pandemic, or the violence that we see in our country today.

On a personal note, I have enjoyed my time with Matt & Trinh, and thank God for their friendship. They have demonstrated a willingness to be responsible, take ownership of poor decisions, grow spiritually, and work on strengthening their marriage and relationship with their children. I have found them to be very caring about others in general, and extremely committed to their families. Matt has recently sought employment and is currently working a full time position. I appreciate his willingness to work and provide for his family during this time. I believe Matt & Trinh are truly going through a transformation in their lives that will honor and please God, resulting in them being productive citizens in this church, and this city.

Sincerely,

Craig Fennell
Pastor of Care
Community Bible Church
912-355-3281

From: Trinh K [redacted]
Subject: Character letter from our accountant doug Martin
Date: Apr 17, 2023 at 10:02:01 AM
To: stephanie.calhoun@llr.sc.gov

Doug Martin Accounting
PO Box 7465
527D Highway 80
Garden City, GA 31418
(912) 964-4355
(912) 964-4356 fax
jdougjr@comcast.net

June 9, 2020

Judge Stan Baker
U.S. District Court, Southern District of Georgia
Savannah, GA

RE: Trinh Kapu and Matthew Dulin

I am writing to you on behalf of Trinh and Matt. I have been the family accountant for the past fifteen (15) years. Trinh and Matt took over the family business, completely, several years ago. They built it up and were conscientious to pay the bills and taxes in a timely manner. Through their hard work the business was profitable again.

They both have stated that they made mistakes in conducting illegal activities at the business and their home. They are remorseful that they have caused this unnecessary burden to their children and their family.

Matt and Trinh have always been polite and have been trying to be sure that everything, from the accounting end of the business, has been done lawfully. They provided the necessary information so that monthly taxes could be filed and paid and yearly information was given in a timely manner as well.

If I can provide any further information, please feel free to contact me.

Warm regards.

Doug Martin

Doug Martin
Accountant

From: Trinh K [redacted]
Subject: Character letter from Mary Iacono
Date: Apr 17, 2023 at 10:00:36 AM
To: stephanie.calhoun@llr.sc.gov

Sent from my iPhone

Begin forwarded message:

From: Trinh K <[redacted]>
Date: July 15, 2020 at 4:52:12 AM PDT
To: Dow Bonds <dowbonds@yahoo.com>
Subject: Fwd: Matt Dulin

Sent from my iPhone

Begin forwarded message:

From: Mary Iacono <mkiacono@aol.com>
Date: July 15, 2020 at 7:49:36 AM EDT
To: triny529@yahoo.com
Subject: Matt Dulin

To the Honorable Judge Stan Baker,

I worked with Matt Dulin for 5 months in 2019, from the summer to early fall.

He was always courteous and kind to his coworkers. He was punctual and

From: Trinh K [redacted]
Subject: Character letter from chris waters
Date: Apr 17, 2023 at 9:59:19 AM
To: stephanie.calhoun@llr.sc.gov

Sent from my iPhone

Begin forwarded message:

From: Trinh K <[redacted]>
Date: July 20, 2020 at 7:46:33 PM PDT
To: Amit Navare <attorneynavare@gmail.com>, Dow Bonds <dowbonds@yahoo.com>
Subject: Fwd: Letter

Sent from my iPhone

Begin forwarded message:

From: CA Waters <cwatersevents@gmail.com>
Date: July 20, 2020 at 7:28:58 PM EDT
To: triny529@yahoo.com
Subject: Letter

Christina Waters
PO Box 30393
Savannah, Ga 31410

Honorable Stan Baker:

Trisha Patel
CEO of Fulfill4me
6409 Abercorn Abercorn St. Suite B2
Savannah, GA. 31405
912-200-4499

June 19, 2020

Dearest Honorable Judge Stan Baker,

I am a close friend of Trinh Kapu and Matthew Dulin. Both Trinh and Matthew have always demonstrated good moral character in my presence. I have known them both for quite sometime now and have whitnessed their continuous participation in the community and non-profit organizations such as Companions for Heroes and the Alzheimer's Dancing with the Stars.

They both are dependable, hard working, family oriented, and reliable friends. They have been there for me, willing to advise me in life's tets. At this point in my life, I do not think I would have gotten through some of life's obstacles without them and a few of our good friends.

They are positive and uplifiting people who are not a risk to our community. They are selfless human beings who would give their shirt off their back to anyone who would need it. I cherish their friendship and despite their current case, I truly believe them to be valuable members of our community and overall good human beings.

Sincerely,

Trisha Patel

1 September 2020

Honorable R. Stan Baker

US District Court- Southern District of Georgia

Your Honor,

My name is Jon Coppinger and I am a registered pharmacist in both Georgia and Tennessee. I currently serve as a pharmacist at Erlanger Hospital in Chattanooga, Tennessee.

I have known Matthew Dulin and Trinh Kapu since the summer of 2010. Matthew and I were classmates and friends at South University School of Pharmacy in Savannah, Georgia. Soon after classes started, Matt and I began spending time together outside of school. We played basketball together at several gyms around the Savannah area. Soon after meeting Matt, he introduced me to his girlfriend, Trinh, and her children. I then began spending time with their family. I spent several nights at their house in Savannah, playing games, swimming, and listening to Matt tell stories about his experiences in the United States Army. Their family accepted me as one of their own, which I very much appreciated since I was new to town and far from home in Chattanooga.

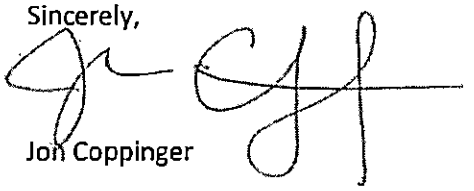
Upon graduation, Matt and I became pharmacists. He worked for Walgreen's before moving to Florida. He then transferred to Publix pharmacy, while in Florida, and remained with the company upon transferring back to the Savannah area. Trinh continued to work as the primary caregiver for her children, as well as for a grandchild. She also spent much of her time running Nancy's Seafood Shop. They were a hard-working family, and everyone had a role.

I remember the day I received the news that Matt, Trinh, Ikaika, Micah, and Paul (Junior) had been arrested for drug trafficking. I was beyond shocked, as I had seen no evidence of any drug activity in the 5 years that we all lived in Savannah at the same time. I had to search the internet the day after the initial shock to ensure this was not all some sort of mistake. Unfortunately, it was not. I reached out to Matt and Trinh in an attempt to see if there was anything I could do for them. They had already been detained, and we were not able to speak until several weeks later. When I was finally able to correspond with them, I was able to find out a few more details. Matt expressed his need for my prayer and he expressed the shame he and Trinh felt for being in this situation.

I know my friends have made a mistake. I know they regret this every day of their lives. These are good people, your honor. They have done everything they can to make the best of a bad situation. Matt has recently told me that both he and Trinh have gotten much closer with God through this experience. They continue to receive spiritual counseling regularly and pray for God's will in all the uncertainty they

are facing. Matt and Trinh are both compassionate, caring human beings who made a mistake. They are willing to face the consequences that are to come. While some punishment may be necessary for this offense, I am asking for your leniency in your sentencing of Matt and Trinh. I hope that you are able to see their true character and allow them to contribute to society once again.

Sincerely,



Jon Coppinger

LIC. NO. 36987
EFFECTIVE: 06/15/2023
EXPIRES 04/30/2024

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

MATTHEW WILLIAM DULIN
PHARMACIST

2023-2024

Lauren B. Thomas, Board Chair

Heather C. Harris, Vice Chair

Traci Collier, Administrator

South Carolina Department of Labor, Licensing and Regulation
Board of Pharmacy
CERTIFIES THAT:

Matthew William Dulin

IS AUTHORIZED TO PRACTICE

Pharmacist

LICENSE NO.
PH .36987 PH

EXPIRATION DATE: 04/30/2024

To verify current license status, go to http://verify.llronline.com/LicLookup/LookupMain.aspx

Print this page

South Carolina Board of Pharmacy

Matthew William Dulin

Company name:
License number: 36987
License type: Pharmacist
Status: Active
First Issue Date: 02/10/2017
Expiration: 04/30/2024

File a Complaint against this licensee

No disciplinary action taken by the Board. This certifies that the above licensee is in good standing.

Board Public Action History:

View Orders View Other License for this Person

No Orders Found

Department of Health

MATTHEW WILLIAM DULIN

License Number: PS52833

Data As Of 6/29/2023

Profession	Pharmacist
License	PS52833
License Status	CLEAR/ACTIVE
Qualifications	Certified To Administer Immunizations
License Expiration Date	9/30/2023
License Original Issue Date	11/05/2014
Address of Record	18230 ridge rd PINE GROVE, CA 95665
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

AC# 1174267

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
04/28/2023	PS 52833	369580

THE PHARMACIST

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

QUALIFICATION(S):
Certified To Administer Immunizations

Expiration Date: SEPTEMBER 30, 2023
MATTHEW WILLIAM DULIN
18230 RIDGE RD
PINE GROVE, CA - 95665

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

VOID

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

AC# 1174267

DATE	LICENSE NO.	CONTROL NO.
04/28/2023	PS 52833	369580

THE PHARMACIST
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

Expiration Date : SEPTEMBER 30, 2023
MATTHEW WILLIAM DULIN

LICENSEE SIGNATURE

QUALIFICATION(S):
Certified To Administer Immunizations

********** CRIMINAL HISTORY RECORD **********

********** Introduction **********

This rap sheet was produced in response to the following request:

FBI Number	648969EG4
State Id Number	GA4913557K ()
Purpose Code	R
Attention	E2023102000000316620;T

The information in this rap sheet is subject to the following caveats:

**THIS RESPONSE IS BEING PRODUCED FOR YOUR REQUEST SENT: 2023-04-12

Important! Criminal history record information is obtained one of two ways: 1) by conducting an inquiry using personal identifiers such as name and date of birth (name search), or 2) by submitting fingerprint cards to the Georgia Crime Information Center (GCIC). When conducting a name search for criminal history record information, there is a possibility that the information returned belongs to a different person with the same, or similar, identifiers. In this case, a positive match of the person whose criminal history record is sought requires submission of fingerprint cards to GCIC. When conducting a fingerprint search for criminal history record information, the information returned does, in fact, belong to the individual. In this case, conducting a name search using the individual's personal identifiers would be the same information.

When the information contained in a criminal history report causes an adverse employment or licensing decision the individual, business or agency making the decision must inform the applicant of all information pertinent to the decision. The disclosure must include information that a criminal history record check was conducted, the specific contents of the record and the effect the record had upon the decision. Failure to provide all such information to the person subject to the adverse decision is a misdemeanor offense under Georgia law. Additionally, any unauthorized dissemination of this record or information herein also violates Georgia law. The plea of nolo contendere may be considered a conviction for some purposes: however, except as otherwise provided by law, it shall not be used against the defendant in any other court as a conviction or admission of guilt or for the purpose of effecting any civil disqualification of the defendant to hold public office, to vote, to serve upon any jury, or any other civil disqualification imposed upon a person convicted of any offense under the laws of this state.

In the event that identifiers are not clearly associated to a specific cycle, the information is most likely non-fingerprint based information received from the Department of Corrections at the time of release from incarceration.

********** IDENTIFICATION **********

Subject Name(s)

DULIN, MATTHEW WILLIAM

Subject Description

State Id Number
GA4913557K

Social Security Number
[redacted]

Sex	Race	
Male	White	
Height	**Weight**	**Date of Birth**
5'05" (2019-08-19)	170 (2019-08-19)	[redacted]
Hair Color	**Eye Color**	
Black (2019-08-19)	Brown (2019-08-19)	

Place of Birth
TEXAS

********** CRIMINAL HISTORY **********

========== Cycle 001 ==========

Tracking Number	88418802334
Earliest Event Date	2019-08-19 Incident Date 2019-08-19
Arrest Date	2019-08-19
Arrest Case Number	
Arresting Agency	GA0251800 CHATHAM SAVANNAH NARCOTICS TEAM
Subject's Name	DULIN, MATTHEW WILLIAM
Arrest Type	Adult
Charge	1
Charge Number	88418802334001
Charge Tracking Number	88418802334
Charge Literal	POSSESSION OF FIREARM OR KNIFE DURING COMMISSION OF OR ATTEMPT TO COMMIT CERTAIN FELONIES
Statute	(16-11-106 GA)
NCIC Offense Code	5299
State Offense Code	5254
Severity	Felony
Disposition	Other(2019-08-23; TRANSFERRED TO SUPERIOR COURT)
Charge	2
Charge Number	88418802334002
Charge Tracking Number	88418802334
Charge Literal	POSSESSION OF METHAMPHETAMINE
Statute	(16-13-30(a) GA)
NCIC Offense Code	3572
State Offense Code	3509
Severity	Felony
Disposition	Other(2019-08-23; TRANSFERRED TO SUPERIOR COURT)

Court Case Number	SPUN19-02440-J4
Court Agency	GA025015J CHATHAM COUNTY SUPERIOR COURT
Subject's Name	DULIN, MATTHEW WILLIAM
Charge	1
Charge Number	88418802334001
Charge Tracking Number	88418802334
Charge Literal	POSSESSION OF FIREARM OR KNIFE DURING COMMISSION OF OR ATTEMPT TO COMMIT CERTAIN FELONIES
Charge Description	CHARGE DISMISSED BY DA OFFICE
Statute	(16-11-106 GA)
NCIC Offense Code	5299
State Offense Code	5254
Severity	Felony
Disposition	Dismissed(2022-05-18; DISMISSED)
Charge	2
Charge Number	88418802334002
Charge Tracking Number	88418802334
Charge Literal	POSSESSION OF METHAMPHETAMINE
Charge Description	CHARGE DISMISSED BY DA OFFICE
Statute	(16-13-30(a) GA)
NCIC Offense Code	3572
State Offense Code	3509
Severity	Felony
Disposition	Dismissed(2022-05-18; DISMISSED)

********** INDEX OF AGENCIES **********

Agency	CHATHAM COUNTY SUPERIOR COURT; GA025015J;
Agency Telephone	(912) 652-7513
Agency Facsimile	(912) 652-7380
Address	PO BOX 10227 SAVANNAH, GA 314010000

Agency	CHATHAM SAVANNAH NARCOTICS TEAM; GA0251800;
Agency Telephone	(912) 652-3903
Address	71 ROSS ROAD SAVANNAH, GA 314050000

Agency	CHATHAM SAVANNAH NARCOTICS TEAM; GA0251800;

Agency	CHATHAM COUNTY SUPERIOR COURT; GA025015J;

* * * END OF RECORD * * *

Certificate of Achievement

Federal Correctional Complex, Lompoc, CA

Awarded to:

Matthew Dulin

#23321-021

For successful completion of the

NON-RESIDENTIAL DRUG ABUSE PROGRAM

July 27, 2022

Date

Dr. K. Liberatore
Drug Abuse Program Coordinator

M. Caro, DTS, Facilitator

Certificate of Completion

Presented to

Matthew Dulin

#23321-021

For successfully completing the

Drug Abuse Education Course

The Drug Abuse Education Course is a minimum of 12 hours. The goal of this program is to help the offender to make an accurate evaluation of the consequences of his/her alcohol/drug use and consider the need for treatment.

M. CARO, Drug Treatment Specialist — **November 15, 2022** **DATE**

LOMPOC FEDERAL CORRECTIONAL COMPLEX

3550

3551

Certificate of Completion

Kairos 32, Lompoc, CA

September 2-5, 2022

KAIROS® PRISON MINISTRY

Presented to:

Matthew Dulin

Reg. number 23321-021

40 Hours of Attendance

The Kairos short-course is a total immersion three-and-one-half-day instructional introduction to living in Christian community. Forgiveness of others, self-examination, goal setting, self-esteem, small group interaction, communication, responsibility, trust and respect are intense elements of the curriculum.

This certificate should be a permanent part of the official records of the named individual. It certifies participation in a significant program, which entails extensive follow-up participation and is hereby entitled to participate in Kairos activities when they are offered at other Bureau of Prisons institutions to which this individual may be assigned.

Rich Antles, Sr., Weekend Leader

Michael Powers, Council Chairman

Certificate of Completion

Is awarded to

For successfully completing

Dulin, Matthew #23321-021

Talk With Doctor (First Step Act)

Your Achievement has been noted on this day, July 27th, 2022

At Federal Correctional Complex, Lompoc California

E. Zarate, Recreation Specialist



3552

FEDERAL CORECTIONAL COMPLEX, LOMPOC

CERTIFICATE OF COMPLETION
AWARDED TO:

MATTHEW DULIN

Successful Completion of the First Step Act Essentials
Education Program (EEP)

In Recognition of Successfully Completing 10 hours

On

May 10 2022

Reentry Affairs Coordinator

Reentry Affairs Coordinator

Certificate of Completion

Is awarded to

For successfully completing

Dulin, Matthew #23321-021

Brain Health (First Step Act)

Your Achievement has been noted on this day, August 24th, 2022

At Federal Correctional Complex, Lompoc California

E. Zarate, Recreation Specialist

Certificate of Completion

Is awarded to

MATTEW DULIN

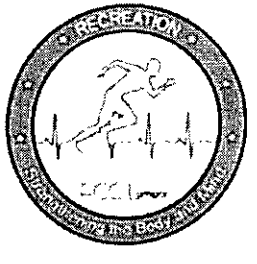
For successfully completing

Walk With Ease / First Step Act Class

Your Achievement has been noted on this day, 17 November 2022

At Federal Correctional Complex, Lompoc California

J. Brady, Recreation Specialist



Federal Correctional Complex, Lompoc

Certificate of Completion Awarded to:

Matthew Dulin

Successful Completion of a First Step Act program
Resilience Support

In Recognition of Successfully Completing 10 hours

On

December 13, 2022

M. Wolfe-Reentry Affairs Coordinator

B. Austin-Reentry Affairs Coordinator

3556

FCC LOMPOC – FCI
PSYCHOLOGY PROGRAMS

CERTIFICATE OF COMPLETION

TO

Matthew Dulin

23321-021

FOR SUCCESSFUL COMPLETION OF

First Step Act:

Traumatic Stress and Resilience

T. Kab, Psy.D., Staff Psychologist
December 27, 2022

CERTIFICATE OF COMPLETION

FCC LOMPOC EDUCATION DEPARTMENT

This certifies that

DULIN, MATTHEW

Has satisfactorily completed 20 participation hours on this 21st day of September, 2022 in

REAL ESTATE

B. Cantu

B. Cantu, ACE Coordinator

3558

Certificate of Completion

This certifies that

Matthew Dulin

Registration #23321-021

Has successfully completed a 20 hour study of
"No Other Gospel: Paul's Letter to the Galatians" DVD series,
by Derek W. H. Thomas, PhD

At the FCI Lompoc Chapel, in Lompoc, California

On the Twenty-ninth day of August in the year 2022

Robert B, chaplain
Witness By

Facilitator

Certificate of Completion

This certifies that

MATTHEW DULIN

has successfully completed the

InsideOut Dad® Program

National Fatherhood Initiative®

Conducted on

January 23, 2023 in Federal Correctional Complex, Lompoc, CA

A. RAZO, Correctional Counselor

Facilitator's Name/Signature

Christopher A. Brown
President
National Fatherhood Initiative®

3560

CERTIFICATE OF COMPLETION

FCC LOMPOC EDUCATION DEPARTMENT

This certifies that

MATTHEW DULIN

Has satisfactorily completed 20 participation hours on this 12t^{h} day of December 2023 in

Financial Peace Series

C. Luhar

C. Luhar ACE Coordinator

3561

14B

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist Application
Non-Refundable $250 fee
Rev (06/28/2022)

Section 1: Select how will you be obtaining your Nevada Pharmacist Registration

☐ **Examination**

☐ **Score Transfer** (Transfer your NAPLEX SCORE to Nevada within 89 days after taking your exam at https://nabp.pharmacy/ before completing this application.)

☑ **Reciprocation** (Complete NABP's Electronic Licensure Transfer Program (e-LTP) application at https://nabp.pharmacy/ before completing this application.)

Are you submitting this application to RETAKE the NAPLEX and/or MPJE? ☐ Yes ☑ No

Section 2: General Information

First: Erin Middle: Ashley Last: Sosebee
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X
Mailing Address: [redacted] Brooks Lake Dr.
City: Newnan State: GA Zip: 30263
Telephone: [redacted] Email: [redacted]

Section 3: Employment Information

Pharmacy Name: Innovation compounding pharmacy NV Pharmacy License # (if applicable): N/A
Address: 6095 Pine mountain Rd. Suite 108
City: Kennesaw State: GA Zip: 30152
Telephone: 800-547-1399 Email:

Section 4: College of Pharmacy Information

School Name: University of Georgia College of Pharmacy
Address: 250 W Green St
City: Athens State: GA Zip: 30602
Country/Territory/Province: United States
Graduation Date: 5/2013 Degree: ☑ PharmD ☐ BS in Pharmacy ☐ Other

Section 5: ONLY COMPLETE this section if you are applying for a Nevada Pharmacist Registration by RECIPROCATION.

Original State of licensure/registration you are reciprocating from must be active and issued by exam (passing the NAPLEX and that state's MPJE).

State: GA License #: rph027201 Date of Issuance: 6/25/13 Expiry Date: 12/31/24

Section 6: List all pharmacist license/registration you have/had in other states. Use another sheet if additional space is needed.								
State	License/ Registration #	Issued Date	Expiry Date	License/Registration Status (check applicable box)				
				Active	Inactive	Expired	Revoked	Surrendered
GA	rpn027201	6/25/13	12/31/24					

Section 7: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 8: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 9: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?	✓	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?	✓	
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 9 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1+3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
01/2017	N/A	GA		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		Georgia Board of Pharmacy		
Reason/Charge				
Entered treatment for addiction to prescription medications				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

Please see typed letter (attached)

Original Signature (electronic, copies or stamps not accepted)

1/16/23
Date

To whom it may concern:

My name is Erin Sosebee and I am applying for a pharmacy license in the state of Nevada. In January of 2017, my license with the Georgia Board of Pharmacy was voluntarily surrendered to seek treatment for addiction to prescription medications. My license was suspended for one year, but on May 23, 2018, my license was reinstated via a private consent order. Pending successful completion of a drug addiction rehabilitation program, my probationary consent order is set to expire on May 23, 2023.

As part of my treatment program, I work with Mark Clayton, a Georgia Pharmacy Board approved addiction and substance use disorder counselor. My treatment began with 90 AA meetings in 90 days. I also participated in weekly counseling sessions, both individual and group. Per the guidance of Mark's group, I still attend 3 AA meetings per week, and a minimum of 2 meetings each month with Mark Clayton and my peers over zoom. As part of the program, I am required to undergo random testing for the use of drugs or alcohol. I have recorded approximately 6 years of clean drug/alcohol screenings.

Recently, I was given the opportunity to work with Innovation Compounding Pharmacy in Kennesaw, GA. As part of this opportunity, I am responsible for verifying the safety and accuracy of prescriptions from all over the United States. It is for this reason I am humbly asking for you to grant me the opportunity to apply for a license in the state of Nevada.

Thank you for your time and for your consideration of my request.



3/01/2023

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Erin Sosebee

Print Name

Original Signature, no copies or stamps accepted

1/16/23

Date

Board Use Only	Date Received: 3-27-23	Amount: 250.00CC
	NAPLEX:	MPJE:

Name: Erin Ashley Sosebee

Owner:

DBA:

Address: [redacted]Brooks Lake Drive
Newnan GA 30263

Profession:	Pharmacy	**License No:**	RPH027201	**License Status:**	Active
License Type:	Pharmacist	**Obtained By Method:**	Application/Examination	**License Subtype:**	
Issue Date:	6/25/2013	**Expiration Date:**	12/31/2024	**Last Renewal Date:**	12/16/2022

- Public Board Orders -

If a public board order exists, it may be listed below.
Public Board Order means that there is a public document concerning the licensee.
The existence of a public Board order does not necessarily mean the licensee is currently under any type of disciplinary action.

Please understand that the absence of a scanned order linked to this record does not necessarily mean that no public actions exist.
No scanned public board order documents exist.

Relationship:	Self Automatic		
Prerequisite Licensee:	Sosebee, Erin Ashley	**Prerequisite License:**	PHI-014402
Association Date:		**Expiration Date:**	

Data current as of: March 29, 2023 10:9:1

This website is to be used as a primary source verification for licenses issued by the Boards of Dentistry and Pharmacy. Paper verifications are available for a fee. Please contact the Boards of Dentistry and Pharmacy at 404-651-8000.

15

15A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Y

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☑ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☐ Schedule V

Section 1: Personal Information

First: DAISY Middle: de Guia Last: de Guzman

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Home Address: [redacted] HOMEWARD WAY

City: HENDERSON State: NV Zip: 89011

Telephone: [redacted] Email: [redacted]

Degree: M.D. Practitioner License #: 18593 Specialty: INTERNAL MEDICINE

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Advanced Medical Weight Loss and Wellness Center, INC

Practice Address: 1450 West HORIZON Ridge Parkway Suite #: B-313

City: Henderson State: NV Zip: 89012

Telephone: 702-897-9797 Fax: 702-897-9795 Email: AdvMed@aol.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		NA

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Question 2 and 3 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Dec 2011	JAN 2013	NJ	NEWARK	ESSEX

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2:12CR-389 (CCC)	United State District court of New Jersey

Reason/Charge
ANTI KICKBACK STATUE

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
United State of America VS Daisy de Guzman	

Name of Business/Industry/Entity
DAISY de Guezman MD

Provide explanation below:

SEE ATTACHed Page for explanation and documents

Daisy de Guezman
Original Signature (electronic, copies or stamps not accepted)

April 30, 2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DAISY de GUZMAN — Print Name (First, Last)

April 30, 2023 — Date

Daisy de Guzman — Original Signature (electronic, copies or stamps not accepted)

April 30, 2023 — Date

Board Use Only: Date Processed: _____ Amount: 200.00 CC

Daisy De Guia DE GUZMAN

License Number: 18593

License Type: Medical Doctor

License Status: Active

Initial License Date: Jan-18-2019

Expiration Date: Jun-30-2023

Public Address: 2828 E Lake Mead Blvd

Public City: North Las Vegas

Public State: Nevada

Public ZIP Code: 89030

Public Country: United States

Public Phone Number: 7025512222

Credential: M.D.

Specialties

Specialty
Internal Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
University of Santo Tomas / Manila, Philippines	Medical Doctor Degree	N/A	May-18-1965

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Elizabeth General Hospital / Elizabeth, NJ	Internship	Rotating	Jul-01-1966	Jun-30-1967
Bronx Lebanon Hospital / Bronx, NY	Residency	Internal Medicine	Jul-01-1967	Jun-30-1968
Veterans Administrative Hospital / Manhatten, NY	Residency	Internal Medicine	Jul-01-1968	Jun-30-1969
Bronx Lebanon Hospital / Bronx, NY	Residency	Internal Medicine	Jul-01-1969	Jun-30-1970

Powered by Thentia Cloud (https://www.thentia.com)

Institution	Program Type	Specialty Type	Start Date	End Date
Mount Sinai Hospital / New York City, NY	Fellowship	Internal Medicine	Jul-01-1971	Dec-31-1973

Board Actions

Summary	Attachments
None.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

Supervisor To

Licensee	Relationship	Date of Association
FLANAGAN, Jermaine Kareem	Additional Supervisor	Jan-26-2023

ANSWER TO PAGE 3 NO 2 AND 3

IN DEC.2011,I WAS ONE OF THE 14 NEW JERSEY DOCTORS ACCUSED OF ANTI- KICKBACK STATUE.THE FEDERAL GOVERNMENT SENT A SUPPOSED TO BE MARKETING AGENT FROM A PRIVATE MRI COMPANY AND GAVE ME A MONETARY GIFT AS A GRATITUDE FOR SENDING MRI REQUEST TO THEIR OFFICE,I RECEIVED $1,000.00 IN OCT 2011,$1,500.00 IN NOV 2011 AND ANOTHER $ 1,000.00 IN DEC 2011.

THIS EVENT WAS VIDEOD AND MY LAWYER RECOMMENDED TO PLEAD GUILTY FOR A LESSER OFFENSE.I LOST MY NJ LICENSE FOR 1 YEAR AND WAS SUSPENDED FROM MEDICAID AND MEDICARE FOR 10 YEARS,I WAS REINSTATED BY OFFICE OF INSPECTOR GENERAL IN MARCH 2019

ENCLOSED HEREWITH IS A COPY OF REINSTATEMENT FROM OFFICE OF INSPECTOR GENERAL,NPDB FROM CENTERS OF MEDICARE AND MEDICAID AND NJ MEDICAID.

State of New Jersey
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
PO BOX 712
TRENTON, NJ 08625-0712

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

CAROLE JOHNSON
Commissioner

JENNIFER LANGER JACOBS
Assistant Commissioner

September 22, 2020

Daisy De Guzman, MD
285 Homeward Way
Henderson, NV 89011

Re: Reinstatement Request

Dear Dr. De Guzman,

This is to inform you that you are hereby reinstated to participate in the programs administered in whole or part by the Division of Medical Assistance and Health Services.

Your reinstatement is effective as of the date of this letter. However, please note that this reinstatement letter does not reactivate your New Jersey Medicaid provider number. Rather you must first submit a completed enrollment packet, along with a copy of this letter, to reactivate provider status. Provider Enrollment packets can be found online at www.njmmis.com or by calling the Provider Enrollment Unit at DXC Technology at 609-588-6036 to have an enrollment packet mailed to you.

Sincerely,

Jennifer Langer Jacobs
Assistant Commissioner

c: Kim Ranke, MFD

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Daisy G. De Guzman, M.D.
285 Homeward Way
Henderson, NV 89011

MAR 13 2019

Dear Daisy G. De Guzman:

RE: OI File No. 2-11-40392-9

Your request for the reinstatement of your eligibility to participate as a provider of items and services covered by the title XVIII (Medicare) program has been approved. The reinstatement is effective with the date of this notice.

We have notified the appropriate State agencies of this action. However, the States are not obligated to reinstate you to their programs if they have imposed a longer period of exclusion under their own authority.

We recommend that you contact the Medicare carrier to determine your options for participating in that program.

Although your right to participate in the Federal health care programs has been reinstated effective with the date of this letter, your name will remain on the List of Excluded Individuals/Entities (LEIE) until the next monthly update. You can access the LEIE online at http://oig.hhs.gov/exclusions/index.asp. You should use this letter to demonstrate that your right to participate in the Federal health care programs has been reinstated until your name is removed from the LEIE.

Sincerely,

William T. Echols
Reviewing Official
Health Care Program Exclusions

National Practitioner Data Bank
Health Resources and Services Administration
U.S. Department of Health and Human Services
P.O. Box 10832
Chantilly, VA 20153-0832
https://www.npdb.hrsa.gov

DCN: 5500000191821111
Process Date: 06/15/2022
Page: 1 of 3
DE GUZMAN, DAISY

DE GUZMAN, DAISY

CENTERS FOR MEDICARE AND MEDICAID SERVICES

REVISION TO GOVERNMENT ADMINISTRATIVE ACTION

Date of Action: 02/01/2020

Subsequent Action	Basis for Initial Action
- REINSTATEMENT	- OTHER, SEE SECTION C. OF THE REPORT FOR DETAILS - CRIMINAL CONVICTION

A. REPORTING ENTITY

Entity Name:	CENTERS FOR MEDICARE AND MEDICAID SERVICES
Address:	7500 SECURITY BLVD
	C3-03-14
City, State, Zip:	BALTIMORE, MD 21244-1849
Country:	
Name or Office:	PROVIDERENROLLMENT@CMS.HHS.GOV
Title or Department:	PROVIDERENROLLMENT@CMS.HHS.GOV
Telephone:	(000) 000-0000
Entity Internal Report Reference:	
Type of Report:	REVISION
Related Report Number:	5500000174078262

B. SUBJECT IDENTIFICATION INFORMATION (INDIVIDUAL)

Subject Name:	DE GUZMAN, DAISY
Other Name(s) Used:	
Gender:	FEMALE
Date of Birth:	**/**/****
Organization Name:	
Work Address:	111 MULBERRY ST
City, State, ZIP:	NEWARK, NJ 07102
Organization Type:	
Home Address:	
City, State, ZIP:	
Deceased:	NO
Federal Employer Identification Numbers (FEIN):	
Social Security Numbers (SSN):	***-**-****
Individual Taxpayer Identification Numbers (ITIN):	
National Provider Identifiers (NPI):	
Professional School(s) & Year(s) of Graduation:	
Occupation/Field of Licensure:	PHYSICIAN (MD)
State License Number, State of Licensure:	
Drug Enforcement Administration (DEA) Numbers:	
Unique Physician Identification Numbers (UPIN):	
Name(s) of Health Care Entity (Entities) With Which Subject Is Affiliated or Associated (Inclusion Does Not Imply Complicity in the Reported Action):	
Business Address of Affiliate:	
City, State, ZIP:	
Nature of Relationship(s):	

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CONFIDENTIAL DOCUMENT - FOR AUTHORIZED USE ONLY

ANSWER TO PAGE 3 NO 2 AND 3

IN DEC.2011,I WAS ONE OF THE 14 NEW JERSEY DOCTORS ACCUSED OF ANTI- KICKBACK STATUE.THE FEDERAL GOVERNMENT SENT A SUPPOSED TO BE MARKETING AGENT FROM A PRIVATE MRI COMPANY AND GAVE ME A MONETARY GIFT AS A GRATITUDE FOR SENDING MRI REQUEST TO THEIR OFFICE,I RECEIVED $1,000.00 IN OCT 2011,$1,500.00 IN NOV 2011 AND ANOTHER $ 1,000.00 IN DEC 2011.

THIS EVENT WAS VIDEOD AND MY LAWYER RECOMMENDED TO PLEAD GUILTY FOR A LESSER OFFENSE.I LOST MY NJ LICENSE FOR 1 YEAR AND WAS SUSPENDED FROM MEDICAID AND MEDICARE FOR 10 YEARS,I WAS REINSTATED BY OFFICE OF INSPECTOR GENERAL IN MARCH 2019

ENCLOSED HEREWITH IS A COPY OF REINSTATEMENT FROM OFFICE OF INSPECTOR GENERAL,NPDB FROM CENTERS OF MEDICARE AND MEDICAID AND NJ MEDICAID.

National Practitioner Data Bank
Health Resources and Services Administration
U.S. Department of Health and Human Services
P.O. Box 10832
Chantilly, VA 20153-0832
https://www.npdb.hrsa.gov

DCN: 5500000191821111
Process Date: 06/15/2022
Page: 1 of 3
DE GUZMAN, DAISY

DE GUZMAN, DAISY

CENTERS FOR MEDICARE AND MEDICAID SERVICES

REVISION TO GOVERNMENT ADMINISTRATIVE ACTION

Date of Action: 02/01/2020

Subsequent Action	Basis for Initial Action
- REINSTATEMENT	- OTHER, SEE SECTION C. OF THE REPORT FOR DETAILS - CRIMINAL CONVICTION

A. REPORTING ENTITY

Entity Name:	CENTERS FOR MEDICARE AND MEDICAID SERVICES
Address:	7500 SECURITY BLVD C3-03-14
City, State, Zip:	BALTIMORE, MD 21244-1849
Country:	
Name or Office:	PROVIDERENROLLMENT@CMS.HHS.GOV
Title or Department:	PROVIDERENROLLMENT@CMS.HHS.GOV
Telephone:	(000) 000-0000
Entity Internal Report Reference:	
Type of Report:	REVISION
Related Report Number:	5500000174078262

B. SUBJECT IDENTIFICATION INFORMATION (INDIVIDUAL)

Subject Name:	DE GUZMAN, DAISY
Other Name(s) Used:	
Gender:	FEMALE
Date of Birth:	**/**/****
Organization Name:	
Work Address:	111 MULBERRY ST
City, State, ZIP:	NEWARK, NJ 07102
Organization Type:	
Home Address:	
City, State, ZIP:	
Deceased:	NO
Federal Employer Identification Numbers (FEIN):	
Social Security Numbers (SSN):	***-**-****
Individual Taxpayer Identification Numbers (ITIN):	
National Provider Identifiers (NPI):	
Professional School(s) & Year(s) of Graduation:	
Occupation/Field of Licensure:	PHYSICIAN (MD)
State License Number, State of Licensure:	
Drug Enforcement Administration (DEA) Numbers:	
Unique Physician Identification Numbers (UPIN):	
Name(s) of Health Care Entity (Entities) With Which Subject Is Affiliated or Associated (Inclusion Does Not Imply Complicity in the Reported Action):	
Business Address of Affiliate:	
City, State, ZIP:	
Nature of Relationship(s):	

CONFIDENTIAL DOCUMENT - FOR AUTHORIZED USE ONLY

000000 02 03 010874 028262 P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Daisy G. De Guzman, M.D.
[redacted] Homeward Way
Henderson, NV 89011

MAR 13 2019

Dear Daisy G. De Guzman:

RE: OI File No. 2-11-40392-9

Your request for the reinstatement of your eligibility to participate as a provider of items and services covered by the title XVIII (Medicare) program has been approved. The reinstatement is effective with the date of this notice.

We have notified the appropriate State agencies of this action. However, the States are not obligated to reinstate you to their programs if they have imposed a longer period of exclusion under their own authority.

We recommend that you contact the Medicare carrier to determine your options for participating in that program.

Although your right to participate in the Federal health care programs has been reinstated effective with the date of this letter, your name will remain on the List of Excluded Individuals/Entities (LEIE) until the next monthly update. You can access the LEIE online at http://oig.hhs.gov/exclusions/index.asp. You should use this letter to demonstrate that your right to participate in the Federal health care programs has been reinstated until your name is removed from the LEIE.

Sincerely,

William T. Echols
Reviewing Official
Health Care Program Exclusions

State of New Jersey
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
PO Box 712
TRENTON, NJ 08625-0712

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

CAROLE JOHNSON
Commissioner

JENNIFER LANGER JACOBS
Assistant Commissioner

September 22, 2020

Daisy De Guzman, MD
[redacted]Homeward Way
Henderson, NV 89011

Re: Reinstatement Request

Dear Dr. De Guzman,

This is to inform you that you are hereby reinstated to participate in the programs administered in whole or part by the Division of Medical Assistance and Health Services.

Your reinstatement is effective as of the date of this letter. However, please note that this reinstatement letter does not reactivate your New Jersey Medicaid provider number. Rather you must first submit a completed enrollment packet, along with a copy of this letter, to reactivate provider status. Provider Enrollment packets can be found online at www.njmmis.com or by calling the Provider Enrollment Unit at DXC Technology at 609-588-6036 to have an enrollment packet mailed to you.

Sincerely,

Jennifer Langer Jacobs
Assistant Commissioner

c: Kim Ranke, MFD

16

16A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR VETERINARIAN AUTHORITY TO DISPENSE DRUGS

Non-Refundable $150 fee

Rev (06/09/2021)

What types of drug(s) will you be dispensing?

☒ Dangerous Drugs AND Controlled Substances

☐ Dangerous Drugs ONLY

Section 1: Personal Information

First: Vincent Middle: P. Last: Alexis

Date of Birth: [redacted] SSN or ITIN [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted] Watercreek Dr.

City: N. Las Vegas State: NV Zip: 89032

Telephone: [redacted] Email: [redacted]

Degree: DVM Practitioner License #: NV 1109

(You MUST have a current and active license with your respective BOARD to apply for and maintain a dispensing registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Relief Veterinary Services

Practice Address: 1401 Watercreek Dr Suite #:

City: N. LV State: NV Zip: 89032

Telephone: 725 251 8369 Fax: — Email: Winstrol.41a Yahoo.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable?		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable?		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable?		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

SCANNED

AUG 31 2023

Section 4: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
	TX	2013	Unknown

Criminal Action:	State:	Date:	Case #:	County:	Court:
	NY	12-4-13	13CR-00155-FJS	Unknown	USDC, N. NY

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vincent Alexis DVM

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-4-2023

Date

Board Use Only Received: 1-9-23 Amount: 150.00 CK - 142

STATE OF NEVADA
NEVADA BOARD OF PHARMACY
RENO, NEVADA

Vincent P. Alexis, DVM Applicant, v. Nevada Board of Pharmacy Respondent.	Date: January 4, 2023 Nevada Veterinary Lic. No. 1109 Nevada Controlled Substance No. CS32984 DEA No. FA1174856

VINCENT P. ALEXIS, DVM
HEREBY PROVIDES ANSWERS TO APPLICATION
QUESTION #2, IN REGARD TO HIS
DECEMBER 2013 FELONY CONVICTION
DOCKET #13-CR-00155-GTS, N.D. NEW YORK

Affidavit of Applicant: Vincent P. Alexis
Via 28 U.S.C. Section 1746, States as Follows:

[1] On December 4, 2013, Dr. Alexis was convicted of one count of Attempted Travel in Interstate & Foreign Commerce to Engage in Illicit Sexual Conduct, a Class B Felony.

[2] On July 23rd & 24th of 2011, Dr. Alexis was forced to sign a confession under duress by former Syracuse special agent Sean Boutot.

[3] This confession was then immediately used against Dr. Alexis, and quickly events unfolded which made it impossible for him to mount a proper defense.

[4] Dr. Alexis is factually, actually, & legally innocent. Unfortunately, he was unable to appeal his conviction due to Ineffective Assistance of Counsel, multiple Constitutional Rights violations, and due to a prolonged, life-threatening, illness (sepsis & bilateral, multifocal, lung abscesses) which struck shortly after his sentencing.

[5] For more thorough details, please see:

I. USA v. Alexis, #13-CR-00155-GTS (N.D. New York);

II. USA v. Alexis, #18-1622 (Dr. Alexis's attempt to obtain a copy of the Grand Jury Minutes) USCA (2nd Circuit);

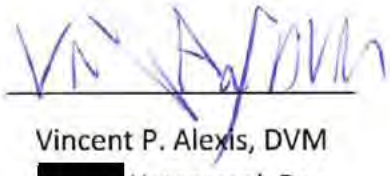
III. Dr. Alexis's Petition for Commutation/Pardon/Clemency/Reduction of Prison Sentence, Office of the Pardon Attorney/President Donald Trump, February 9. 2019. Case File # C285151;

IV. Nevada State Board of Veterinary Medical Examiners Board Meeting Minutes, April 22, 2021;

V. Dr. Alexis's Petition for License Reinstatement to the Nevada State Board of Veterinary Medical Examiners, April 18, 2019. Please note that the State Board reinstated Dr. Alexis's license to practice veterinary medicine in the State of Nevada on August 19, 2021.

Signed under 28 U.S.C. §1746,
Under penalties of perjury the above
& the following to be true, correct,
& complete. Pro-se.

Respectfully Submitted by:



Vincent P. Alexis, DVM
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032

STATE OF NEVADA
NEVADA BOARD OF PHARMACY
RENO, NEVADA

Vincent P. Alexis, DVM Applicant, v. Nevada Board of Pharmacy Respondent.	Date: January 4, 2023 Nevada Veterinary Lic. No. 1109 Nevada Controlled Substance No. CS32984 DEA No. FA1174856

VINCENT P. ALEXIS, DVM HEREBY PROVIDES ANSWERS TO APPLICATION QUESTION #3, IN REGARD TO HIS JANUARY 2013 TEXAS BOARD OF VETERINARY MEDICAL EXAMINERS ACTION AGAINST HIS LICENSE TO PRACTICE VETERINARY MEDICINE IN THE STATE OF TEXAS

Affidavit of Applicant: Vincent P. Alexis, DVM
Via 28 U.S.C. Section 1746,
States as Follows:

[1] In January of 2013, the Texas Board of Veterinary Medical Examiners found Vincent P. Alexis, DVM (hereinafter referred to as Dr. Alexis) guilty of working for a non-DVM owned hospital in the State of Texas.

[2] In a separate action, "Texas Attorney General Opinion #GA-0064 states that under Section 53.021 of the Occupational Code, a license holder's license is revoked by operation of law upon the license holder's imprisonment following a felony conviction..." (Exhibit: 2). Dr. Alexis's Texas license was "Automatically revoked by operation of law on December 4, 2013."

[3] The attached Exhibits (Exhibits: 1-8), and Affidavits, will explain the above circumstances (many of which were unfair and poorly handled by the Texas Board of Veterinary Medical Examiners) more clearly.

Signed under 28 U.S.C. §1746,
Under penalties of perjury the above
& the following to be true, correct,
& complete. Pro-se.

Respectfully Submitted by:

Vincent P. Alexis, DVM
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032

Exhibits

1) Vincent P. Alexis, DVM v. State of Texas Secretary of State & Texas Board of Veterinary Medical Examiners, Petition, 7 pages, November 1, 2018.
2) Texas Board of Veterinary Medical Examiners, Order, 1 page, February 18, 2014.
3) Vincent P. Alexis, DVM Petition for License Reinstatement to the Nevada State Board of Veterinary Medical Examiners, 12 pages, April 18, 2019.
4) Vincent P. Alexis, DVM Addendum to Petition for License Reinstatement to the Nevada State Board of Veterinary Medical Examiners, 4 pages, September 14, 2020.
5) Vincent P. Alexis License Reinstatement Verification, 1 page, August 19, 2021.
6) Vincent P. Alexis, DVM Proof of active licensure, 1 page, January 4, 2023.
7) Vincent P. Alexis, DVM NV Controlled Substance Registration, 1 page.
8) Vincent P. Alexis, DVM DEA License, 1 page.

State of Texas
Secretary of State
Travis County
Austin, Texas

Exhibit: 1

Vincent P. Alexis, DVM Petitioner, v. State of Texas Secretary of State, Texas Board of Veterinary Medical Examiners Respondants.	Texas DVM Lic. # 11628 November 1, 2018

Affidavit of Petitioner: Alexis, in support of complaint against the Texas Board of Veterinary Medical Examiners, signed under 28 U.S.C. §1746 under penalties of perjury the above & the following to be true, correct, & complete. Pro-se.

PETITIONER: ALEXIS RESPECTFULLY REQUESTS THAT THE TEXAS SECRETARY OF STATE VACATE THE JANUARY 2013 GUILTY VERDICT HANDED DOWN BY THE TEXAS BOARD OF VETERINARY MEDICAL EXAMINERS AGAINST ALEXIS FOR A PRACTICE ACT VIOLATION, BECAUSE OF HIS WORKING FOR A NON-DVM OWNED ANIMAL HOSPITAL.

Background

[1] In January of 2011, Dr. Alexis signed on as a relief veterinarian with Relief Services for the Veterinary Practitioner (RSVP), operating out of Denton, Texas.

[2] Dr. Alexis was routinely called upon by RSVP to work fill-in (relief) shifts at various Texas animal hospitals. His work with/for RSVP lasted through April of 2013.

[3] Dr. Alexis was called upon to work throughout Texas, while residing fifteen minutes East of Austin. His work called upon him to commute as far North as Dallas/Ft. Worth, & as far South as Harlingen.

Exhibit: 1

[4] It was common for Dr. Alexis to receive a work assignment just days before the shift (that's the nature of relief work, as you cannot easily predict when a hospital's staff veterinarian becomes ill, or cannot work their shift).

[5] When RSVP asked Dr. Alexis to cover a shift, he always agreed to do so. He quickly became one of RSVP's "go to" veterinarians, & took pride in his work ethic and availability.

[6] In 2011, RSVP placed Dr. Alexis at two different non-DVM owned animal hospitals - one in Houston, & one in LaMarque. No incidents or concerns arose from his relief work at these hospitals.

[7] Approximately three days after Christmas 2011, Dr. Alexis was asked to work at Furry Friends Animal Hospital (FFAH), located in Harlingen, Texas. This relief work was to last approximately one month, & was scheduled to begin on the first work-day of 2012.

[8] A few days into the first week of work at FFAH, the receptionist (Alina Scovell) mentioned to Dr. Alexis that the Texas State Board of Veterinary Medical Examiners (TXBVME) had visited the hospital, un-announced, in mid-November, 2011. They met with Christine (Chris) Morris, the owner, & with Dr. Hayes, another RSVP veterinarian who was providing coverage.

[9] Ms. Scovell elaborated that at that meeting, the TXBVME informed Ms. Morris & Dr. Hayes that the Board believed that the operation of FFAH was illegal/in violation of TXBVME practice laws, since the hospital was not "owned by a veterinarian." The TXBVME stated that they would issue a decision, within 10 days, by certified mail.

Exhibit: 1

[10] Obviously, Dr. Alexis was concerned to hear about the State Board's visit, & their concerns about the legality of Ms. Morris's venture. He spoke about this with Ms. Morris & she assured Dr. Alexis that her attorney had contacted the TXBVME, & that "Everything was in order." Furthermore, Ms. Morris was quick to point out that the TXBVME never did send the certified mailing instructing her to cease & desist operation of FFAH.

[11] Later that same day, Ms. Morris called her attorney. She wanted to assure Dr. Alexis that he would be able to practice at her hospital without concerns, so she asked him to speak with her attorney. Dr. Alexis did speak to Ms. Morris's attorney at that time. He informed Dr. Alexis that Ms. Morris & FFAH were in full compliance with all TXBVME rules & regulations, & that the TXBVME never did send a certified mailing or issue a cease & desist order.

[12] Ms. Scovell, who as the only receptionist received all the mail, also verified to Dr. Alexis that there was no certified mailing sent to FFAH from the TXBVME, after that mid-November 2011 visit/meeting.

[13] After speaking with Ms. Scovell, Ms. Morris, & her attorney, Dr. Alexis obtained Dr. Hayes' phone number & called him. Dr. Hayes verified that the TXBVME had visited the hospital, unannounced, in mid-November 2011. He also verified to Dr. Alexis that there was no certified mailing sent to FFAH from the TXBVME, after that visit. Dr. Hayes further commented that he hadn't heard from the TXBVME at all since mid-November.

Exhibit: 1

[14] Dr. Alexis also discussed this concern with Monica Hughes at RSVP. She informed Dr. Alexis that they had no knowledge of any TXBVME action or concerns regarding FFAH.

[15] Since RSVP had provided services to FFAH, without concerns, prior to his coverage, & since Ms. Morris, her attorney, Ms. Scovell, & Dr. Hayes all verified that the TXBVME never did issue a cease & desist order, Dr. Alexis continued to provide relief services to FFAH. He had made a commitment to RSVP and to FFAH (a one doctor practice) & its clients, and had no reason to abruptly cancel his coverage.

[16] Ms. Morris had been looking for a full-time staff veterinarian, without success. For this reason, she turned to RSVP for coverage, & in early February 2012 she asked Dr. Alexis to extend his stay. Dr. Alexis agreed to stay for up to one year, so that Ms. Morris would have more time to hire a staff veterinarian.

[17] Approximately eight weeks later, while working at FFAH, Dr. Alexis received a phone call from his brother (& attorney) Drew L. Alexis. Drew informed Dr. Alexis that he had just received a phone call from the TXBVME's attorney. That attorney informed Drew that FFAH was operating illegally, & that Dr. Alexis needed to immediately stop working there. Drew was told by the TXBVME that they wanted to stop Ms. Morris, & that they "Had no interest in pursuing charges against Dr. Alexis, as long as he cooperated & left the practice right away." The TXBVME did not contact Dr. Alexis directly (either by U.S. mail or by phone).

Exhibit: 1

[18] Dr. Alexis agreed to leave the practice. He immediately informed Drew Alexis, RSVP, & Ms. Morris of his intention to comply with the TXBVME order.

[19] Dr. Alexis was now faced with a few acute problems:

[A] Dr. Alexis had just finished up with an OHE (spay) surgery on a dog who was in dystocia & unable to give birth. The queen & her pups needed his care. Dr. Alexis was not willing to depart from Harlingen until these patients were doing well.

[B] Dr. Alexis was not willing to leave behind the controlled drugs which he had ordered under his DEA license (there were no controlled drugs in the hospital upon Dr. Alexis's arrival).

[20] Within 48 hours, Dr. Alexis departed Harlingen & headed North for his home. He took all of the controlled drugs which he had ordered/purchased with him. He did not take any other biologicals or pharmaceuticals which were stocked at FFAH - Dr. Alexis did not purchase/own these items, & therefore had no legal right to remove the items from the premesis (to do so would have been grand theft).

[21] Dr. Alexis is unsure if a cease & desist order was issued to Ms. Morris & FFAH. It does appear, however, that FFAH did not close when the TXBVME ordered Dr. Alexis to leave on/about mid/late April 2012.

Exhibit: 1

[22] Many months later, Dr. Alexis received notice (by U.S. mail) that the TXBVME was pursuing charges against him. The charges included:

[A] Violations of a Practice Act by working for a non-DVM owned hospital.

[B] Violations resulting from Dr. Alexis's decision to leave behind the biologicals/pharmaceuticals which were stocked at FFAH when he departed (see points 19 & 20 above).

[23] On/about January 2013 Dr. Alexis & his San Antonio attorney Keith O'Connell met with the TXBVME in Austin. At that hearing, Dr. Alexis was found **Guilty** of a Practice Act Violation, stemming from his relief work at Furry Friends Animal Hospital from January 3, 2012 through mid/late April 2012.

Conclusion

[24] The TXBVME did not perform their duty in a timely & appropriate manner. The TXBVME was clearly aware of Ms. Morris & her venture, Furry Friends Animal Hospital, in **mid-November 2011**. Nevertheless, the TXBVME failed to act in 2011. The Board waited five full months before taking appropriate action, in **mid/late April 2012.**

Exhibit: 1

[25] Had the TXBVME performed their duty in a timely manner, RSVP would have been aware of their concerns. In turn, Dr. Alexis would also have been aware of the TXBVME's concerns, & never would have agreed to provide relief services at Furry Friends Animal Hospital.

Relief Requested

[26] Dr. Alexis is requesting, for the above stated reasons, that the **Guilty** verdict handed down by the TXBVME in January of 2013, for the above mentioned Practice Act Violation, be **Vacated.** The TXBVME was well aware of Ms. Morris & her illegal venture in mid-November 2011. A five month delay in acting is unconscionable, & is a clear failure by the Texas Board of Veterinary Medical Examiners to protect its veterinarians & the public from unscrupulous business owners like Ms. Morris.

Signed under 28 U.S.C. §1746,
Respectfully Submitted by
Petitioner/Affiant:

Vincent P. Alexis, DVM
3905 Lemon Ave
Long Beach, CA 90807

Exhibit: 2

TEXAS BOARD OF VETERINARY MEDICAL EXAMINERS

DOCKET NO. 2013-123

ORDER PERTAINING TO REVOCATION OF

LICENSE NO. 11628

WHEREAS, the Texas Board of Veterinary Medical Examiners (Board) finds that on December 4, 2013, VINCENT ALEXIS, D.V.M., formerly of Elgin, Texas, License No. 11628, was convicted by the United States District Court for the Northern District of New York, of Attempted Travel in Interstate and Foreign Commerce to Engage in Illicit Sexual Conduct, a Class B felony, and sentenced to confinement in the Institutional Division of the Texas Department of Criminal Justice; and

WHEREAS, under current law, VINCENT ALEXIS, D.V.M., began his imprisonment upon the date of his conviction; and

WHEREAS, Texas Attorney General Opinion No. GA-0064 states that under Section 53.021 of the Occupations Code, a license holder's license is revoked by operation of law upon the license holder's imprisonment following a felony conviction, felony community supervision revocation, revocation of parole, or revocation of mandatory supervision;

THEREFORE, the Board FINDS that:

1. License No. 11628 issued to VINCENT ALEXIS, D.V.M., was automatically revoked by operation of law on December 4, 2013.

2. VINCENT ALEXIS, D.V.M., may apply for re-licensure in the same manner as a person applying for a new license and shall be subject to the requirements of Board Rule 575.22 relating to license reinstatement.

The Board ORDERS that:

A copy of this Order shall be mailed by first class mail to VINCENT ALEXIS' last known mailing address as reflected in the Board's records on this date.

RATIFIED and ADOPTED THIS THE 18th DAY OF FEBRUARY, 2014, BY AN AFFIRMATIVE VOTE OF THE BOARD.

Bud. E. Alldredge, Jr., D.V.M., President

Exhibit: 3

Remit to:

State of Nevada Board of Veterinary Medical Examiners

4600 Kietzke Lane, Bldg. O, #265, Reno, NV 89502

(775) 688-1788 phone / (775) 688-1808 fax

Reinstatement of License to Practice Veterinary Medicine in the State of Nevada $200.00

PERSONAL INFORMATION

Name: Vincent Alexis

Address: [redacted] Lemon Ave

City: Long Beach State: CA Zip: 90807

Telephone: [redacted]

Social Security Number: [redacted]

Date of Birth: [redacted]

Place of Birth: White Plains, New York

Other Name(s) used: N/A

Email: None

Are you a citizen of the U.S. ☒ Yes ☐ No . *If not you must provide proof that you are lawfully entitled to remain and work in the U.S.*

CONTINUING EDUCATION HOURS COMPLETED IN THE LAST 12 MONTHS

Name: _____ Date Attended: _____

Continuing Education Hours obtained: _____ Location: _____

** PLEASE PROVIDE A COPY OF THE CE DOCUMENTS

List of State(s) you are licensed in or have been licensed in:

State	License Number	Date Issued
Nevada	1109	1997
Colorado	5835	May, 1994
New York	7242	August 1995
Utah	6959488-2801	March 2008
Texas	11628	

Are you a Board Certified Diplomate? ☐ Yes ☒ No If so, what is your specialty? _____

EMPLOYER IN NEVADA

Employer Name: Dr. Ylarde, East Charleston Animal Hosp Starting Date: Fall 2019

Address: 601 E. Charleston City: Las Vegas State: NV Zip: 89104

EMPLOYMENT HISTORY FOR THE LAST 5 YEARS

Employer Name: _____

Address: _____

City: _____ State: ____ Zip: _____

Employer Name: _____

Address: _____

City: _____ State: ____ Zip: _____

Employer Name: _____

Address: _____

City: _____ State: ____ Zip: _____

Employer Name: _____

Address: _____

City: _____ State: ____ Zip: _____

Exhibit: 3

1. **Have you previously filed an application with the Nevada State Board of Veterinary Medical Examiners?** ..... **Yes:** X **No:** _____
   If yes, when? 1997
2. **Have you ever been charged, arrested or convicted of a felony or gross misdemeanor?** ..... **Yes:** X **No:** _____
3. **Have you ever been found guilty, pleaded guilty, or entered a plea of nolo contendere to any administrative or legal offense in connection with the practice of veterinary medicine?** ..... **Yes:** X **No:** _____
4. **Have you ever surrendered a professional license?** (Revoked). **Yes:** X **No:** _____
5. **Do you have a medical condition which in any way impairs or limits your ability to practice with reasonable skill and safety?** ..... **Yes:** _____ **No:** X
6. **Do you take a chemical substance(s) which in any way impairs or limits your ability to practice with reasonable skill and safety?** ..... **Yes:** _____ **No:** X
   If yes, please answer the following questions.
7. **Are the limitations or impairments caused by your medical condition reduced or ameliorated because you receive ongoing treatment (with or without medications) or participate in a monitoring program?** ..... **Yes:** _____ **No:** _____
8. **Are the limitations or impairments caused by your medical condition reduced or ameliorated because of the field of practice, the setting or the manner in which you have chosen to practice?** ..... **Yes:** _____ **No:** _____

**If your answer is yes to any of the above questions, please attach a signed statement of explanation. Copies of any documents that identify the circumstances or contain a court order, agreement, or other disposition are required.*

Please Attach
Photo Here

**Please include a passport sized photo of yourself. It must have been taken within 60 days preceding the date of this application.
**Failure to provide any of the requested information or falsifying information will result in the application being rejected.

Exhibit:3

WAIVER FORM

I hereby authorize the Nevada State Board of Veterinary Medical Examiners, its agents, servants, and employees, to conduct such investigations of my business, professional, social and moral background, qualifications and reputation as it or its members or any of them deem necessary, proper or desirable.

This authorization is given in connection with my application for a license to practice as a Veterinarian in the State of Nevada and to enable the said Nevada State Board of Veterinary Medical Examiners to give intelligent and proper consideration to such application.

No liability of any sort or kind shall attach to the said Nevada State Board of Veterinary Medical Examiners, its members, agents, servants, employees or anyone furnishing them information about me or my past activities, because or by reason of the use of this authorization.

I Vincent Alexis, being first duly sworn, depose and state that I am the person referred to by said name of Vincent Alexis in the above and annexed questions, answers, and statements. I have read all of said questions, answers and statements, and know the contents thereof. I hereby certify under penalty of perjury that the information furnished in this document is true and correct.

Dated this 18th day of April, 2019

Signature of Applicant

State of New Jersey, County of Burlington

Dated this 18th day of April, A.D., 2019. personally appeared before me, a Notary Public in and for the County of Burlington known to me to be the person described in and who executed the foregoing instrument, who acknowledged to me that he executed the same freely and voluntarily and for the uses and purposes therein mentioned.

IN WITNESS THEREOF, I have hereunto set my hand and affixed my official seat at my office in the County of Burlington, the day and year in this Certificate first above written. S. Boyd

SHONDEL A. BOYD
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 8/9/2023

CHILD SUPPORT INFORMATION

Professional or occupational licenses, certified, or permits may be denied or restricted if back child support is owed by the person holding the license. Any license by the State of Nevada Board of Veterinary Medical Examiners is subject to this new requirement mandated by the federal government of all states including Nevada.

Please mark the appropriate response
(failure to mark one of the three will result in denial of the application)

X I am not subject to a court order for the support of a child.

____ I am subject to a court order for the support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

____ I am subject to a court order for the support of one or more children and am not in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Signature

April 18 2019
Date

Exhibit: 3

STATE OF NEVADA
BOARD OF VETERINARY MEDICAL EXAMINERS
RENO, NEVADA

Vincent P. Alexis, DVM Applicant, v. Nevada State Board of Veterinary Medical Examiners Respondent.	Date April 18 2019 Nevada License #1109

VINCENT P. ALEXIS, DVM
HEREBY PROVIDES ANSWERS TO APPLICATION
QUESTION #2, IN REGARDS TO HIS
DECEMBER 2013 FELONY CONVICTION
DOCKET #13-CR-00155-GTS, N.D.NY/SYRACUSE

Affidavit of Applicant: Vincent P. Alexis
via 28 U.S.C. §1746, States as Follows:

[1] On December 4, 2013 Alexis was convicted of one count of Attempted Travel in Interstate & Foreign Commerce to Engage in Illicit Sexual Conduct, a Class B Felony.

[2] On July 23rd & 24th of 2011, Alexis was forced to sign a confession under duress by Syracuse Special Agent Sean Boutot.

[3] This confession was then immediately used against Alexis, and quickly events unfolded which made it impossible for him to mount a proper defense.

Exhibit: 3

[4] Alexis is factually, actually, & legally innocent. Unfortunately, he was unable to appeal his conviction due to Ineffective Assistance of Counsel, & due to a prolonged, life-threatening, illness (sepsis & bilateral, multifocal, lung abscesses) which struck shortly after his sentencing.

[5] For more thorough details, please see:

A) USA v. Alexis, #13-CR-00155-GTS (N.D.NY/Syracuse).

B) USA v. Alexis, #18-1622 (Alexis's attempt to obtain a copy of the Grand Jury Minutes), USCA (2nd Circuit).

C) Alexis's Petition for Commutation/Pardon/Clemency/or Reduction of Prison Sentence, Office of the Pardon Attorney/President Donald Trump, February 9, 2019. Case File #C285151.

Signed under 28 U.S.C. §1746, under penalties of perjury the above & the following to be true, correct, & complete. Pro-se.

Respectfully Submitted By:
Applicant/Affiant

Vincent P. Alexis, DVM
19213-052
FCI Fort Dix
Box 2000
J.B. MDL, NJ 08640

Exhibit:3

STATE OF NEVADA
BOARD OF VETERINARY MEDICAL EXAMINERS
RENO, NEVADA

Vincent P. Alexis, DVM
Petitioner,

v.

Nevada State Board of
Veterinary Medical Examiners
Respondent.

Date_____

Nevada License #1109

VINCENT P. ALEXIS, DVM REQUESTS THE NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS REINSTATE HIS LICENSE TO PRACTICE VETERINARY MEDICINE IN THE STATE OF NEVADA (#1109) TO ACTIVE STATUS, ON A PROVISIONAL BASIS, FOR THE FOLLOWING CONSIDERATIONS, & WITH THE FOLLOWING STIPULATIONS APPROVED BY THE BOARD

Affidavit of Petitioner: Vincent P. Alexis, hereinafter referred to as Alexis, via 28 U.S.C. §1746, states as follows:

Background

[1] Alexis was issued Nevada license #1109, a license to practice veterinary medicine in the State of Nevada, in 1997.

[2] Alexis practiced veterinary medicine in Nevada, on a full-time basis, from 1997-2011, with no State Board actions against him during those 15 years.

[3] Alexis practiced veterinary medicine in New York State from 1994-1997, with no State Board actions against him during those 3 years.

[4] Alexis practiced veterinary medicine in the State of Utah for 5 months during 2008, with no State Board actions against him during that time.

[5] Alexis practiced veterinary medicine in the State of Colorado for 4 months during 1994, with no State Board actions against him during that time.

[6] Alexis practiced veterinary medicine as a relief veterinarian in the State of Texas from 2011-April 2013. Alexis did receive a State Board incident/sanction, resulting in discipline in 2013 (please see Exhibit:1 for a thorough explanation of this issue).

[7] Alexis has been incarcerated since April of 2013, & has been unable to participate in CE conferences/meetings.

[8] Alexis understands the importance of a veterinarian's responsibility to obtain regular CE in order to expand his/her knowledge and to stay updated on current topics & developments.

[9] Alexis has, from 1994 through 2012, religiously attended CE conferences. During this time period, he has amassed twice as many CE credits as required by the states in which he is/was licensed.

Exhibit: 3

[10] Alexis will attend the first available CE conference upon his return to Nevada. He will also immediately complete the maximum amount of online CE, which has been approved by the Board. A second CE conference will be attended within 3-5 months of Alexis's first conference. With this course of action, Alexis should quickly amass enough CE credits to cover 2019 & 2020.

Status of State Licenses

[11] **Colorado**
License #5835

Alexis did not renew his Colorado license. The license expired in/around 2012 (Alexis is unsure of the precise date).

[12] **Utah**
License #6959488-2801

Alexis did not renew his Utah license. Alexis is unsure of the date when the license expired.

[13] **New York**
License #7242

Alexis did not renew his New York license. The license expired in/around 2013 (Alexis is unsure of the precise date).

Exhibit:3

[14] **Texas License #11628**

"Texas Attorney General Opinion #GA-0064 states that under §53.021 of the Occupations Code, a license holder's license is revoked by operation of law upon the license holder's imprisonment following a felony conviction..." (Exhibit:2). Alexis's Texas license was "Automatically revoked by operation of law on December 4, 2013."

[15] Alexis has requested a "Letter of Good Standing" from New York, Colorado, Utah, & Texas be sent to the Nevada Board of Veterinary Medical Examiners.

Discussion

[16] Alexis is asking for help & understanding, as he strives to put his life, and career, back on track.

[17] Alexis will almost certainly be restricted from traveling outside of the Southern Nevada region for an extended period of time, upon his release from Fort Dix. This will clearly limit his CE options to Las Vegas Conferences (such as Western States), and online CE.

[18] Obviously, it's extremely important that Alexis is able to earn a living immediately upon his release from Fort Dix. This, clearly centers around his ability to practice veterinary medicine in Nevada.

Exhibit 3

[19] So, Alexis has an obvious dilemma - there might be a significant delay before Alexis has the required amount of CE credits for the Nevada Board of Veterinary Medical Examiners to reinstate his license to practice veterinary medicine.

Relief Requested

[20] WHEREFORE, for the above stated reasons, Dr. Alexis respectfully requests that the Nevada Board of Veterinary Medical Examiners reinstates his license to practice veterinary medicine in Nevada immediatley upon receipt of his application and the $200 fee.

[21] Dr. Alexis will (at the first opportunity approved by U.S. Probation) immediately complete the maximum amount of online CE, which has been approved by the Board.

[22] Dr. Alexis will attend the first available CE conference upon his return to Nevada.

[23] A second CE conference will be attended within 3-5 months of the first conference (with the approval of U.S. Probation).

[24] With this course of action, Dr. Alexis should quickly amass enough CE credits to cover the Board's requirement for his license reinstatement.

Exhibit:3

Conclusion

[25] Dr. Alexis has a proven history of 15 years of active, full-time, practice in Nevada with no state disciplinary actions. During that time, one client filed a complaint against Dr. Alexis. The Board quickly dismissed that sole complaint (Dr. Alexis had not treated the dog in question, an employee of Paw Prints Animal Hospital/Alexis Veterinary Services, LLC [Dr. Paguyo] had treated the client's pet and apparently missed its splenic neoplasia).

[26] Dr. Alexis is asking for help & understanding, as he strives to put his life, and career, back on track. He has employment waiting for his return to Las Vegas, with Dr. Julie Ylarde at East Charleston Animal Hospital.

[27] Dr. Alexis has been accepted into a Las Vegas release program called Hope for Prisoners (Exhibit:5). This program will provide support, so that he can have the best chance of success in the future.

[28] Other than the one charge that resulted in his incarceration, Dr. Alexis has had no prior criminal history/arrests/convictions. He's a first-time, non-violent, offender, and is no threat to anyone, (Exhibits:3 & 4).

[29] Dr. Alexis would like very much to move forward with life. There's a lot that he has to offer to the pets, people, & wildlife of Southern Nevada.

Exhibit: 3

Signed under 28 U.S.C. §1746,
under penalties of perjury the above
& the following to be true, correct,
& complete. Pro-se.

Respectfully Submitted By
Petitioner:

Vincent P. Alexis, DVM
19213-052
FCI Fort Dix
Box 2000
J.B. MDL, NJ
08640

Certificate of Service

I, Vincent Alexis, hereby certify
that I have sent a copy of this
Petition
via United States Mail/Postage Prepaid
on this ___ day of April, 2019
to the following:

Nevada Board of Veterinary Medical Examiners
4600 Kietzke Lane
Building O-265
Reno, Nevada
89502

Vincent P. Alexis, DVM

Exhibit: 4

STATE OF NEVADA
BOARD OF VETERINARY MEDICAL EXAMINERS
RENO, NEVADA

VINCENT P. ALEXIS, DVM Petitioner, v. NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS Respondent.	ADDENDUM Date: September 14, 2020 Nevada License # 1109

PETITIONER, VINCENT P. ALEXIS DVM, HEREBY SUBMITS AN ADDENDUM TO HIS APRIL 18, 2019 PETITION TO THE NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS FOR REINSTATEMENT OF HIS LICENSE TO PRACTICE VETERINARY MEDICINE IN THE STATE OF NEVADA

Affidavit of Applicant Vincent P. Alexis DVM,
Via 28 U.S.C §1746, States as Follows:

General Background

[1] On April 18, 2019, Petitioner: Vincent P. Alexis, DVM submitted a Petition for license reinstatement with the Nevada State Board of veterinary Medical Examiners.

Exhibit:4

[2] Today, Dr. Alexis submits an addendum to that Petition. The purpose of this addendum is to update the State Board of events which transpired since the initial submission, and to provide additional letters of reference in support of Dr. Alexis's Petition for license reinstatement.

Factual Statement

[3] Dr. Alexis attended the February, 2020 Western States Veterinary Conference, and completed 5 hours of online continuing education. He now has 38 Continuing Education credits.

[4] Dr. Alexis was released from FCI Fort Dix on September 18, 2019 and returned to Las Vegas, Nevada.

[5] Dr. Alexis is now under the authority of U.S. Probation Officer Steven M. Goldner {300 Las Vegas Blvd. South, Suite 1200, Las Vegas, Nevada 89101, (702) 591-0895}.

Exhibit: 4

[6] Dr. Alexis graduated into the Hope for Prisoners program in January of 2020. This program offers an amazing amount of support for people returning to society. The program has a record-low recidivism rate (approximately 7%), which is far below the national average (approximately 90%).

[7] The evidence before The Board shows that Dr. Alexis has taken many positive steps, and has done everything asked and required of him, since July of 2011. Dr. Alexis has served his debt to society. Dr. Alexis has been patient throughout this license reinstatement process (having applied 18 months ago). Dr. Alexis poses no threat to society. In fact, he is an asset to society.

Relief Requested

[8] Dr. Alexis respectfully requests that The Nevada Board of Veterinary Medical Examiners reinstitute his license to practice veterinary medicine (Lic. No. 1109).

Exhibit: 4

CERTIFICATION

Pursuant to the provisions of 28 Section 1746(2),
I hereby declare under the penalty of perjury that the foregoing
Is true and correct.

Respectfully Submitted,

VINCENT P. ALEXIS, DVM
[redacted] Watercreek Drive
N. Las Vegas, Nevada 89032

VERIFICATION

I have read the foregoing complaint and hereby verify that the matters alleged therein are true, except as to matters alleged on information and belief, and as to those, I believe them to be true. I certify under the penalty of perjury that the foregoing is true and correct.

Executed at North Las Vegas, Nevada, on September 14, 2020.

Exhibit: 5

Active Licensure

From: Jennifer Pedigo (vetbdinfo@vetboard.nv.gov)

To: winstrol.41@yahoo.com

Cc: dalexis@alexislawfirm.com; louisling@me.com

Date: Thursday, August 19, 2021, 02:53 PM PDT

Good afternoon Dr. Alexis,

I went ahead and made your license active per our conversation. Your license number is 1109 and your license information is now searchable on the license verification page at https://nvvetboard.nv.gov



nvvetboard.nv.gov - Nevada Board of Veterinary Medical Examiners

Search This Site Search All Sites Close State Agencies State Jobs ADA Assistance. Home

nvvetboard.nv.gov

We will go ahead and send a new wall certificate out to East Charleston so you have a new copy. You can also log in to the licensee portal using the email address above and print on-demand wallet cards as well.

Please let me know if you have any questions and I will be in touch if I hear anything from Mr. Stark or his office.

Thank you,
Jennifer Pedigo
Executive Director

Nevada State Board of
Veterinary Medical Examiners

LICENSE CARD

This is to certify that
Vincent Alexis
holds

status as a
Veterinarian
in the state of Nevada in accordance with
Nevada Revised Statutes Chapter 630.

License #
1109

Issue Date:
January 08, 1997

Expiration Date:
June 30, 2023

For the most up-to-date information about this licensee
please visit our online licensee lookup at medboard.nv.gov.

PLEASE NOTIFY THE NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS OF ANY CHANGE OF ADDRESS IMMEDIATELY

Exhibit: 6

Nevada State Board Of Pharmacy

Exhibit: 7

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 10/05/2022
Amount: $ 210.00
License #: CS32984

VINCENT P. ALEXIS
1401 Watercreek Dr
North Las Vegas NV 89032

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Controlled Substance
Effective Date:11/01/2022
Expires:10/31/2024

VINCENT P. ALEXIS
1401 Watercreek Dr
North Las Vegas NV 89032

License #
CS32984
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Controlled Substance

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Expires: 10/31/2024
STATUS: Active

License Type: Controlled Substance
License #: CS32984
Effective Date:11/01/2022
DEA #: FA1174856/22N33N4&5

VINCENT P. ALEXIS
1401 Watercreek Dr
North Las Vegas NV 89032

NONTRANSFERABLE

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

Exhibit: 8

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA1174856	06-30-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	PRACTITIONER	02-11-2022

ALEXIS, VINCENT PAUL
LOCUM TENENS
1401 WATERCREEK DRIVE
NORTH LAS VEGAS, NV 89032-0000

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA1174856	06-30-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	PRACTITIONER	02-11-2022

ALEXIS, VINCENT PAUL
LOCUM TENENS
1401 WATERCREEK DRIVE
NORTH LAS VEGAS, NV 89032-0000

CONTROLLED SUBSTANCE/REGULATED CHEMICAL REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

REPORT

CHANGES

PROMPTLY

Form DEA-223/511 (9/2016)

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51

January 4, 2023

Dr. Vincent P. Alexis
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032
[redacted]

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy
Suite 206
Reno, NV 89521

To Whom It May Concern:

Enclosed, please find my Application for Veterinary Authority to Dispense Drugs. I am a Southern Nevada Relief Veterinarian. The location of my shifts varies because of the nature of relief work. I will be practicing veterinary medicine at Homestead Animal Hospital (Pahrump, Nevada) and at Paradise Pet Hospital (Las Vegas, Nevada). Other shifts (and shift locations) will inevitably occur as well.

Please contact me if you have any questions or concerns. Thank you so much for your time and help in this matter.

Vincent Alexis, DVM
NV Lic. No. 1109

January 26, 2023

Vincent Alexis, DVM
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032
[redacted]

Nevada State Board of Pharmacy
J. David Wuest
Executive Secretary
985 Damonte Ranch Pkwy, Stuite 206
Reno, NV 89521

Mr. Wuest:

Enclosed, please find a copy of the Court document which lists the final orders/dispensations from the court (N.D. New York). I believe this document supplies you with the needed information. If not, please be certain to contact me and let me know. I have seen hundreds of documents over the past 12 years, and I am not certain as to exactly which document you need.

Thank you for your time and help in this matter.

Sincerely,

Vincent Alexis, DVM
NV Lic. No. 1109
NV CS No. CS32984
DEA Lic. No. FA1174856

AO 245B NNY(Rev. 09/12) Judgment in a Criminal Case
Sheet 1

UNITED STATES DISTRICT COURT

Northern District of New York

UNITED STATES OF AMERICA
V.
VINCENT ALEXIS

JUDGMENT IN A CRIMINAL CASE

Case Number: DNYN513CR000155-001

USM Number: 19213-052

David M. Hoovler
111 Main Street, P.O. Box 509
Chester, New York 10918
(845)469-7577
Defendant's Attorney

THE DEFENDANT:

X pleaded guilty to count(s) 1 of the Information on April 26, 2013.

☐ pleaded nolo contendere to count(s) _____ which was accepted by the court.

☐ was found guilty on count(s) _____ after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
18 U.S.C. §§ 2423(b) & (e)	Attempted Travel in Interstate and Foreign Commerce to Engage in Illicit Sexual Conduct	07/23/11	1

The defendant is sentenced as provided in pages 2 through 6 of this judgment. The sentence is imposed in accordance with 18 U.S.C. § 3553 and the Sentencing Guidelines.

☐ The defendant has been found not guilty on count(s) _____

X Indictment 5:12-CR-439 X is ☐ are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

December 4, 2013
Date of Imposition of Judgment

Hon. Glenn T. Suddaby
U.S. District Judge

December 9, 2013
Date

JAK

AO 245B NNY(Rev. 10/05) Judgment in a Criminal Case
Sheet 2 — Imprisonment

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

IMPRISONMENT

The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a total term of:

97 months

X The court makes the following recommendations to the Bureau of Prisons:

The defendant receive mental health and sex offender treatment when and if eligible.

X The defendant is remanded to the custody of the United States Marshal.

☐ The defendant shall surrender to the United States Marshal for this district:

☐ at _____ ☐ a.m. ☐ p.m. on _____.

☐ as notified by the United States Marshal.

☐ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

☐ before 2 p.m. on _____.

☐ as notified by the United States Marshal.

☐ as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to _____

at _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

By _____
DEPUTY UNITED STATES MARSHAL

David Wuest

From: David Wuest
Sent: Monday, January 23, 2023 3:45 PM
To: [redacted]
Cc: Yenh Long
Subject: Nevada Board of Pharmacy

Dr. Alexis.

Thank you for your time on the phone last week.

In order to proceed with processing your application to dispense drugs in Nevada, we will need the supporting documentation regarding your disclosures listed on page 2 of the application. Under Section 4: Personal and Professional History you answered in the affirmative to questions #2 and #3. You have supplied a detailed summary of your disclosures, but Board staff needs the final orders/dispensations from the courts and/or licensing boards. We need the court order (criminal court) and/or administrative order (regulatory board – i.e., Texas, Nevada...) for each of your disclosures. You have included as "exhibit 2" the December 4, 2013 order from the Texas Board of Veterinary Medical Examiners.

Alternatively, we can place you on the next (April) Board Meeting.

Respectfully,

Dave

J. David Wuest
Executive Secretary
Nevada State Board of Pharmacy

775-850-1440 ext 112

February 21, 2023

Vincent Alexis, DVM
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032
[redacted]

J. David Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy
Suite 206
Reno, NV 89521

Mr. Wuest:

I mailed you the requested document about 3 weeks ago. Can you please tell me the status of my application?

Thank you so much!

Sincerely,

Vincent Alexis, DVM
NV Lic No. 1109
Controlled Substance # CS32984
DEA # FA1174856

FEB 28 2023

Fw: Vincent Alexis, DVM Application for License Reinstatement

Pharmacy Board <pharmacy@pharmacy.nv.gov>
Mon 10/4/2021 1:49 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>

From: Vincent Alexis <[redacted]>
Sent: Monday, October 4, 2021 10:54 AM
To: Pharmacy Board <pharmacy@pharmacy.nv.gov>
Subject: Vincent Alexis, DVM Application for License Reinstatement

I am writing you to inquire about the status of my application for license reinstatement. Originally, I had submitted an old, incorrect, form. I did resubmit the new form with the appropriate additional fee. Did you have a chance to review my application? I spoke to one of the administrators a few weeks ago, and he informed me that my application would be approved.

Thank you for your time and help in this matter.

Sincerely,
Vincent Alexis, DVM
NV Lic. No. 1109
[redacted]

Copy

January 4, 2023

Dr. Vincent P. Alexis
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032
[redacted]

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy
Suite 206
Reno, NV 89521

To Whom It May Concern:

Enclosed, please find my Application for Veterinary Authority to Dispense Drugs. I am a Southern Nevada Relief Veterinarian. The location of my shifts varies because of the nature of relief work. I will be practicing veterinary medicine at Homestead Animal Hospital (Pahrump, Nevada) and at Paradise Pet Hospital (Las Vegas, Nevada). Other shifts (and shift locations) will inevitably occur as well.

Please contact me if you have any questions or concerns. Thank you so much for your time and help in this matter.

Vincent Alexis, DVM
NV Lic. No. 1109

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR VETERINARIAN AUTHORITY TO DISPENSE DRUGS

Non-Refundable $150 fee

Rev (06/09/2021)

What types of drug(s) will you be dispensing?

☒ Dangerous Drugs AND Controlled Substances

☐ Dangerous Drugs ONLY

Section 1: Personal Information

First: Vincent Middle: P. Last: Alexis

Date of Birth: [redacted] SSN or ITIN [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted] Watercreek Dr.

City: N. Las Vegas State: NV Zip: 89032

Telephone: [redacted] Email: [redacted]

Degree: DVM Practitioner License #: NV 1109

(You MUST have a current and active license with your respective BOARD to apply for and maintain a dispensing registration.)

Section 2: Practice Information (A practice address is required for processing of your application)

Practice Name (If any): Relief Veterinary Services

Practice Address: 1401 Watercreek Dr Suite #:

City: N. LV State: NV Zip: 89032

Telephone: 725 251-8369 Fax: — Email: Winstrol.41a Yahoo.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable?		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable?		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable?		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 4: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action	State	Date	Case #
	TX	2013	Unknown

Criminal Action	State	Date	Case #	County	Court
	NY	12-4-13	13CR-00155-FJS	Unknown	USDC N. NY

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vincent Alexis DVM

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-4-2023

Date

Board Use Only Received: _____ Amount: _____

Copy

January 26, 2023

Vincent Alexis, DVM
[redacted]Watercreek Dr.
N. Las Vegas, NV 89032
[redacted]

Nevada State Board of Pharmacy
J. David Wuest
Executive Secretary
985 Damonte Ranch Pkwy, Stuite 206
Reno, NV 89521

Mr. Wuest:

Enclosed, please find a copy of the Court document which lists the final orders/dispensations from the court (N.D. New York). I believe this document supplies you with the needed information. If not, please be certain to contact me and let me know. I have seen hundreds of documents over the past 12 years, and I am not certain as to exactly which document you need.

Thank you for your time and help in this matter.

Sincerely,

Vincent Alexis, DVM
NV Lic. No. 1109
NV CS No. CS32984
DEA Lic. No. FA1174856

Vincent Alexis, DVM Copy

From: Vincent Alexis [redacted]

To: dwuest@pharmacy.nv.gov

Date: Friday, February 10, 2023 at 01:02 PM PST

Hello. I mailed you the requested document about 10 days ago. Can you please tell me the status of my application?

Thank you so much!

Sincerely,
Vincent Alexis, DVM
NV Lic No. 1109
Controlled Substance # CS32984
DEA # FA1174856

Copy

February 21, 2023

Vincent Alexis, DVM
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032
[redacted]

J. David Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy
Suite 206
Reno, NV 89521

Mr. Wuest:

I mailed you the requested document about 3 weeks ago. Can you please tell me the status of my application?

Thank you so much!

Sincerely,

Vincent Alexis, DVM
NV Lic No. 1109
Controlled Substance # CS32984
DEA # FA1174856

Copy

STATE OF NEVADA
NEVADA BOARD OF PHARMACY
RENO, NEVADA

Vincent P. Alexis, DVM Applicant, v. Nevada Board of Pharmacy Respondent.	Date: January 4, 2023 Nevada Veterinary Lic. No. 1109 Nevada Controlled Substance No. CS32984 DEA No. FA1174856

VINCENT P. ALEXIS, DVM
HEREBY PROVIDES ANSWERS TO APPLICATION
QUESTION #2, IN REGARD TO HIS
DECEMBER 2013 FELONY CONVICTION
DOCKET #13-CR-00155-GTS, N.D. NEW YORK

Affidavit of Applicant: Vincent P. Alexis
Via 28 U.S.C. Section 1746, States as Follows:

[1] On December 4, 2013, Dr. Alexis was convicted of one count of Attempted Travel in Interstate & Foreign Commerce to Engage in Illicit Sexual Conduct, a Class B Felony.

[2] On July 23rd & 24th of 2011, Dr. Alexis was forced to sign a confession under duress by former Syracuse special agent Sean Boutot.

[3] This confession was then immediately used against Dr. Alexis, and quickly events unfolded which made it impossible for him to mount a proper defense.

[4] Dr. Alexis is factually, actually, & legally innocent. Unfortunately, he was unable to appeal his conviction due to Ineffective Assistance of Counsel, multiple Constitutional Rights violations, and due to a prolonged, life-threatening, illness (sepsis & bilateral, multifocal, lung abscesses) which struck shortly after his sentencing.

[5] For more thorough details, please see:

I. USA v. Alexis, #13-CR-00155-GTS (N.D. New York);

II. USA v. Alexis, #18-1622 (Dr. Alexis's attempt to obtain a copy of the Grand Jury Minutes) USCA (2nd Circuit);

III. Dr. Alexis's Petition for Commutation/Pardon/Clemency/Reduction of Prison Sentence, Office of the Pardon Attorney/President Donald Trump, February 9. 2019. Case File # C285151;

IV. Nevada State Board of Veterinary Medical Examiners Board Meeting Minutes, April 22, 2021;

V. Dr. Alexis's Petition for License Reinstatement to the Nevada State Board of Veterinary Medical Examiners, April 18, 2019. Please note that the State Board reinstated Dr. Alexis's license to practice veterinary medicine in the State of Nevada on August 19, 2021.

Signed under 28 U.S.C. §1746,

Under penalties of perjury the above

& the following to be true, correct,

& complete. Pro-se.

Respectfully Submitted by:

_____

Vincent P. Alexis, DVM
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032

Copy 3639

AO 245B NNY(Rev. 09/12) Judgment in a Criminal Case
Sheet 1

UNITED STATES DISTRICT COURT

Northern District of New York

UNITED STATES OF AMERICA
V.
VINCENT ALEXIS

JUDGMENT IN A CRIMINAL CASE

Case Number: DNYN513CR000155-001

USM Number: 19213-052

David M. Hoovler
111 Main Street, P.O. Box 509
Chester, New York 10918
(845)469-7577
Defendant's Attorney

THE DEFENDANT:

X pleaded guilty to count(s) 1 of the Information on April 26, 2013.

☐ pleaded nolo contendere to count(s) _____ which was accepted by the court.

☐ was found guilty on count(s) _____ after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
18 U.S.C. §§ 2423(b) & (e)	Attempted Travel in Interstate and Foreign Commerce to Engage in Illicit Sexual Conduct	07/23/11	1

The defendant is sentenced as provided in pages 2 through 6 of this judgment. The sentence is imposed in accordance with 18 U.S.C. § 3553 and the Sentencing Guidelines.

☐ The defendant has been found not guilty on count(s) _____

X Indictment 5:12-CR-439 X is ☐ are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

December 4, 2013
Date of Imposition of Judgment

Hon. Glenn T. Suddaby
U.S. District Judge

December 9, 2013
Date

JAK

AO 245B NNY(Rev. 10/05) Judgment in a Criminal Case
Sheet 2 — Imprisonment

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

IMPRISONMENT

The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a total term of:

97 months

X The court makes the following recommendations to the Bureau of Prisons:

The defendant receive mental health and sex offender treatment when and if eligible.

X The defendant is remanded to the custody of the United States Marshal.

☐ The defendant shall surrender to the United States Marshal for this district:

☐ at _____ ☐ a.m. ☐ p.m. on _____.

☐ as notified by the United States Marshal.

☐ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

☐ before 2 p.m. on _____.

☐ as notified by the United States Marshal.

☐ as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to _____

at _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

By _____
DEPUTY UNITED STATES MARSHAL

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SUPERVISED RELEASE

Upon release from imprisonment, the defendant shall be on supervised release for a term of: **20 years**

The defendant must report to the probation office in the district to which the defendant is released within 72 hours of release from the custody of the Bureau of Prisons.

The defendant shall not commit another federal, state or local crime.

The defendant shall not unlawfully possess a controlled substance. The defendant shall refrain from any unlawful use of a controlled substance. The defendant shall submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court.

☐ The above drug testing condition is suspended, based on the court's determination that the defendant poses a low risk of future substance abuse. (Check, if applicable.)

x The defendant shall not possess a firearm, destructive device, or any other dangerous weapon.

x The defendant shall cooperate in the collection of DNA as directed by the probation officer. (Deselect, if inapplicable.)

x The defendant shall register with the state sex offender registration agency in the state where the defendant resides, works, or is a student, as directed by the probation officer. (Check, if applicable.)

☐ The defendant shall participate in an approved program for domestic violence. (Check, if applicable.)

If this judgment imposes a fine or restitution, it is a condition of supervised release that the defendant pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant must comply with the standard conditions that have been adopted by this court as well as with any additional conditions on the attached page.

STANDARD CONDITIONS OF SUPERVISION

1) the defendant shall not leave the judicial district without the permission of the court or probation officer;
2) the defendant shall report to the probation officer in a manner and frequency directed by the court or probation officer;
3) the defendant shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;
4) the defendant shall support his or her dependents and meet other family responsibilities;
5) the defendant shall work regularly at a lawful occupation, unless excused by the probation officer for schooling, training, or other acceptable reasons;
6) the defendant shall notify the probation officer at least ten days prior to any change in residence or employment, or if such prior notification is not possible, then within five days after such change;
7) the defendant shall refrain from excessive use of alcohol and shall not purchase, possess, use, distribute, import, or manufacture any and all controlled substance and all controlled substance analogues, as defined in 21 U.S.C. § 802, and any paraphernalia related to any controlled substances, except that possession and use of a controlled substance properly prescribed by a licensed medical practitioner is permitted;
8) the defendant shall not frequent places where controlled substances are illegally sold, used, distributed, or administered;
9) the defendant shall not associate with any persons engaged in criminal activity and shall not associate with any person convicted of a felony, unless granted permission to do so by the probation officer;
10) the defendant shall permit a probation officer to visit him or her at any time at home or elsewhere and shall permit confiscation of any contraband observed in plain view of the probation officer;
11) the defendant shall notify the probation officer within seventy-two hours of being arrested or questioned by a law enforcement officer;
12) the defendant shall not enter into any agreement to act as an informer or a special agent of a law enforcement agency without the permission of the court;
13) as directed by the probation officer, the defendant shall notify third parties of risks that may be occasioned by the defendant's criminal record or personal history or characteristics and shall permit the probation officer to make such notifications and to confirm the defendant's compliance with such notification requirement;
14) the defendant shall not possess a firearm, destructive device, or any other dangerous weapon;
15) the defendant shall provide the probation officer with access to any requested financial information; and
16) the defendant shall submit his or her person, and any property, house, residence, vehicle, papers, effects, computer, electronic communications devices, and any data storage devices or media, to search at any time, with or without a warrant, by any federal probation officer, or any other law enforcement officer from whom the Probation Office has requested assistance, with reasonable suspicion concerning a violation of a condition of probation or supervised release or unlawful conduct by the defendant. Any items seized may be removed to the Probation Office or to the office of their designee for a more thorough examination.

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SPECIAL CONDITIONS OF SUPERVISION

1. The defendant shall not have direct or indirect contact with the identified victim known as AC.
2. The defendant shall not have any direct contact with a person under the age of 18 unless it is supervised by a person approved of by the probation officer. The defendant shall not have indirect contact with a person under the age of 18 through another person or through a device (including a telephone, computer, radio, or other means) unless it is supervised by a person approved of by the probation officer. The defendant shall reasonably avoid and remove himself or herself from situations in which the defendant has any other form of contact with a minor.
3. The defendant shall not be in any area in which persons under the age of 18 are likely to congregate, such as school grounds, child care centers, or playgrounds, without the permission of the probation officer.
4. The defendant shall participate in a mental health program, which will include, but will not be limited to, participation in a treatment program for sexual disorders. The program shall be approved by the United States Probation Office.
5. The defendant's supervised release may include examinations using a polygraph, computerized voice stress analyzer, or other similar device to obtain information necessary for supervision, case monitoring, and treatment. The defendant shall answer the questions posed during the examination, subject to his or her right to challenge in a court of law the use of such statements as violations of the defendant's Fifth Amendment rights. In this regard, the defendant shall be deemed to have not waived his or her Fifth Amendment rights. The results of any examinations shall be disclosed to the United States Probation Office and the Court, but shall not be further disclosed without the approval of the Court.
6. The defendant shall contribute to the cost of any evaluation, testing, treatment and/or monitoring services rendered in an amount to be determined by the probation officer based on the defendant's ability to pay and the availability of third party payments.
7. The defendant shall not use or possess any computer or any other device with online capabilities, at any location, except at his or her place of employment, unless the defendant participates in the Computer Restriction and Monitoring Program. The defendant shall permit the United States Probation Office to conduct periodic, unannounced examinations of any computer equipment the defendant uses or possesses, limited to all hardware and software related to online use (e.g., use of the World Wide Web, e-mail, instant messaging, etc.). These examinations may include retrieval and copying of data related to online use, and the viewing of pictures and movies which may be potential violations of the terms and conditions of supervised release from this computer equipment including any internal or external peripherals, internet-capable devices, and data storage media. This computer equipment may be removed to the Probation Office or to the office of their designee for a more thorough examination. The Probation Office may use and/or install any hardware or software system that is needed to monitor the defendant's computer use, subject to the limitations described above.
8. If the defendant's employment requires the use of a computer, the defendant may use a computer in connection with the employment approved by the probation officer, at the defendant's place of employment, provided the defendant notifies his or her employer of: (1) the nature of his or her conviction; and (2) the fact that the defendant's conviction was facilitated by the use of the computer. The Probation Office must confirm the defendant's compliance with this notification requirement.

DEFENDANT'S ACKNOWLEDGMENTOF APPLICABLE CONDITIONS OF SUPERVISION

Upon a finding of a violation of probation or supervised release, I understand that the court may (1) revoke supervision, (2) extend the term of supervision, and/or (3) modify the conditions of supervision.

The conditions of supervision have been read to me. I fully understand the conditions and have been provided a copy of them.

Defendant _____ Date _____

U.S. Probation Officer/Designated Witness _____ Date _____

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	Fine	Restitution
TOTALS	$ 100	$ Waived	$ N/A

☐ The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

☐ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss*	Restitution Ordered	Priority or Percentage

TOTALS	$_____	$_____

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties are due as follows:

A X In full immediately; or

B ☐ Lump sum payment of $ _____ due immediately, balance due

☐ not later than _____ , or
☐ in accordance with ☐ D, ☐ E, ☐ F, or ☐ G below; or

C ☐ Payment to begin immediately (may be combined with ☐ D, ☐ E, or ☐ G below); or

D ☐ Payment in equal _____ (e.g., weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after the date of this judgment; or

E ☐ Payment in equal _____ (e.g., weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after release from imprisonment to a term of supervision; or

F ☐ Payment during the term of supervised release will commence within _____ (e.g., 30 or 60 days) after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

G ☐ Special instructions regarding the payment of criminal monetary penalties:

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to **Clerk, U.S. District Court, Federal Bldg., 100 S. Clinton Street, P.O. Box 7367, Syracuse, N.Y. 13261-7367**, unless otherwise directed by the court, the probation officer, or the United States attorney. If a victim cannot be located, the restitution paid to the Clerk of the Court for that victim shall be sent to the Treasury, to be retrieved if and when the victim is located.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

☐ Defendant and Co-Defendant Names and Case Numbers (including defendant number), Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

☐ The Court gives notice that this case involves other defendants who may be held jointly and severally liable for payment of all or part of the restitution ordered herein and may order such payment in the future.

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

X The defendant shall forfeit the defendant's interest in the following property to the United States:
The defendant shall forfeit to the United States all right, title, and interest in the items listed in the Preliminary Order of Forfeiture signed by the Court on May 17, 2013.

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal,(5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

COPY

STATE OF NEVADA
NEVADA BOARD OF PHARMACY
RENO, NEVADA

Vincent P. Alexis, DVM Applicant, v. Nevada Board of Pharmacy Respondent.	Date: January 4, 2023 Nevada Veterinary Lic. No. 1109 Nevada Controlled Substance No. CS32984 DEA No. FA1174856

VINCENT P. ALEXIS, DVM HEREBY PROVIDES ANSWERS TO APPLICATION QUESTION #3, IN REGARD TO HIS JANUARY 2013 TEXAS BOARD OF VETERINARY MEDICAL EXAMINERS ACTION AGAINST HIS LICENSE TO PRACTICE VETERINARY MEDICINE IN THE STATE OF TEXAS

Affidavit of Applicant: Vincent P. Alexis, DVM
Via 28 U.S.C. Section 1746,
States as Follows:

[1] In January of 2013, the Texas Board of Veterinary Medical Examiners found Vincent P. Alexis, DVM (hereinafter referred to as Dr. Alexis) guilty of working for a non-DVM owned hospital in the State of Texas.

[2] In a separate action, "Texas Attorney General Opinion #GA-0064 states that under Section 53.021 of the Occupational Code, a license holder's license is revoked by operation of law upon the license holder's imprisonment following a felony conviction..." (Exhibit: 2). Dr. Alexis's Texas license was "Automatically revoked by operation of law on December 4, 2013."

[3] The attached Exhibits (Exhibits: 1-8), and Affidavits, will explain the above circumstances (many of which were unfair and poorly handled by the Texas Board of Veterinary Medical Examiners) more clearly.

Signed under 28 U.S.C. §1746,
Under penalties of perjury the above
& the following to be true, correct,
& complete. Pro-se.

Respectfully Submitted by:

Vincent P. Alexis, DVM
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032

Copy

State of Texas
Secretary of State
Travis County
Austin, Texas

Vincent P. Alexis, DVM Petitioner,	
v.	Texas DVM Lic. # 11628
State of Texas Secretary of State, Texas Board of Veterinary Medical Examiners Respondants.	November 1, 2018

Affidavit of Petitioner: Alexis, in support of complaint against the Texas Board of Veterinary Medical Examiners, signed under 28 U.S.C. §1746 under penalties of perjury the above & the following to be true, correct, & complete. Pro-se.

PETITIONER: ALEXIS RESPECTFULLY REQUESTS THAT THE TEXAS SECRETARY OF STATE VACATE THE JANUARY 2013 GUILTY VERDICT HANDED DOWN BY THE TEXAS BOARD OF VETERINARY MEDICAL EXAMINERS AGAINST ALEXIS FOR A PRACTICE ACT VIOLATION, BECAUSE OF HIS WORKING FOR A NON-DVM OWNED ANIMAL HOSPITAL.

Background

[1] In January of 2011, Dr. Alexis signed on as a relief veterinarian with Relief Services for the Veterinary Practitioner (RSVP), operating out of Denton, Texas.

[2] Dr. Alexis was routinely called upon by RSVP to work fill-in (relief) shifts at various Texas animal hospitals. His work with/for RSVP lasted through April of 2013.

[3] Dr. Alexis was called upon to work throughout Texas, while residing fifteen minutes East of Austin. His work called upon him to commute as far North as Dallas/Ft. Worth, & as far South as Harlingen.

[4] It was common for Dr. Alexis to receive a work assignment just days before the shift (that's the nature of relief work, as you cannot easily predict when a hospital's staff veterinarian becomes ill, or cannot work their shift).

[5] When RSVP asked Dr. Alexis to cover a shift, he always agreed to do so. He quickly became one of RSVP's "go to" veterinarians, & took pride in his work ethic and availability.

[6] In 2011, RSVP placed Dr. Alexis at two different non-DVM owned animal hospitals - one in Houston, & one in LaMarque. No incidents or concerns arose from his relief work at these hospitals.

[7] Approximately three days after Christmas 2011, Dr. Alexis was asked to work at Furry Friends Animal Hospital (FFAH), located in Harlingen, Texas. This relief work was to last approximately one month, & was scheduled to begin on the first work-day of 2012.

[8] A few days into the first week of work at FFAH, the receptionist (Alina Scovell) mentioned to Dr. Alexis that the Texas State Board of Veterinary Medical Examiners (TXBVME) had visited the hospital, unannounced, in mid-November, 2011. They met with Christine (Chris) Morris, the owner, & with Dr. Hayes, another RSVP veterinarian who was providing coverage.

[9] Ms. Scovell elaborated that at that meeting, the TXBVME informed Ms. Morris & Dr. Hayes that the Board believed that the operation of FFAH was illegal/in violation of TXBVME practice laws, since the hospital was not "owned by a veterinarian." The TXBVME stated that they would issue a decision, within 10 days, by certified mail.

[10] Obviously, Dr. Alexis was concerned to hear about the State Board's visit, & their concerns about the legality of Ms. Morris's venture. He spoke about this with Ms. Morris & she assured Dr. Alexis that her attorney had contacted the TXBVME, & that "Everything was in order." Furthermore, Ms. Morris was quick to point out that the TXBVME never did send the certified mailing instructing her to cease & desist operation of FFAH.

[11] Later that same day, Ms. Morris called her attorney. She wanted to assure Dr. Alexis that he would be able to practice at her hospital without concerns, so she asked him to speak with her attorney. Dr. Alexis did speak to Ms. Morris's attorney at that time. He informed Dr. Alexis that Ms. Morris & FFAH were in full compliance with all TXBVME rules & regulations, & that the TXBVME never did send a certified mailing or issue a cease & desist order.

[12] Ms. Scovell, who as the only receptionist received all the mail, also verified to Dr. Alexis that there was no certified mailing sent to FFAH from the TXBVME, after that mid-November 2011 visit/meeting.

[13] After speaking with Ms. Scovell, Ms. Morris, & her attorney, Dr. Alexis obtained Dr. Hayes' phone number & called him. Dr. Hayes verified that the TXBVME had visited the hospital, unannounced, in mid-November 2011. He also verified to Dr. Alexis that there was no certified mailing sent to FFAH from the TXBVME, after that visit. Dr. Hayes further commented that he hadn't heard from the TXBVME at all since mid-November.

[14] Dr. Alexis also discussed this concern with Monica Hughes at RSVP. She informed Dr. Alexis that they had no knowledge of any TXBVME action or concerns regarding FFAH.

[15] Since RSVP had provided services to FFAH, without concerns, prior to his coverage, & since Ms. Morris, her attorney, Ms. Scovell, & Dr. Hayes all verified that the TXBVME never did issue a cease & desist order, Dr. Alexis continued to provide relief services to FFAH. He had made a commitment to RSVP and to FFAH (a one doctor practice) & its clients, and had no reason to abruptly cancel his coverage.

[16] Ms. Morris had been looking for a full-time staff veterinarian, without success. For this reason, she turned to RSVP for coverage, & in early February 2012 she asked Dr. Alexis to extend his stay. Dr. Alexis agreed to stay for up to one year, so that Ms. Morris would have more time to hire a staff veterinarian.

[17] Approximately eight weeks later, while working at FFAH, Dr. Alexis received a phone call from his brother (& attorney) Drew L. Alexis. Drew informed Dr. Alexis that he had just received a phone call from the TXBVME's attorney. That attorney informed Drew that FFAH was operating illegally, & that Dr. Alexis needed to immediately stop working there. Drew was told by the TXBVME that they wanted to stop Ms. Morris, & that they "Had no interest in pursuing charges against Dr. Alexis, as long as he cooperated & left the practice right away." The TXBVME did not contact Dr. Alexis directly (either by U.S. mail or by phone).

[18] Dr. Alexis agreed to leave the practice. He immediately informed Drew Alexis, RSVP, & Ms. Morris of his intention to comply with the TXBVME order.

[19] Dr. Alexis was now faced with a few acute problems:

[A] Dr. Alexis had just finished up with an OHE (spay) surgery on a dog who was in dystocia & unable to give birth. The queen & her pups needed his care. Dr. Alexis was not willing to depart from Harlingen until these patients were doing well.

[B] Dr. Alexis was not willing to leave behind the controlled drugs which he had ordered under his DEA license (there were no controlled drugs in the hospital upon Dr. Alexis's arrival).

[20] Within 48 hours, Dr. Alexis departed Harlingen & headed North for his home. He took all of the controlled drugs which he had ordered/purchased with him. He did not take any other biologicals or pharmaceuticals which were stocked at FFAH - Dr. Alexis did not purchase/own these items, & therefore had no legal right to remove the items from the premesis (to do so would have been grand theft).

[21] Dr. Alexis is unsure if a cease & desist order was issued to Ms. Morris & FFAH. It does appear, however, that FFAH did not close when the TXBVME ordered Dr. Alexis to leave on/about mid/late April 2012.

[22] Many months later, Dr. Alexis received notice (by U.S. mail) that the TXBVME was pursuing charges against him. The charges included:

[A] Violations of a Practice Act by working for a non-DVM owned hospital.

[B] Violations resulting from Dr. Alexis's decision to leave behind the biologicals/pharmaceuticals which were stocked at FFAH when he departed (see points 19 & 20 above).

[23] On/about January 2013 Dr. Alexis & his San Antonio attorney Keith O'Connell met with the TXBVME in Austin. At that hearing, Dr. Alexis was found **Guilty** of a Practice Act Violation, stemming from his relief work at Furry Friends Animal Hospital from January 3, 2012 through mid/late April 2012.

Conclusion

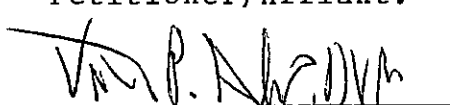
[24] The TXBVME did not perform their duty in a timely & appropriate manner. The TXBVME was clearly aware of Ms. Morris & her venture, Furry Friends Animal Hospital, in **mid-November 2011.** Nevertheless, the TXBVME failed to act in 2011. The Board waited five full months before taking appropriate action, in **mid/late April 2012.**

[25] Had the TXBVME performed their duty in a timely manner, RSVP would have been aware of their concerns. In turn, Dr. Alexis would also have been aware of the TXBVME's concerns, & never would have agreed to provide relief services at Furry Friends Animal Hospital.

Relief Requested

[26] Dr. Alexis is requesting, for the above stated reasons, that the **Guilty** verdict handed down by the TXBVME in January of 2013, for the above mentioned Practice Act Violation, be **Vacated.** The TXBVME was well aware of Ms. Morris & her illegal venture in mid-November 2011. A five month delay in acting is unconscionable, & is a clear failure by the Texas Board of Veterinary Medical Examiners to protect its veterinarians & the public from unscrupulous business owners like Ms. Morris.

Signed under 28 U.S.C. §1746,
Respectfully Submitted by
Petitioner/Affiant:



Vincent P. Alexis, DVM
3905 Lemon Ave
Long Beach, CA 90807

April 13, 2023

Vincent Alexis, DVM
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032
[redacted]

J. David Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

Mr. Wuest:

Thank you for clarifying what information you need in order finalize my Application for Veterinarian Authority to Dispense Drugs. I have enclosed some of those documents today.

Document A is a 2-page document from the Nevada State Board of Veterinary Medical Examiners which lists the stipulations of my license reinstatement. The Board forgot to date this document, but it was issued to me on/about August 19, 2021 (at the time The Board reinstated my license).

Document B is a 6-page document from United States District Court which lists the conditions of my supervised release (pages 3 and 4). Please note, this document also lists the sole instant offense, the date of arrest (page 1 in the middle, July 23, 2011) and the date of conviction (page 1 at the bottom, December 4, 2013).

APR 17 2023

I Have also enclosed a printout from the BOP Inmate Locator which shows the date of my release (March 10, 2020).

I have made The Nevada State Board of Pharmacy fully aware of the sole legal problem I've encountered in my life. Likewise, I have made you fully aware of the issue with the Texas Board of Veterinary Medical Examiners. I have practiced in The State of Nevada since 1997 and have had no Board actions whatsoever. I have also practiced in Colorado, New York, and Utah with no Board actions whatsoever.

I hope this information is all which you need in order to finalize my application. Please let me know if this makes my application complete. Thank you.

Sincerely,

Vincent Alexis, DVM
NV Lic No. 1109
Controlled Substance # CS32984
DEA # FA1174856

Federal Bureau of Prisons

Courage. Respect. Integrity. Correctional Excellence.

Search bop.gov

Find an inmate.

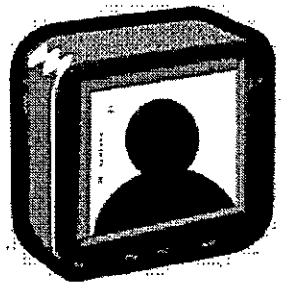
Locate the whereabouts of a federal inmate incarcerated from 1982 to the present. Due to the First Step Act, sentences are being reviewed and recalculated to address pending Federal Time Credit changes. As a result, an inmate's release date may not be up-to-date. Website visitors should continue to check back periodically to see if any changes have occurred.

Find By Number | **Find By Name**

First	Middle	Last	Race	Age	Sex
vincent		alexis			

1 Result for search **vincent alexis**

Clear Form | Search



VINCENT ALEXIS

Register Number: 19213-052

Age: 56
Race: White
Sex: Male

Released On: 03/10/2020

Related Links

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Visit
Voice a concern

About the inmate locator & record availability ▸

A

STATE OF NEVADA

BOARD OF VETERINARY MEDICAL EXAMINERS

4600 Kietzke Lane, Building O-265
Reno, Nevada 89502
Phone (775) 688-1788 / Fax (775) 688-1808
vetbdinfo@vetboard.nv.gov
www.nvvetboard.us

Vincent Alexis, DVM
[redacted] Watercreek Dr.
N. Las Vegas, Nv 89032

Dr. Alexis:

This letter is to document the action that the Nevada State Board of Veterinary Medicine took on April 22, 2021 at its regular meeting that was held via Zoom related to your application for reinstatement of your license that you filed with the Board on May 4, 2019. At the Board's meeting, you appeared and answered the Board members' questions. Additionally, the Board members had been presented and had reviewed a packet of documents containing your application and 141 additional pages related to your criminal conviction and the licensure actions taken by Texas, Colorado, and New York. Based upon all of the above, the Board determined to reinstate your license to practice veterinary medicine in Nevada (License No. 1109) subject to the following terms and conditions:

(1) Your license shall be on probation. You may not seek to terminate the probation unless and until:
   a. You have fully satisfied all the terms and conditions of your Judgement in a Criminal Case in the case of *U.S. v. Alexis*, (USDC Northern Dist. NY Case No. DNYN513CR000155-001) and are no longer subject to the terms and conditions thereof as those terms and conditions were originally issued and as they may have been subsequently modified by the Court;
   b. If the Court modifies any of the terms and conditions of the Judgement, within 10 days of any such modification, you have provided copies of any such document modifying the terms and conditions;
   c. You have provided to the Board's office documents evidencing the satisfaction of the preceding Judgement as originally issued or as modified;
   d. You have continued successfully your treatment with Evergreen Counseling or any other treatment providers you may subsequently seek treatment with or have been discharged from further treatment (written proof of such

discharge having been provided to the Board's office within 10 days of such discharge); and

e. You have appeared before the Board at the next available regular meeting after the completion of the preceding four paragraphs and the Board has determined in its discretion that removal of your terms of probation is in the interest of the Nevada public's health, safety, and welfare.

(2) You shall execute any documents necessary to authorize those who are overseeing your compliance with the Judgement and your medical and mental health treatments so that they will provide quarterly reports regarding the status of your compliance or treatments and, if you fail in such compliance, reports of such failure within five business days of any such failure.

(3) You shall inform any present or future employers of the terms of this letter and shall provide them with a copy of the Judgement that each shall sign and date and return to the Board office to evidence that the employer or prospective employer is aware of the restrictions contained in the Judgment.

(4) You shall cooperate with any and all requests from or communications from the Board and its staff.

(5) You shall work not practice veterinary medicine in Nevada except as an employee of another veterinarian and veterinary facility and you shall not serve as a veterinarian-in-charge at any such facility.

(6) You shall keep your Nevada license current and active unless and until you determine to retire or otherwise cease practicing veterinary medicine in Nevada.

(7) Any violation of the terms of the Judgement as originally issued or as modified by the Court, any failure to succeed with your treatment, or any violation of the terms and conditions in this letter will result in an immediate and summary suspension of your license and disciplinary action which may include revocation of your license.

If you have any questions, please contact me.

Sincerely,

Jennifer Pedigo
Executive Director

Active Licensure

From: Jennifer Pedigo (vetbdinfo@vetboard.nv.gov)

To: [redacted]

Cc: dalexis@alexislawfirm.com; louisling@me.com

Date: Thursday, August 19, 2021 at 02:53 PM PDT

Good afternoon Dr. Alexis,

I went ahead and made your license active per our conversation. Your license number is 1109 and your license information is now searchable on the license verification page at https://nvvetboard.nv.gov



nvvetboard.nv.gov - Nevada Board of Veterinary Medical Examiners

Search This Site Search All Sites Close State Agencies State Jobs ADA Assistance. Home

nvvetboard.nv.gov

We will go ahead and send a new wall certificate out to East Charleston so you have a new copy. You can also log in to the licensee portal using the email address above and print on-demand wallet cards as well.

Please let me know if you have any questions and I will be in touch if I hear anything from Mr. Stark or his office.

Thank you,
Jennifer Pedigo
Executive Director

B

AO 245B NNY(Rev. 09/12) Judgment in a Criminal Case
Sheet 1

UNITED STATES DISTRICT COURT

Northern District of New York

UNITED STATES OF AMERICA
V.

VINCENT ALEXIS

JUDGMENT IN A CRIMINAL CASE

Case Number: DNYN513CR000155-001

USM Number: 19213-052

David M. Hoovler
111 Main Street, P.O. Box 509
Chester, New York 10918
(845)469-7577
Defendant's Attorney

THE DEFENDANT:

X pleaded guilty to count(s) 1 of the Information on April 26, 2013.

☐ pleaded nolo contendere to count(s) _____ which was accepted by the court.

☐ was found guilty on count(s) _____ after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
18 U.S.C. §§ 2423(b) & (e)	Attempted Travel in Interstate and Foreign Commerce to Engage in Illicit Sexual Conduct	07/23/11	1

The defendant is sentenced as provided in pages 2 through 6 of this judgment. The sentence is imposed in accordance with 18 U.S.C. § 3553 and the Sentencing Guidelines.

☐ The defendant has been found not guilty on count(s) _____

X Indictment 5:12-CR-439 X is ☐ are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

December 4, 2013
Date of Imposition of Judgment

Hon. Glenn T. Suddaby
U.S. District Judge

December 9, 2013
Date

JAK

AO 245B NNY(Rev. 10/05) Judgment in a Criminal Case
Sheet 2 — Imprisonment

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

IMPRISONMENT

The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a total term of:

97 months

X The court makes the following recommendations to the Bureau of Prisons:

The defendant receive mental health and sex offender treatment when and if eligible.

X The defendant is remanded to the custody of the United States Marshal.

☐ The defendant shall surrender to the United States Marshal for this district:

☐ at _____ ☐ a.m. ☐ p.m. on _____.

☐ as notified by the United States Marshal.

☐ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

☐ before 2 p.m. on _____.

☐ as notified by the United States Marshal.

☐ as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to _____

at _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

By _____
DEPUTY UNITED STATES MARSHAL

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SUPERVISED RELEASE

Upon release from imprisonment, the defendant shall be on supervised release for a term of: **20 years**

The defendant must report to the probation office in the district to which the defendant is released within 72 hours of release from the custody of the Bureau of Prisons.

The defendant shall not commit another federal, state or local crime.

The defendant shall not unlawfully possess a controlled substance. The defendant shall refrain from any unlawful use of a controlled substance. The defendant shall submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court.

☐ The above drug testing condition is suspended, based on the court's determination that the defendant poses a low risk of future substance abuse. (Check, if applicable.)

x The defendant shall not possess a firearm, destructive device, or any other dangerous weapon.

x The defendant shall cooperate in the collection of DNA as directed by the probation officer. (Deselect, if inapplicable.)

x The defendant shall register with the state sex offender registration agency in the state where the defendant resides, works, or is a student, as directed by the probation officer. (Check, if applicable.)

☐ The defendant shall participate in an approved program for domestic violence. (Check, if applicable.)

If this judgment imposes a fine or restitution, it is a condition of supervised release that the defendant pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant must comply with the standard conditions that have been adopted by this court as well as with any additional conditions on the attached page.

STANDARD CONDITIONS OF SUPERVISION

1) the defendant shall not leave the judicial district without the permission of the court or probation officer;
2) the defendant shall report to the probation officer in a manner and frequency directed by the court or probation officer;
3) the defendant shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;
4) the defendant shall support his or her dependents and meet other family responsibilities;
5) the defendant shall work regularly at a lawful occupation, unless excused by the probation officer for schooling, training, or other acceptable reasons;
6) the defendant shall notify the probation officer at least ten days prior to any change in residence or employment, or if such prior notification is not possible, then within five days after such change;
7) the defendant shall refrain from excessive use of alcohol and shall not purchase, possess, use, distribute, import, or manufacture any and all controlled substance and all controlled substance analogues, as defined in 21 U.S.C. § 802, and any paraphernalia related to any controlled substances, except that possession and use of a controlled substance properly prescribed by a licensed medical practitioner is permitted;
8) the defendant shall not frequent places where controlled substances are illegally sold, used, distributed, or administered;
9) the defendant shall not associate with any persons engaged in criminal activity and shall not associate with any person convicted of a felony, unless granted permission to do so by the probation officer;
10) the defendant shall permit a probation officer to visit him or her at any time at home or elsewhere and shall permit confiscation of any contraband observed in plain view of the probation officer;
11) the defendant shall notify the probation officer within seventy-two hours of being arrested or questioned by a law enforcement officer;
12) the defendant shall not enter into any agreement to act as an informer or a special agent of a law enforcement agency without the permission of the court;
13) as directed by the probation officer, the defendant shall notify third parties of risks that may be occasioned by the defendant's criminal record or personal history or characteristics and shall permit the probation officer to make such notifications and to confirm the defendant's compliance with such notification requirement;
14) the defendant shall not possess a firearm, destructive device, or any other dangerous weapon;
15) the defendant shall provide the probation officer with access to any requested financial information; and
16) the defendant shall submit his or her person, and any property, house, residence, vehicle, papers, effects, computer, electronic communications devices, and any data storage devices or media, to search at any time, with or without a warrant, by any federal probation officer, or any other law enforcement officer from whom the Probation Office has requested assistance, with reasonable suspicion concerning a violation of a condition of probation or supervised release or unlawful conduct by the defendant. Any items seized may be removed to the Probation Office or to the office of their designee for a more thorough examination.

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SPECIAL CONDITIONS OF SUPERVISION

1. The defendant shall not have direct or indirect contact with the identified victim known as AC.
2. The defendant shall not have any direct contact with a person under the age of 18 unless it is supervised by a person approved of by the probation officer. The defendant shall not have indirect contact with a person under the age of 18 through another person or through a device (including a telephone, computer, radio, or other means) unless it is supervised by a person approved of by the probation officer. The defendant shall reasonably avoid and remove himself or herself from situations in which the defendant has any other form of contact with a minor.
3. The defendant shall not be in any area in which persons under the age of 18 are likely to congregate, such as school grounds, child care centers, or playgrounds, without the permission of the probation officer.
4. The defendant shall participate in a mental health program, which will include, but will not be limited to, participation in a treatment program for sexual disorders. The program shall be approved by the United States Probation Office.
5. The defendant's supervised release may include examinations using a polygraph, computerized voice stress analyzer, or other similar device to obtain information necessary for supervision, case monitoring, and treatment. The defendant shall answer the questions posed during the examination, subject to his or her right to challenge in a court of law the use of such statements as violations of the defendant's Fifth Amendment rights. In this regard, the defendant shall be deemed to have not waived his or her Fifth Amendment rights. The results of any examinations shall be disclosed to the United States Probation Office and the Court, but shall not be further disclosed without the approval of the Court.
6. The defendant shall contribute to the cost of any evaluation, testing, treatment and/or monitoring services rendered in an amount to be determined by the probation officer based on the defendant's ability to pay and the availability of third party payments.
7. The defendant shall not use or possess any computer or any other device with online capabilities, at any location, except at his or her place of employment, unless the defendant participates in the Computer Restriction and Monitoring Program. The defendant shall permit the United States Probation Office to conduct periodic, unannounced examinations of any computer equipment the defendant uses or possesses, limited to all hardware and software related to online use (e.g., use of the World Wide Web, e-mail, instant messaging, etc.). These examinations may include retrieval and copying of data related to online use, and the viewing of pictures and movies which may be potential violations of the terms and conditions of supervised release from this computer equipment including any internal or external peripherals, internet-capable devices, and data storage media. This computer equipment may be removed to the Probation Office or to the office of their designee for a more thorough examination. The Probation Office may use and/or install any hardware or software system that is needed to monitor the defendant's computer use, subject to the limitations described above.
8. If the defendant's employment requires the use of a computer, the defendant may use a computer in connection with the employment approved by the probation officer, at the defendant's place of employment, provided the defendant notifies his or her employer of: (1) the nature of his or her conviction; and (2) the fact that the defendant's conviction was facilitated by the use of the computer. The Probation Office must confirm the defendant's compliance with this notification requirement.

DEFENDANT'S ACKNOWLEDGMENTOF APPLICABLE CONDITIONS OF SUPERVISION

Upon a finding of a violation of probation or supervised release, I understand that the court may (1) revoke supervision, (2) extend the term of supervision, and/or (3) modify the conditions of supervision.

The conditions of supervision have been read to me. I fully understand the conditions and have been provided a copy of them.

Defendant _____ Date _____

U.S. Probation Officer/Designated Witness _____ Date _____

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	Fine	Restitution
TOTALS	$ 100	$ Waived	$ N/A

☐ The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

☐ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss*	Restitution Ordered	Priority or Percentage

TOTALS	$_____	$_____

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties are due as follows:

A X In full immediately; or

B ☐ Lump sum payment of $ _____ due immediately, balance due

☐ not later than _____ , or
☐ in accordance with ☐ D, ☐ E, ☐ F, or ☐ G below; or

C ☐ Payment to begin immediately (may be combined with ☐ D, ☐ E, or ☐ G below); or

D ☐ Payment in equal _____ (e.g., weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after the date of this judgment; or

E ☐ Payment in equal _____ (e.g., weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after release from imprisonment to a term of supervision; or

F ☐ Payment during the term of supervised release will commence within _____ (e.g., 30 or 60 days) after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

G ☐ Special instructions regarding the payment of criminal monetary penalties:

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to **Clerk, U.S. District Court, Federal Bldg., 100 S. Clinton Street, P.O. Box 7367, Syracuse, N.Y. 13261-7367**, unless otherwise directed by the court, the probation officer, or the United States attorney. If a victim cannot be located, the restitution paid to the Clerk of the Court for that victim shall be sent to the Treasury, to be retrieved if and when the victim is located.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

☐ Defendant and Co-Defendant Names and Case Numbers (including defendant number), Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

☐ The Court gives notice that this case involves other defendants who may be held jointly and severally liable for payment of all or part of the restitution ordered herein and may order such payment in the future.

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

X The defendant shall forfeit the defendant's interest in the following property to the United States:
The defendant shall forfeit to the United States all right, title, and interest in the items listed in the Preliminary Order of Forfeiture signed by the Court on May 17, 2013.

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal,(5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

August 17, 2023

Dr. Vincent Alexis
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032
[redacted]

Nevada State Board of Pharmacy
J. David Wuest, Executive Secretary
985 Damonte Ranch Pkwy
Suite 206
Reno, NV 89521

Mr. Wuest:

Enclosed, please find the requested documents (the complaint/charging document and the actual order) which your office requested in order to finalize my Application for Veterinary Authority to Dispense Drugs. I'm sorry it took some time for me to gather these documents. As I mentioned, I have seen hundreds of documents since 2011, and it's all very confusing.

Thank you for your patience and for your help in this matter.

Sincerely,

Dr. Vincent Alexis
NV Lic No. 1109
Controlled Substance #CS32984
DEA # FA1174856

U.S. DISTRICT COURT - N.D. OF N.Y.
FILED
APR 26 2013
AT ____ O'CLOCK
Lawrence K. Baerman, Clerk - Syracuse

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

****

UNITED STATES OF AMERICA

v.

VINCENT ALEXIS

Defendant.

Criminal Action No. 13-CR-155 (GTS)

VIO: 18 U.S.C. § 2423(b) and (e)

INFORMATION

County: Jefferson

****

THE UNITED STATES ATTORNEY CHARGES:

On or about July 23, 2011, in Jefferson County, in the Northern District of New York, the defendant,

VINCENT ALEXIS,

a United States citizen, traveled in interstate commerce and attempted to travel in foreign commerce with intent to engage in illicit sexual conduct, as defined in Title 18, United States Code, Section 2423(f), with another person, in violation of Title 18, United States Code, Section 2423(b) and (e).

THE UNITED STATES ATTORNEY FURTHER CHARGES:
FORFEITURE ALLEGATIONS

1. The allegations contained in Count 1 of this Information are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Section 2428.

2. Pursuant to Title 18, United States Code, Section 2428, upon conviction of an offense in violation of Title 18, United States Code, Section 2423(b) and (e), the defendant, **VINCENT ALEXIS**, shall forfeit to the United States of America any property, real or personal, that was used or intended to be used to commit or to facilitate the commission of the offense. The property to be forfeited includes, but is not limited to, the following:

a. **$2,000.00 in U.S. Currency**

3. If any of the property described above, as a result of any act or omission of the defendant[s]:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c).

Date: April 26, 2013

RICHARD S. HARTUNIAN
UNITED STATES ATTORNEY

By: Tamara B. Thomson
Tamara B. Thomson
Assistant United States Attorney

AO 245B NNY(Rev. 09/12) Judgment in a Criminal Case
Sheet 1

UNITED STATES DISTRICT COURT

Northern District of New York

UNITED STATES OF AMERICA
V.

JUDGMENT IN A CRIMINAL CASE

VINCENT ALEXIS

Case Number: DNYN513CR000155-001

USM Number: 19213-052

David M. Hoovler
111 Main Street, P.O. Box 509
Chester, New York 10918
(845)469-7577
Defendant's Attorney

THE DEFENDANT:

X pleaded guilty to count(s) 1 of the Information on April 26, 2013.

G pleaded nolo contendere to count(s) _____ which was accepted by the court.

G was found guilty on count(s) _____ after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
18 U.S.C. §§ 2423(b) & (e)	Attempted Travel in Interstate and Foreign Commerce to Engage in Illicit Sexual Conduct	07/23/11	1

The defendant is sentenced as provided in pages 2 through 6 of this judgment. The sentence is imposed in accordance with 18 U.S.C. § 3553 and the Sentencing Guidelines.

G The defendant has been found not guilty on count(s) _____

X Indictment 5:12-CR-439 X is G are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

December 4, 2013
Date of Imposition of Judgment

Hon. Glenn T. Suddaby
U.S. District Judge

December 9, 2013
Date

JAK

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

IMPRISONMENT

The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a total term of:

97 months

X The court makes the following recommendations to the Bureau of Prisons:

The defendant receive mental health and sex offender treatment when and if eligible.

X The defendant is remanded to the custody of the United States Marshal.

G The defendant shall surrender to the United States Marshal for this district:

G at _____ G a.m. G p.m. on _____.

G as notified by the United States Marshal.

G The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

G before 2 p.m. on _____.

G as notified by the United States Marshal.

G as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to _____

at _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

By _____
DEPUTY UNITED STATES MARSHAL

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SUPERVISED RELEASE

Upon release from imprisonment, the defendant shall be on supervised release for a term of: **20 years**

The defendant must report to the probation office in the district to which the defendant is released within 72 hours of release from the custody of the Bureau of Prisons.

The defendant shall not commit another federal, state or local crime.

The defendant shall not unlawfully possess a controlled substance. The defendant shall refrain from any unlawful use of a controlled substance. The defendant shall submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court.

G The above drug testing condition is suspended, based on the court's determination that the defendant poses a low risk of future substance abuse. (Check, if applicable.)

x The defendant shall not possess a firearm, destructive device, or any other dangerous weapon.

x The defendant shall cooperate in the collection of DNA as directed by the probation officer. (Deselect, if inapplicable.)

x The defendant shall register with the state sex offender registration agency in the state where the defendant resides, works, or is a student, as directed by the probation officer. (Check, if applicable.)

G The defendant shall participate in an approved program for domestic violence. (Check, if applicable.)

If this judgment imposes a fine or restitution, it is a condition of supervised release that the defendant pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant must comply with the standard conditions that have been adopted by this court as well as with any additional conditions on the attached page.

STANDARD CONDITIONS OF SUPERVISION

1) the defendant shall not leave the judicial district without the permission of the court or probation officer;
2) the defendant shall report to the probation officer in a manner and frequency directed by the court or probation officer;
3) the defendant shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;
4) the defendant shall support his or her dependents and meet other family responsibilities;
5) the defendant shall work regularly at a lawful occupation, unless excused by the probation officer for schooling, training, or other acceptable reasons;
6) the defendant shall notify the probation officer at least ten days prior to any change in residence or employment, or if such prior notification is not possible, then within five days after such change;
7) the defendant shall refrain from excessive use of alcohol and shall not purchase, possess, use, distribute, import, or manufacture any and all controlled substance and all controlled substance analogues, as defined in 21 U.S.C. § 802, and any paraphernalia related to any controlled substances, except that possession and use of a controlled substance properly prescribed by a licensed medical practitioner is permitted;
8) the defendant shall not frequent places where controlled substances are illegally sold, used, distributed, or administered;
9) the defendant shall not associate with any persons engaged in criminal activity and shall not associate with any person convicted of a felony, unless granted permission to do so by the probation officer;
10) the defendant shall permit a probation officer to visit him or her at any time at home or elsewhere and shall permit confiscation of any contraband observed in plain view of the probation officer;
11) the defendant shall notify the probation officer within seventy-two hours of being arrested or questioned by a law enforcement officer;
12) the defendant shall not enter into any agreement to act as an informer or a special agent of a law enforcement agency without the permission of the court;
13) as directed by the probation officer, the defendant shall notify third parties of risks that may be occasioned by the defendant's criminal record or personal history or characteristics and shall permit the probation officer to make such notifications and to confirm the defendant's compliance with such notification requirement;
14) the defendant shall not possess a firearm, destructive device, or any other dangerous weapon;
15) the defendant shall provide the probation officer with access to any requested financial information; and
16) the defendant shall submit his or her person, and any property, house, residence, vehicle, papers, effects, computer, electronic communications devices, and any data storage devices or media, to search at any time, with or without a warrant, by any federal probation officer, or any other law enforcement officer from whom the Probation Office has requested assistance, with reasonable suspicion concerning a violation of a condition of probation or supervised release or unlawful conduct by the defendant. Any items seized may be removed to the Probation Office or to the office of their designee for a more thorough examination.

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SPECIAL CONDITIONS OF SUPERVISION

1. The defendant shall not have direct or indirect contact with the identified victim known as AC.

2. The defendant shall not have any direct contact with a person under the age of 18 unless it is supervised by a person approved of by the probation officer. The defendant shall not have indirect contact with a person under the age of 18 through another person or through a device (including a telephone, computer, radio, or other means) unless it is supervised by a person approved of by the probation officer. The defendant shall reasonably avoid and remove himself or herself from situations in which the defendant has any other form of contact with a minor.

3. The defendant shall not be in any area in which persons under the age of 18 are likely to congregate, such as school grounds, child care centers, or playgrounds, without the permission of the probation officer.

4. The defendant shall participate in a mental health program, which will include, but will not be limited to, participation in a treatment program for sexual disorders. The program shall be approved by the United States Probation Office.

5. The defendant's supervised release may include examinations using a polygraph, computerized voice stress analyzer, or other similar device to obtain information necessary for supervision, case monitoring, and treatment. The defendant shall answer the questions posed during the examination, subject to his or her right to challenge in a court of law the use of such statements as violations of the defendant's Fifth Amendment rights. In this regard, the defendant shall be deemed to have not waived his or her Fifth Amendment rights. The results of any examinations shall be disclosed to the United States Probation Office and the Court, but shall not be further disclosed without the approval of the Court.

6. The defendant shall contribute to the cost of any evaluation, testing, treatment and/or monitoring services rendered in an amount to be determined by the probation officer based on the defendant's ability to pay and the availability of third party payments.

7. The defendant shall not use or possess any computer or any other device with online capabilities, at any location, except at his or her place of employment, unless the defendant participates in the Computer Restriction and Monitoring Program. The defendant shall permit the United States Probation Office to conduct periodic, unannounced examinations of any computer equipment the defendant uses or possesses, limited to all hardware and software related to online use (e.g., use of the World Wide Web, e-mail, instant messaging, etc.). These examinations may include retrieval and copying of data related to online use, and the viewing of pictures and movies which may be potential violations of the terms and conditions of supervised release from this computer equipment including any internal or external peripherals, internet-capable devices, and data storage media. This computer equipment may be removed to the Probation Office or to the office of their designee for a more thorough examination. The Probation Office may use and/or install any hardware or software system that is needed to monitor the defendant's computer use, subject to the limitations described above.

8. If the defendant's employment requires the use of a computer, the defendant may use a computer in connection with the employment approved by the probation officer, at the defendant's place of employment, provided the defendant notifies his or her employer of: (1) the nature of his or her conviction; and (2) the fact that the defendant's conviction was facilitated by the use of the computer. The Probation Office must confirm the defendant's compliance with this notification requirement.

DEFENDANT'S ACKNOWLEDGMENTOF APPLICABLE CONDITIONS OF SUPERVISION

Upon a finding of a violation of probation or supervised release, I understand that the court may (1) revoke supervision, (2) extend the term of supervision, and/or (3) modify the conditions of supervision.

The conditions of supervision have been read to me. I fully understand the conditions and have been provided a copy of them.

Defendant _____ Date _____

U.S. Probation Officer/Designated Witness _____ Date _____

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	Fine	Restitution
TOTALS	$ 100	$ Waived	$ N/A

G The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

G The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss*	Restitution Ordered	Priority or Percentage

TOTALS	$_____	$_____

G Restitution amount ordered pursuant to plea agreement $ _____

G The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

G The court determined that the defendant does not have the ability to pay interest and it is ordered that:

G the interest requirement is waived for the G fine G restitution.

G the interest requirement for the G fine G restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties are due as follows:

A X In full immediately; or

B G Lump sum payment of $ _____ due immediately, balance due

G not later than _____, or
G in accordance with G D, G E, G F, or G G below; or

C G Payment to begin immediately (may be combined with G D, G E, or G G below); or

D G Payment in equal _____ (e.g., weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after the date of this judgment; or

E G Payment in equal _____ (e.g., weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after release from imprisonment to a term of supervision; or

F G Payment during the term of supervised release will commence within _____ (e.g., 30 or 60 days) after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

G G Special instructions regarding the payment of criminal monetary penalties:

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to **Clerk, U.S. District Court, Federal Bldg., 100 S. Clinton Street, P.O. Box 7367, Syracuse, N.Y. 13261-7367**, unless otherwise directed by the court, the probation officer, or the United States attorney. If a victim cannot be located, the restitution paid to the Clerk of the Court for that victim shall be sent to the Treasury, to be retrieved if and when the victim is located.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

G Joint and Several

G Defendant and Co-Defendant Names and Case Numbers (including defendant number), Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

G The Court gives notice that this case involves other defendants who may be held jointly and severally liable for payment of all or part of the restitution ordered herein and may order such payment in the future.

G The defendant shall pay the cost of prosecution.

G The defendant shall pay the following court cost(s):

X The defendant shall forfeit the defendant's interest in the following property to the United States:
The defendant shall forfeit to the United States all right, title, and interest in the items listed in the Preliminary Order of Forfeiture signed by the Court on May 17, 2013.

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal,(5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

CLOSED

U.S. District Court
Northern District of New York - Main Office (Syracuse) [NextGen CM/ECF Release 1.7 (Revision 1.7.1.2)] (Syracuse)
CRIMINAL DOCKET FOR CASE #: 5:13-cr-00155-GTS-1

Case title: USA v. Alexis

Date Filed: 04/26/2013

Date Terminated: 12/09/2013

Assigned to: U.S. District Judge Glenn T Suddaby

Defendant (1)

Vincent Alexis
TERMINATED: 12/09/2013

represented by **Vincent Alexis**
[redacted] Watercreek Dr.
N. Las Vegas, NV 89032
PRO SE

David M. Hoovler
Ostrer, Hoovler Law Firm
111 Main Street
P.O. Box 509
Chester, NY 10918
845-469-7577
Fax: 845-469-8690
Email: dhoovler@orlawllp.com
Designation: Retained

Pending Counts

18:2423.F - COERCION OR ENTICEMENT OF MINOR
(1)

Disposition

Term of imprisonment: 97 months; Supervised release: 20 years with standard and special conditions. Special assessment: $100; fine: waived.

Highest Offense Level (Opening)

Felony

Terminated Counts

None

Disposition

Highest Offense Level (Terminated)

None

Complaints

None

Disposition

Plaintiff

USA

represented by **Tamara Thomson**
Office of United States Attorney - Syracuse Office
100 South Clinton Street
P.O. Box 7198
Syracuse, NY 13261
315-448-0672
Fax: 315-448-0658
Email: tamara.thomson@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Geoffrey J.L. Brown
Office of United States Attorney - Syracuse Office
100 South Clinton Street
P.O. Box 7198
Syracuse, NY 13261
315-448-0695
Fax: 315-448-0689
Email: geoffrey.brown2@usdoj.gov
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
04/26/2013	1	WAIVER OF INDICTMENT as to Vincent Alexis. (lmw) (Entered: 04/26/2013)
04/26/2013	2	INFORMATION as to Vincent Alexis (1) on count 1. (lmw) (Entered: 04/26/2013)
04/26/2013	3	PLEA AGREEMENT as to Vincent Alexis. (lmw) (Entered: 04/26/2013)
04/26/2013		TEXT MINUTE ENTRY for Waiver of Indictment and Change of Plea Hearing held on 4/26/13 before Judge Glenn T. Suddaby as to Vincent Alexis (1): Defendant waives personal appearance and agrees to proceed via video conference. Defendant is sworn, questioned by the Court and advised of his constitutional rights and consequences of waiving Indictment. The Waiver of Indictment was signed by Defendant and Defendants attorney before Court. The Judge signed the waiver of indictment, and it is accepted by the Court for filing in case #5:13-cr-155. Defendant is advised of his constitutional rights and the consequences of pleading guilty. Defendant is arraigned and pleads guilty to Count 1 of the Information and admits to the forfeiture allegation. Government states a factual basis for the plea. Maximum possible penalties are stated for the record. Court accepts plea of Guilty to Count 1 of the Information. Plea agreement is incorporated into the record, without the changes made by defendant. Court orders a Pre-Sentence Investigation Report from Probation. Sentencing is scheduled for 9/10/13 at 10:00 A.M. in Syracuse, New York. Indictment in case 5:12-cr-439 to be dismissed at sentencing. Defendant is remanded to USMS. APP: Tamara Thomson, AUSA; David Hoovler, Esq. for Defendant. CRD: L. Welch (Court Reporter: Diane Martens) (lmw) (Entered: 04/26/2013)

04/26/2013	4	GUIDELINE ORDER as to Vincent Alexis: Sentencing set for 9/10/2013 at 10:00 AM in Syracuse before Judge Glenn T. Suddaby. Government Sentencing Memo Deadline 8/20/2013. Defendant Sentencing Memo Deadline 8/20/2013. Signed by Judge Glenn T. Suddaby on 4/26/13. (lmw) (Entered: 04/26/2013)
04/30/2013	5	NOTICE OF ATTORNEY APPEARANCE Geoffrey J.L. Brown appearing for USA *for the forfeiture aspects of the case.* (Brown, Geoffrey) (Entered: 04/30/2013)
04/30/2013	6	Letter from Geoffrey J. L. Brown as to Vincent Alexis requesting that the proposed Preliminary Order of Forfeiture be signed, and filed, and copies returned. (Attachments: # 1 Proposed Order/Judgment proposed Preliminary Order of Forfeiture)(Brown, Geoffrey) (Entered: 04/30/2013)
05/17/2013	7	PRELIMINARY ORDER OF FORFEITURE as to Vincent Alexis.. Signed by Judge Glenn T. Suddaby on 5/17/2013. (lah) (Entered: 05/17/2013)
05/23/2013	8	PROCESS RECEIPT AND RETURN of Department of Homeland Security, Returned Executed as to as to the arrest of $2,000.00 in U.S. Currency on May 17, 2013. The currency was originally seized and taken into custody by CBP on July 23, 2011, and is being held in the CBP suspense account pending final disposition. filed by USA (Brown, Geoffrey) (Entered: 05/23/2013)
06/26/2013	9	SERVICE by Publication of Notice of Publication; Last publication date June 16, 2013 in the official government internet site, www.forfeiture.gov. *Claim deadline is July 17, 2013.* filed by USA (Brown, Geoffrey) (Entered: 06/26/2013)
08/01/2013	10	PRESENTENCE INVESTIGATION REPORT - INITIAL DISCLOSURE [LODGED] as to Vincent Alexis. The Presentence Investigation Report in this matter is now available for review. Any objections to the report shall be served on the Probation Office within 14 days of this notice, by mailing a hard copy to the Probation Officer. Please contact the probation officer who prepared the report if you have any questions. **[This document has been electronically lodged with the Court and is viewable by ONLY the attorney for the government, the attorney for the defendant, and the presiding judge. It is not a filed document, therefore is not available for public inspection. Any further distribution or dissemination is prohibited.]** (dct,) (Entered: 08/01/2013)
08/07/2013	11	Letter from David M. Hoovler as to Vincent Alexis requesting Extension of 9/10/13 sentencing date (Hoovler, David) (Entered: 08/07/2013)
08/07/2013		TEXT NOTICE OF HEARING as to Vincent Alexis: Pursuant to defense counsel's request, Sentencing is RESCHEDULED for 10/30/2013 at 10:00 AM in Syracuse before Judge Glenn T. Suddaby. Sentencing memorandum are due by 10/9/13.(lmw) (Entered: 08/07/2013)
09/30/2013	12	Letter from David M. Hoovler, Esq. as to Vincent Alexis requesting Extension of defendant's 10/30/13 sentencing date (Hoovler, David) (Entered: 09/30/2013)
09/30/2013	13	TEXT ORDER granting # 12 Letter Request as to Vincent Alexis: Sentencing is RESCHEDULED for 12/4/2013 at 10:45 AM in Syracuse before Judge Glenn T. Suddaby. Sentencing memorandum are due by 11/13/13.(lmw) (Entered: 09/30/2013)
10/22/2013	14	PRESENTENCE INVESTIGATION REPORT - FINAL DISCLOSURE [LODGED] as to Vincent Alexis. The final version of the Presentence Investigation Report, including all revisions and the most recent Addendum is now available for review. This version of the report will be used by the Court at the time of sentencing. **[This document has been electronically lodged with the Court and is viewable by ONLY the attorney for the government, the attorney for the defendant, and the presiding judge. Any further distribution or dissemination is prohibited.]** (dct,) (Entered: 10/22/2013)

11/13/2013	15	SENTENCING MEMORANDUM by Vincent Alexis (Hoovler, David) (Entered: 11/13/2013)
11/13/2013	16	SENTENCING MEMORANDUM by USA as to Vincent Alexis (Attachments: # 1 Affidavit)(Thomson, Tamara) (Entered: 11/13/2013)
12/04/2013		TEXT Minute Entry for Sentencing held on 12/4/13 before Judge Glenn T. Suddaby for Vincent Paul Alexis (1). No objections to PSR. Defendant sentenced on Count 1 of the Information to a term of imprisonment of 97 months and 20 years of supervised release with standard and special conditions. Special Assessment: $100; fine waived. Court recommends to BOP that defendant receive mental health and sex offender treatment. Defendant advised of appeal rights. The indictment in case 5:12-cr-439 is dismissed on Government motion. Defendant remanded. APP: Tamara Thomson, AUSA; David Hoovler, Esq., attorney for Defendant; Jenna Kulakowski, Probation. CRD: L. Welch (Court Reporter: Jodi Hibbard) (lmw) (Entered: 12/04/2013)
12/04/2013	17	STATUS REPORT *notifying the court that no ancillary claims have been filed and the Preliminary Order of Forfeiture is now final as to the defendant, and no separate final order will be presented* by USA as to Vincent Alexis (Brown, Geoffrey) (Entered: 12/04/2013)
12/09/2013	18	JUDGMENT as to Vincent Alexis (1) on Count 1: Term of imprisonment: 97 months; Supervised release: 20 years with standard and special conditions. Special assessment: $100; fine: waived. Signed by Judge Glenn T. Suddaby on 12/9/13. (lmw) (Entered: 12/09/2013)
12/09/2013	19	STATEMENT OF REASONS [LODGED] as to Vincent Alexis **[This document has been electronically lodged with the Court and is viewable by ONLY the attorney for the government, the attorney for the defendant, and the presiding judge. It is not a filed document, therefore is not available for public inspection. Any further distribution or dissemination is prohibited.]** (dictcbm) (Entered: 12/09/2013)
02/06/2014	20	PROCESS RECEIPT AND RETURN of Department of the Treasury Returned Executed on December 9, 2013 $2,000.00 in U.S. currency was moved to Treasury forfeiture fund account. filed by USA (Brown, Geoffrey) (Entered: 02/06/2014)
06/24/2014	21	Judgment Returned Executed as to Vincent Alexis. Defendant delivered to Bureau of Prisons on 5/5/2014. (lah) (Entered: 06/24/2014)
07/16/2014	22	Letter, dated 7/11/2014, from Vincent Alexis regarding this case. Copy of docket sheet and criminal appeal packet sent to defendant at the address of FCI Fort Dix Federal Correctional Institution, P.O. Box 2000, Fort Dix, NJ 08640 via regular mail. (nmk) (Entered: 07/17/2014)
07/30/2014	23	Letter from Deft Vincent Alexis requesting Return of Property. (lah) (Entered: 07/30/2014)
07/31/2014	24	STATUS REPORT *as to Defendant's letter requesting the return of property* by USA as to Vincent Alexis (Carroll, Gwendolyn) (Entered: 07/31/2014)
08/11/2014	25	Letter Request filed by Vincent Alexis in response to USA letter and request for the Return of Property. (lah) (Entered: 08/11/2014)
08/13/2014	26	TEXT ORDER denying Defendant's # 23 and # 25 letters requesting that this Court order the Government to return his personal property. The defendant must request the return of his personal property directly from the arresting agency, and this Court has no authority to direct the return of personal property. The Court does ask the Government to advise the defendant of the status of the return of his property as requested in letters filed on 7/30/14 (Docket # 23) and August 11, 2014 (Docket # 25). Authorized by Judge Glenn T. Suddaby on 8/13/14. (lmw) (Copy served upon defendant via regular mail) (Entered: 08/13/2014)

10/20/2015	27	STATUS REPORT *as to Defendant's latest request for return of property;* by USA as to Vincent Alexis (Attachments: # 1 Exhibit(s) A, # 2 Exhibit(s) B)(Thomson, Tamara) (Entered: 10/20/2015)
11/29/2016	28	TRANSCRIPT REQUEST by Department of Homeland Security ICE Office of Professional Responsibility as to Vincent Alexis for Sentencing proceedings held on 12/4/2013 before Judge Glenn T. Suddaby.(jlh,) (Entered: 11/29/2016)
12/22/2016	29	NOTICE OF FILING OF OFFICIAL TRANSCRIPT of Proceedings as to Vincent Alexis: Sentencing held on 12/4/2013 before Judge Glenn T. Suddaby, Court Reporter: Jodi L. Hibbard,Telephone number: (315) 234-8547. **IMPORTANT NOTICE - REDACTION OF TRANSCRIPTS:** In order to remove personal identifier data from the transcript, a party must electronically file a Notice of Intent to Request Redaction with the Clerk's Office within 5 business days of this date. The policy governing the redaction of personal information is located on the court website at www.nynd.uscourts.gov. Read this policy carefully. If no Notice of Intent to Redact is filed within 5 business days of this date, the court will assume redaction of personal identifiers is not necessary and the transcript will be made available on the web 90 days from today's date. Transcript may be viewed at the court public terminal or purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 1/12/2017. Redacted Transcript Deadline set for 1/23/2017. Release of Transcript Restriction set for 3/22/2017. Notice of Intent to Redact due by 12/27/2016 (jlh,) (Entered: 12/22/2016)
06/22/2017	30	CHANGE OF ADDRESS NOTICE by Vincent Alexis. Old address: #19213-052, CCI Fort Dix, Box 2000, J.B. MDL, NJ 08640. New Address: 601 E. Charleston Road, Las Vegas, NV 89104. (khr) (Entered: 06/22/2017)
04/19/2018	31	Letter Request and Address Change from Vincent Alexis requesting Docket Sheet. Old address: 601 E. Charleston Road, La Vegas, NV 89104. New Address: 3905 Lemon Ave., Long Beach, CA 90807. (khr) Mailed copy of docket sheet on 4/19/2018. (Entered: 04/19/2018)
04/19/2018	32	Letter request from Vincent Alexis requesting Grand Jury minutes. (khr) (Entered: 04/19/2018)
04/25/2018	33	TEXT ORDER denying # 32 Letter Request filed by Vincent Alexis for a copy of the Grand Jury minutes for his case. SO ORDERED by Chief Judge Glenn T. Suddaby on 4/25/18. (lmw) (Copy served upon Defendant via regular mail to 3905 Lemon Avenue, Long Beach, CA 90807) (Entered: 04/25/2018)
05/11/2018	34	MOTION REQUESTING PRIOR JAIL CREDIT FOR TIME SERVED ON RESTREICTIVE ANKEL BRACELET by Vincent Alexis. (khr) (Entered: 05/11/2018)
05/15/2018	35	TEXT ORDER denying # 34 Defendant's Motion requesting prior jail credit for time he served on restrictive ankle bracelet as to Vincent Alexis (1). SO ORDERED by Chief Judge Glenn T. Suddaby on 5/15/18.(lmw) (Copy served upon Defendant via regular mail) (Entered: 05/15/2018)
05/29/2018	36	Letter request from Vincent Alexis requesting copy of the sentencing transcript. (khr) Mailed via regular mail. (Entered: 05/30/2018)
05/29/2018	37	NOTICE OF APPEAL by Vincent Alexis re 33 Order. (khr) (Entered: 05/30/2018)
05/30/2018	38	ELECTRONIC NOTICE AND CERTIFICATION as to Vincent Alexis sent to US Court of Appeals re 37 Notice of Appeal. (khr) (Entered: 05/30/2018)
07/26/2018	39	MOTION REQUESTING A NEW PRE-SENTENCING INVETIGATION REPORT UNDER RULE 32 OF CRIMINAL PROCEDURE DUE TO ERRORS OF FACT &

		INVESTIGATION MISCONDUCT by Vincent Alexis. (khr) (Entered: 07/27/2018)
08/23/2018	40	TEXT ORDER denying # 39 Defendant's Motion requesting a new presentence investigation report. The time to file objections to the presentence report expired almost five years ago. Furthermore, Defendant was present at sentencing held on 12/4/13 wherein this Court asked defense counsel if there were any objections to the presentence report, and neither Defendant nor Defendant's attorney expressed any objections to the presentence report. (See Dkt. No. 29). SO ORDERED by Chief Judge Glenn T. Suddaby on 8/23/18. (lmw) (Copy served upon Defendant via regular mail) (Entered: 08/23/2018)
10/02/2018	41	ORDER of USCA (certified copy issued on 10/2/2018) as to Vincent Alexis regarding the # 37 Notice of Appeal - Final Judgment. Appellant Vincent Alexis, pro se, moves for leave to proceed in forma pauperis (IFP). The district court must rule on Appellants IFP status before the Court of Appeals can address his motion. See Fed. R. App. P. 24(a)(1), (5). IT IS HEREBY ORDERED that the IFP motion is held in abeyance in this Court. The Clerk is directed to transfer the motion to the district court for determination of IFP status. Upon receipt of the district courts determination, this Court will address the IFP motion. (jmb) (Entered: 10/02/2018)
10/02/2018	42	MOTION for Leave to Appeal In Forma Pauperis filed by Vincent Alexis, Pro Se. {Transferred to the District Court from the Second Circuit Court of Appeals for determination of IFP status} (jmb) (Entered: 10/02/2018)
10/04/2018	43	TEXT ORDER granting # 42 Defendant's Motion for Leave to Appeal In Forma Pauperis as to Vincent Alexis (1). SO ORDERED by Chief Judge Glenn T. Suddaby on 10/4/18.(lmw) (Copy served upon Defendant via regular mail) (Entered: 10/04/2018)
10/04/2018	44	Supplemental Electronic Certification Sent to USCA as to Vincent Alexis re 37 Notice of Appeal - Final Judgment (khr) (Entered: 10/04/2018)
12/28/2018	45	Letter request from Vincent Alexis requesting copy of plea agreement. (khr) Copy of plea agreement emailed to Defendant on 1/2/19. Modified on 1/2/2019 (lmw). (Entered: 12/28/2018)
01/03/2019	46	MANDATE of USCA issued on 1/2/2019 as to Vincent Alexis re 37 Notice of Appeal - Final Judgment filed by Vincent Alexis. Appellant, pro se, moves for leave to proceed in forma pauperis, to compel the submission of a prisoner account statement, and to compel the production of grand jury minutes. Upon due consideration, it is hereby ORDERED that the motions are DENIED and the appeal is DISMISSED because it lacks an arguable basis either in law or in fact. Neitzke v. Williams, 490 U.S. 319, 325 (1989); see also 28 U.S.C. § 1915(e). (khr) (Entered: 01/03/2019)
03/07/2019	47	ORDER MODIFYING CONDITIONS OF SUPERVISED RELEASE as to Vincent Alexis, with Defendant's consent. Signed by Chief Judge Glenn T. Suddaby on 3/7/19. (lmw) (Entered: 03/07/2019)
09/12/2019	48	NOTICE OF CHANGE OF ADDRESS dated September 1, 2019 by Vincent Alexis (jel,) (Entered: 09/13/2019)
11/04/2019	49	NOTICE OF CHANGE OF ADDRESS: Old address: 601 E. Charleston Blvd., Las Vegas, NV 89104; New Address: 1401 Watercreek Dr., N. Las Vegas, NV 89032 by Vincent Alexis (khr) (Entered: 11/04/2019)
05/01/2020	50	Supervised Release Jurisdiction Transferred to District of Nevada as to Vincent Alexis. (Per transmittal letter, District of Nevada will retrieve any documents needed via PACER). (Attachments: # 1 Transmittal Letter)(lmw) (Entered: 05/01/2020)

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

v.

VINCENT ALEXIS,

Defendant.

Case No. : 13-CR- 155 (GTS)

Plea Agreement

The United States of America, by and through its counsel of record, the United States Attorney for the Northern District of New York, and defendant VINCENT ALEXIS (hereinafter "the defendant"), by and through the defendant's counsel of record, hereby enter into the following plea agreement pursuant to Rule 11(c)(1)(A) of the Federal Rules of Criminal Procedure:

1) **The Defendant's Obligations:**

a) **Guilty Plea:** The defendant will waive indictment and plead guilty to the one count in the information in Case No. 5:13-CR- 155 (GTS) charging attempted travel in interstate or foreign commerce with intent to engage in illicit sexual conduct, in violation of 18 U.S.C. § 2423(b) and (e).

b) **Special Assessment:** The defendant will pay an assessment of $100 per count of conviction pursuant to 18 U.S.C. § 3013. The defendant agrees to deliver a check or

money order to the Clerk of the Court in the amount of $100, payable to the U.S. District Court, at the time of sentencing.

c) **Compliance with Other Terms of Agreement:** The defendant will comply in a timely manner with all of the terms of this plea agreement.

d) **Restitution:** The defendant will consent to entry of an order directing the defendant's payment of restitution in full to any person or entity who qualifies as a victim of the offense(s) of conviction under 18 U.S.C. § 3663 or § 3663A.

e) **Forfeiture:** Pursuant to 18 U.S.C. §2428 giving rise to forfeiture and 21 U.S.C. § 853(p), the defendant will consent to entry of an order directing forfeiture to the United States of the property described in the Forfeiture Allegation in the information described above, or to any substitute assets, or to a money judgment, all as more fully set out below:

(1) $2000 United States Currency

2) **The Government's Obligations:**

a) **Dismissal of remaining charges:** Upon imposition of a sentence consistent with the terms of this agreement, the government will move to dismiss all charges against the defendant in Case No. 5:12-CR-439 (GTS). Such dismissal will be without prejudice, permitting the government to seek reinstatement of any and all of those charges if the guilty plea and sentence do not remain in effect.

b) **Non-prosecution for other offenses:** For so long as the defendant's guilty plea and the sentence remain in effect, the government will not seek other federal criminal charges against the defendant based on conduct described in the information in Case No. 5:13-CR 155 (GTS) and/or in the paragraph of this agreement entitled "Factual

Basis for Guilty Plea," occurring before the date on which the defendant signs this agreement.

c) **Compliance with Other Terms of Agreement:** The government will comply in a timely manner with all of the terms of this plea agreement.

3) **Potential Maximum Penalties:** The defendant understands that the Court can impose the following maximum penalties for the offense to which the defendant agrees to plead guilty and may be required to impose mandatory minimum terms of imprisonment, all as set out below:

a) **Maximum term of imprisonment:** 30 years, pursuant to 18 U.S.C. § 2423(b).

b) **Mandatory minimum term of imprisonment:** Not applicable.

c) **Maximum fine:** $250,000.

d) **Supervised release term:** In addition to imposing any other penalty, the sentencing court must require the defendant to serve a term of supervised release between 5 years and life, to begin after imprisonment. *See* 18 U.S.C. § 3583(k). A violation of the conditions of supervised release during that time period may result in the defendant being sentenced to an additional term of imprisonment of up to 5 years.

e) **Required Registration for Sex Offenders:** Under the Sex Offender Registration and Notification Act, the defendant, as a result of the conviction in this case, must register as a sex offender, and keep the registration current, in each jurisdiction where the defendant resides, where the defendant is an employee, and where the defendant is a student. For initial registration purposes, the defendant also must register in New York as a result of this conviction, even if the defendant resides in a different jurisdiction. A sex offender who knowingly fails to register or update a required

registration may be subject to prosecution under 18 U.S.C. § 2250, and face a penalty of up to ten years imprisonment. Further, if the defendant, while on supervised release, commits any criminal offense under chapter 109A, 110, or 117, or section 1201 or 1591, of Title 18 for which imprisonment for a term longer than 1 year can be imposed, the court will revoke the term of supervised release and require the defendant to serve a term of imprisonment of not less than 5 years on the violation.

f) **Other adverse consequences**: Other adverse consequences may result from the defendant's guilty plea as further described in paragraph F below.

4) **Elements of Offense(s)**: The defendant understands that the following are the elements of the offense to which the defendant agrees to plead guilty. The defendant admits that the defendant's conduct satisfies each and every one of these elements.

a) That the defendant traveled or attempted to travel in interstate or foreign commerce;

b) That the defendant's purpose in traveling in interstate or foreign commerce was to engage in illicit sexual conduct with an individual he believed was under the age of eighteen; and

c) That the illicit sexual conduct was a commercial sex act, as defined by 18 U.S.C. §1591, with a person under 18 years of age.

5) **Factual Basis for Guilty Plea:** The defendant admits the following facts, that those facts demonstrate the defendant's guilt for the offense to which the defendant is pleading guilty, and that there are no facts establishing a viable defense to that offense:

a) On July 23, 2011, VINCENT ALEXIS drove through the border at the Port of Entry into Canada from Alexandria Bay, New York. ALEXIS began his trip days earlier, traveling from his home in Texas to Kingston, Ontario. ALEXIS was traveling to

Canada to meet a seventeen year old boy, hereinafter noted by his initials "AC," who resides in Kingston. ALEXIS met the boy when the boy was thirteen through an online internet game. The two communicated via the online game, telephone, skype, and email.

b) Canada Border Services Agency (CBSA) agents refused entry to ALEXIS after reviewing text messages on his cellular telephone. The messages were between ALEXIS and AC and were sexual in nature. CBSA photographed the text messages and forwarded them to U.S. Customs and Border Patrol. A portion of the text messages included the following:

ALEXIS: $? That requires cooperation. I do have thousands ob [sic] me.

AC: Gimme $20 rq

ALEXIS: $ requires cooperation...I got thousands on me lmfao And a gun

ALEXIS: Show me ur tits!

AC: You couldn't afford it srry

ALEXIS: Lmfao sure I can....How much you require?

AC: 5K

ALEXIS: There is a test. Ul need to pass it

ALEXIS: And i was going to give u thousands

AC: Better bring a lot of cash

ALEXIS: lots of cash is for a live show not pics!

ALEXIS: Wuts a lot?

AC: 5 figures

c) When ALEXIS was refused entry into Canada, he came back through the Alexandria Bay Port of Entry and a border search was conducted. ALEXIS was traveling with $2000 cash. Before he arrived, ALEXIS deleted the text messages on his telephone.

d) Agents interviewed ALEXIS and he admitted that he travelled from Austin, Texas to Canada to see AC for the purpose of having a sexual encounter with AC. ALEXIS admitted that he would have paid for sex or for other inappropriate sexual conduct with AC. Specifically, ALEXIS stated that he would have paid $300 for AC to dance naked for him. ALEXIS admitted that he is sexually attracted to children approximately 14 years of age and that he has a sexual desire for young men.

e) AC was interviewed and he acknowledged that ALEXIS had offered to pay him for sex, including an offer to pay AC $1000 for oral sex.

f) ALEXIS traveled to Canada for the purpose of engaging in illicit sexual conduct, that is, a commercial sex act with AC, a person under 18 years of age.

6) **Sentencing Stipulations:**

a) The parties agree that the base offense level is 24 pursuant to U.S.S.G.§2G1.3(a)(4).

b) The government will recommend a 2-level downward adjustment to the applicable federal sentencing guidelines offense level pursuant to U.S.S.G.§3E1.1(a) if, (i) through the time of sentencing, the government is convinced that the defendant has demonstrated "acceptance of responsibility" for the offense(s) to which the defendant is pleading guilty; and (ii) the government does not determine that the defendant, after signing this agreement, committed any other federal, state, or local crimes, or engaged in conduct that constitutes "obstruction of justice," as defined in U.S.S.G.§3C1.1.

c) The government will move for a 1-level downward adjustment to the applicable federal sentencing guidelines offense level pursuant to U.S.S.G.§3E1.1(b) if the government is convinced that the defendant has accepted responsibility within the meaning of U.S.S.G.§3E1.1(a) and further assisted authorities in the investigation or prosecution of the defendant's own misconduct by timely notifying authorities of the defendant's intention to enter a plea of guilty, thereby permitting the government to avoid preparing for trial and permitting the government and the court to allocate their resources efficiently, and the defendant otherwise qualifies for such adjustment by having a combined offense level of 16 before receipt of any acceptance of responsibility adjustment under U.S.S.G.§3E1.1(a).

7) **Waiver of Rights to Appeal and Collateral Attack:** The defendant waives (gives up) any and all rights, including those conferred by 18 U.S.C. § 3742 and/or 28 U.S.C. §§ 2241 and 2255, to appeal and/or to collaterally attack:

a) The conviction(s) resulting from the defendant's guilty plea;

b) Any sentence to a term of imprisonment of 168 months or less;

c) Any sentence to a fine within the maximum permitted by law;

d) Any sentence to a term of supervised release within the maximum permitted by law;

e) Any order of forfeiture or restitution imposed by the Court that is consistent with governing law and is not contrary to the terms of this agreement.

Nothing in this appeal waiver is meant to be or should be construed as a representation of or agreement concerning the appropriate sentence in this case.

A. **Right to Counsel:** The defendant has a right to assistance of counsel in connection with settlement of this case and understands that right. Defense counsel has advised the defendant of nature of the charges to which the defendant is agreeing to plead guilty and the range of possible sentences.

B. **Waiver of Trial-Related Rights:** The defendant has the following additional constitutional rights in connection with the charges in this case: (i) to be presumed innocent until proven guilty beyond a reasonable doubt; (ii) to plead not guilty; (iii) to trial by jury; (iv) to confront, cross-examine, and compel the attendance of witnesses at trial; (v) to present defense evidence; and (vi) to remain silent and be protected against compelled self-incrimination. The defendant understands that by pleading guilty, the defendant waives (gives up) these rights.

C. **Court Not Bound by Plea Agreement:** This plea agreement is made pursuant to Rule 11(c)(1)(A) of the Federal Rules of Criminal Procedure. The Court is neither a party to, nor bound by this Plea Agreement. The Court may accept or reject this Plea Agreement or defer a decision until it has considered the Presentence Investigation Report prepared by the United States Probation Office. If the Court rejects the provisions of this agreement permitting the defendant to plead guilty to certain charges in satisfaction of other charges, the Court will permit the defendant to withdraw the plea of guilty before sentencing, pursuant to Fed. R. Crim. Pro. 11(c)(5) & (d).

D. **Court Not Bound by Agreed-Upon Recommendations, Stipulations, and Requests:** If this agreement contains any provisions under Fed. R. Crim. Pro. 11(c)(1)(B) by which the government agrees to recommend, stipulates, or agrees not to oppose the defendant's request, that a particular sentence or sentencing range is appropriate or that a particular

provision of the federal sentencing guidelines, or a policy statement, or sentencing factor does or does not apply, such a recommendation, stipulation, or request does not bind the Court, which may make independent factual findings by a preponderance of the evidence and may reject such recommendations, requests, and stipulations between the parties. If the Court rejects one or more recommendations, stipulations, or requests, the defendant is not entitled to withdraw the defendant's plea of guilty and is not released from the obligations described in this agreement. Under such circumstances, the government reserves the right to support and defend, in connection with any post-sentencing proceedings, any decision the Court may make with regard to the defendant's sentence, whether or not such decision is consistent with the government's recommendations, stipulations, or requests set out in this agreement.

E. **Sentencing:**

a. **Maximum terms of imprisonment**: The defendant understands that the Court has discretion to impose a sentence within the statutory maximum sentence(s) set out in this agreement. If the defendant is pleading guilty to multiple charges, the Court may be required by law to have the sentences of imprisonment on the convictions resulting from those charges run consecutively to each other. Otherwise, the Court has discretion to have sentences of imprisonment run concurrently or consecutively. *See* 18 U.S.C. § 3584.

b. **Mandatory minimum terms of imprisonment:** If specified in this agreement, the conviction on one or more charges to which the defendant has agreed to plead guilty may require imposition of a mandatory minimum term of imprisonment. In such cases, the court must impose a term of imprisonment no less than the

required mandatory minimum term unless an exception to that requirement applies. Such exception may be dependent on a motion by the government.

c. **Sentencing guidelines:**

i. The actual sentence to be imposed upon the defendant is within the discretion of the sentencing Court, subject to the statutory maximum and mandatory minimum penalties, as described above, and the provisions of the Sentencing Reform Act and the United States Sentencing Guidelines promulgated thereunder. While the Court is not bound to impose a sentence within the applicable sentencing guidelines range, it must take into account the sentencing guidelines, along with the other factors set forth in 18 U.S.C. § 3553(a).

ii. Any estimate of the defendant's offense level, criminal history category, and sentencing guidelines range provided before sentencing is preliminary and is not binding on the parties to this agreement, the Probation Office, or the Court. Until the Probation Office has fully investigated the defendant's criminal history, it is not possible to predict with certainty the defendant's criminal history category and, in some cases, the defendant's offense level.

iii. Under certain circumstances, the defendant's criminal history may affect the defendant's offense level under the federal sentencing guidelines. If the presentence investigation reveals that the defendant's criminal history may support an offense level different than an offense level stipulated in this agreement, the parties are not bound by any such stipulation as to the

defendant's offense level and may advocate with respect to how the defendant's criminal history affects the offense level.

d. **Factual findings:** The defendant understands that the sentencing Court may make factual findings with respect to any and all sentencing factors and issues, including those referenced in the United States Sentencing Guidelines, whether or not such factors or issues have been admitted by the defendant or stipulated by the parties. In making those findings by a preponderance of the evidence, the Court may consider any reliable evidence, including hearsay. The Defendant understands that the sentence imposed may be determined based upon such judicial fact-finding.

e. **Use of the Defendant's Statements:** The defendant understands that the sentencing court may consider any statement that the defendant has made or makes in this Plea Agreement, during the guilty plea, to the Probation Office, and at sentencing when imposing sentence. In addition the government may be able to use the defendant's statements in this agreement and at the guilty plea and at sentencing in any criminal, civil, or administrative proceeding. For example, if the defendant fails to enter a guilty plea (as required by this agreement) or the defendant's guilty plea is later withdrawn or vacated for any reason other than the Court's rejection of this Plea Agreement under Fed. R. Crim. P. 11(c)(5), the government may introduce the defendant's statements into evidence in any prosecution. If, however, the Court rejects this Plea Agreement under Fed. R. Crim. P. 11(c)(5), and the defendant withdraws the guilty plea pursuant to Fed. R. Crim. P. 11(d)(2)(A), the government will not be permitted to use any of the

defendant's statements in this Plea Agreement. To the extent that Rule 11(f) of the Federal Rules of Criminal Procedure and/or Rule 410 of the Federal Rules of Evidence are inconsistent with this paragraph, the defendant waives (gives up) any protections under those rules.

f. **Government's Discretion to Recommend a Sentence:** Unless a stipulation in this agreement explicitly limits the government's discretion with respect to its recommendations at sentencing, this agreement does not prevent the government from urging the sentencing Court to find that a particular offense level, criminal history category, ground for departure, or guidelines range applies; from recommending a specific sentence within the applicable guidelines range as determined by the Court or as urged by the government; or, if the government deems appropriate, recommending that the Court impose a sentence above the applicable guidelines range.

g. **Sentencing-Related Information:** The government has the right to advise the sentencing Court and the Probation Office of any information, in aggravation or mitigation of sentencing, whether or not encompassed within the count(s) to which the defendant has agreed to plead guilty, subject only to the limitation described in U.S.S.G.§1B1.8. No stipulation in this plea agreement limits the obligations of both parties to ensure that the sentencing Court has all information pertinent to its determination of an appropriate sentence. The parties may provide any factual information relevant to sentencing to the Probation Office and/or to the Court, without limitation, before or after the completion of the Presentence Investigation Report. The parties agree that the submission of such information

shall not be deemed "advocacy" in violation of any stipulation in this plea agreement.

h. **Supervised Release Term and Conditions:** If the defendant is placed on supervised release, under some circumstances, including the defendant's violation of one or more supervised release conditions, the Court may extend the term of supervised release, and may modify, reduce, or enlarge the conditions of such release.

F. **Other Adverse Consequences:** The following are some examples of the adverse consequences of pleading guilty other than the sentence imposed by the Court, along with any judicial order of forfeiture and/or restitution:

a. Conviction of a felony may result in the loss of civil rights, including, but not limited to, the right to vote and the right to possess firearms.

b. If the defendant is not a United States citizen, such conviction may result in deportation or removal from the United States, and may bar readmission to the United States if the defendant leaves the country. Under federal law, removal or deportation may be an almost certain consequence of a conviction for a broad range of federal offenses, including, but not limited to, aggravated felonies, as defined in 8 U.S.C. § 1101(a)(43), and crimes of moral turpitude, which includes crimes involving fraud. Removal and other immigration consequences are the subject of a separate proceeding. No one, including the defendant's attorney and the Court, can predict with certainty the effect of the conviction resulting from this agreement on the defendant's immigration status. The defendant understands this uncertainty and nonetheless wishes to plead guilty regardless of any

immigration consequences that the guilty plea may entail, even if the consequence is the defendant's automatic removal from the United States.

c. A felony conviction may adversely affect the defendant's ability to hold certain professional licenses and may impair the defendant's ability to do business with federal, state, and local governments or to receive benefits from such governments.

There may be other adverse consequences as well, some of them unforeseeable. It may be difficult or impossible to predict all of the adverse consequences of the defendant's guilty plea. The defendant agrees that any resulting adverse consequences, whether or not foreseen or foreseeable, will not provide a basis for withdrawing from the guilty plea described in this agreement or otherwise challenging the resulting conviction and sentence.

G. **Restitution:** Independent of any agreement to pay restitution, and whether there is any such agreement, the sentencing Court may be required to order that the defendant pay restitution to any victim of the offense(s) of conviction under the Mandatory Victim Restitution Act, 18 U.S.C. § 3663A. In addition, the sentencing Court may have the authority to order that the defendant pay restitution to any victim of the offense(s) of conviction pursuant to 18 U.S.C. §§ 3663 & 3664.

H. **Forfeiture:** If the defendant has agreed to forfeiture of assets, the defendant agrees to the following terms and conditions:

a. The defendant hereby forfeits, to the United States, all right, title, and interest of any nature in any and all assets that are subject to forfeiture, including substitute

assets, as set forth above, whether those assets are in the possession or control of the defendant, a nominee, or some other third party.

b. The defendant consents to the entry of an order of forfeiture of the assets described above.

c. The defendant is aware that pursuant to Rule 32.2(b)(4)(A) of the Federal Rules of Criminal Procedure, a preliminary order of forfeiture becomes final as to a given defendant at sentencing or at any time before sentencing if the defendant consents. The defendant consents that the preliminary order of forfeiture in this case shall become final as to the defendant before sentencing, as of the date the preliminary order of forfeiture is entered by the Court. The defendant understands that the government, upon entry of the preliminary order of forfeiture, will address any potential third party claims pursuant to Rule 32.2(c), and seek to finalize forfeiture.

d. Forfeiture of the defendant's assets will not satisfy all, or any portion of, a fine, restitution, or other monetary penalty that the Court may impose upon the defendant in addition to forfeiture. Satisfaction of all, or any portion of, any restitution, fine, or other penalty that the Court may impose upon the defendant in addition to forfeiture will not satisfy all, or any portion of, any forfeiture judgment ordered by the Court.

e. In the event that any successful claim is made, by any third party, to the assets described above, the defendant agrees to forfeit substitute assets equal in value to the assets transferred to any such third party. The defendant agrees that forfeiture of substitute assets shall not be deemed an alteration of the Defendant's sentence.

f. The defendant agrees to cooperate with the United States by taking whatever steps are necessary to pass clear title to the United States of any forfeitable assets, including but not limited to, surrendering title; completing any documents or legal proceedings required to transfer assets to the United States; and taking necessary steps to ensure that assets subject to forfeiture are not sold, disbursed, expended, destroyed, damaged, hidden or otherwise made unavailable for forfeiture or removed beyond the jurisdiction of the Court.

g. The defendant waives the right to a jury trial on the forfeiture of assets. The defendant waives all constitutional, legal, and equitable defenses to the forfeiture of assets, as provided by this agreement, in any proceeding, including but not limited to any jeopardy defense or claim of double jeopardy or any claim or defense under the Eighth Amendment to the United States Constitution, including any claim of an excessive fine.

h. The defendant acknowledges that the government may institute civil or administrative proceedings against any or all of the defendant's forfeitable assets, including, but not limited to substitute assets and any forfeitable assets not identified by the defendant, and agrees not to contest any such forfeiture proceedings.

i. The defendant represents and warrants that the defendant has no direct or indirect interest in any property, real or personal, or other asset subject to forfeiture by virtue of this plea agreement, other than those listed above.

j. The defendant acknowledges joint and several liability for the amount of any money judgment set forth above.

k. In the event the government determines that the defendant has breached any condition of this plea agreement, none of the forfeited property shall be returned to the defendant, nor shall the defendant assert any claim to the forfeited property. The defendant shall not reacquire any forfeited property, directly or indirectly, through family members, nominees, friends, or associates.

I. **Determination of Financial Condition and Payment of Interest and Penalties:**

a. In order to facilitate the collection of financial obligations to be imposed in connection with this prosecution, the defendant agrees fully to disclose all assets in which the defendant has any interest or over which the defendant exercises control, directly or indirectly, including those held by a spouse, nominee, or other third party.

b. The defendant will promptly submit a complete, accurate, and truthful financial statement to the United States Attorney's Office, in a form it provides and as it directs.

c. The defendant authorizes the United States Attorney's Office to obtain a credit report on the defendant in order to evaluate the defendant's ability to satisfy any financial obligation imposed by the Court.

d. Interest and penalties may accrue, as a matter of law, on any unpaid financial obligation imposed as part of the defendant's sentence, from as early as the date of sentencing.

J. **Remedies for Breach:**

a. Should the government determine that the defendant, after the date the defendant has signed this plea agreement, (i) has committed any further crime or violated

any condition of release or supervision imposed by the Court (whether or not charged); (ii) has given false, incomplete, or misleading testimony or information; or (iii) has moved to withdraw the defendant's guilty plea for reasons other than those described in this agreement or otherwise has breached any term or condition of this plea agreement or supplemental agreements with the government, the government will have the right, in its sole discretion, to void this agreement, in whole or in part. In the event of such breach, the defendant will remain obligated to plead guilty and otherwise comply with the terms of this agreement and will not be permitted to withdraw the defendant's guilty plea under this agreement. The defendant will be subject to prosecution for any federal criminal violation of which the government has knowledge, including but not limited to charges that this Office has agreed to dismiss or not to prosecute under this agreement.

b. If the defendant breaches this agreement, the government will have the following remedies, among others, available to it:

   i. To bring prosecution for any federal criminal offenses dismissed or not prosecuted under this agreement. The defendant waives (gives up) any defense or objection to the commencement of any such prosecution that is not time-barred by the applicable statute of limitations as of the date on which the defendant signed this plea agreement, notwithstanding the expiration of the statute of limitations between the signing of the agreement and the commencement of any such prosecution.

   ii. In connection with any such prosecution, any information, statement, and testimony provided by the defendant, and all leads derived therefrom, may

be used against the defendant, without limitation and without regard to any rights the defendant may have under Fed. R. Crim. P. 11(f) and Fed. R. Evid. 410.

iii. To utilize any information, statement, or testimony provided by the defendant in any proceeding, including at sentencing, notwithstanding U.S.S.G.§1B1.8;

iv. To advocate if, and how, any particular adjustment or specific offense characteristic affects the applicable Sentencing Guidelines range without regard to any contrary stipulations contained in this agreement;

v. To refrain from making any sentencing-related motion favorable to the defendant without regard to any provision in this agreement obligating the government to consider making or make such motion upon fulfillment of certain conditions;

vi. To urge the sentencing Court to take the defendant's breach into account when imposing sentence;

vii. To recommend any sentence the government deems appropriate, even if such recommendation is at odds with any stipulation in this agreement.

K. **Limitations**: This agreement is between the United States Attorney's Office for the Northern District of New York and the defendant. References to "the government" in this agreement refer only to that Office. This agreement does not bind any other federal, state, or local prosecuting authorities. Furthermore, this agreement does not prohibit the United States, any agency thereof, or any third party from initiating or prosecuting any civil or administrative proceedings directly or indirectly involving the defendant,

including, but not limited to, proceedings by the Internal Revenue Service relating to potential civil tax liability, proceedings relating to the forfeiture of assets, and proceedings by the Department of Homeland Security, Bureau of Citizenship and Immigration Services relating to the immigration status of the defendant.

L. **Agreement Must be Signed; Modifications Must be Written or on the Record:** This agreement, to become effective, must be signed by all of the parties listed below. No promises, agreements, terms, or conditions other than those set forth in this plea agreement will be effective unless memorialized in writing and signed by all parties or confirmed on the record before the Court.

M. **Agreement to Plead Guilty Voluntary:** The defendant acknowledges reading each of the provisions of this plea agreement with the assistance of counsel and understands its provisions. The defendant further acknowledges that the defendant's agreement to plead guilty is voluntary and did not result from any force, threat, or promises (other than the promises in this plea agreement and any written supplemental agreements or amendments).

RICHARD S. HARTUNIAN
United States Attorney
Northern District of New York

Tamara B. Thomson
Assistant United States Attorney
Bar Roll No. 515310

4/4/13
Date

VINCENT ALEXIS

3/27/13
Date

Defendant

David Hoovler, Esq.
Attorney for Defendant
Bar Roll No.

4/1/13
Date

AO 245B NNY(Rev. 10/05) Judgment in a Criminal Case
Sheet 2 — Imprisonment

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

IMPRISONMENT

The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a total term of:

97 months

U.S. DISTRICT COURT - N.D. OF N.Y.
FILED
JUN 24 2014
AT ____ O'CLOCK ____
Lawrence K. Baerman, Clerk - Syracuse

X The court makes the following recommendations to the Bureau of Prisons:

The defendant receive mental health and sex offender treatment when and if eligible.

X The defendant is remanded to the custody of the United States Marshal.

G The defendant shall surrender to the United States Marshal for this district:

G at _____ G a.m G p.m. on _____

G as notified by the United States Marshal.

G The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

G before 2 p.m. on _____

G as notified by the United States Marshal.

G as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on 05/05/2014 to FTD

at New Jersey, with a certified copy of this judgment.

J. Hollingsworth, WARDEN
UNITED STATES MARSHAL

By J. Mathes, CSO.
DEPUTY UNITED STATES MARSHAL

U.S. DISTRICT COURT - N.D. OF N.Y.
FILED
APR 26 2013
AT ____ O'CLOCK
Lawrence K. Baerman, Clerk - Syracuse

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

****

UNITED STATES OF AMERICA

v.

VINCENT ALEXIS

Defendant.

Criminal Action No. 13-CR-155 (GTS)

VIO: 18 U.S.C. § 2423(b) and (e)

INFORMATION

County: Jefferson

****

THE UNITED STATES ATTORNEY CHARGES:

On or about July 23, 2011, in Jefferson County, in the Northern District of New York, the defendant,

VINCENT ALEXIS,

a United States citizen, traveled in interstate commerce and attempted to travel in foreign commerce with intent to engage in illicit sexual conduct, as defined in Title 18, United States Code, Section 2423(f), with another person, in violation of Title 18, United States Code, Section 2423(b) and (e).

THE UNITED STATES ATTORNEY FURTHER CHARGES:
FORFEITURE ALLEGATIONS

1. The allegations contained in Count 1 of this Information are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Section 2428.

2. Pursuant to Title 18, United States Code, Section 2428, upon conviction of an offense in violation of Title 18, United States Code, Section 2423(b) and (e), the defendant, **VINCENT ALEXIS**, shall forfeit to the United States of America any property, real or personal, that was used or intended to be used to commit or to facilitate the commission of the offense. The property to be forfeited includes, but is not limited to, the following:

a. **$2,000.00 in U.S. Currency**

3. If any of the property described above, as a result of any act or omission of the defendant[s]:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c).

Date: April 26, 2013

RICHARD S. HARTUNIAN
UNITED STATES ATTORNEY

By: Tamara B. Thomson
Tamara B. Thomson
Assistant United States Attorney

UNITED STATES DISTRICT COURT

Northern District of New York

UNITED STATES OF AMERICA
V.

VINCENT ALEXIS

JUDGMENT IN A CRIMINAL CASE

Case Number: DNYN513CR000155-001

USM Number: 19213-052

David M. Hoovler
111 Main Street, P.O. Box 509
Chester, New York 10918
(845)469-7577
Defendant's Attorney

THE DEFENDANT:

X pleaded guilty to count(s) 1 of the Information on April 26, 2013.

G pleaded nolo contendere to count(s) _____ which was accepted by the court.

G was found guilty on count(s) _____ after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
18 U.S.C. §§ 2423(b) & (e)	Attempted Travel in Interstate and Foreign Commerce to Engage in Illicit Sexual Conduct	07/23/11	1

The defendant is sentenced as provided in pages 2 through 6 of this judgment. The sentence is imposed in accordance with 18 U.S.C. § 3553 and the Sentencing Guidelines.

G The defendant has been found not guilty on count(s) _____

X Indictment 5:12-CR-439 X is G are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

December 4, 2013
Date of Imposition of Judgment

Hon. Glenn T. Suddaby
U.S. District Judge

December 9, 2013
Date

JAK

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

IMPRISONMENT

The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a total term of:

97 months

X The court makes the following recommendations to the Bureau of Prisons:

The defendant receive mental health and sex offender treatment when and if eligible.

X The defendant is remanded to the custody of the United States Marshal.

G The defendant shall surrender to the United States Marshal for this district:

G at _____ G a.m. G p.m. on _____.

G as notified by the United States Marshal.

G The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

G before 2 p.m. on _____.

G as notified by the United States Marshal.

G as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to _____

at _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

By _____
DEPUTY UNITED STATES MARSHAL

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SUPERVISED RELEASE

Upon release from imprisonment, the defendant shall be on supervised release for a term of: **20 years**

The defendant must report to the probation office in the district to which the defendant is released within 72 hours of release from the custody of the Bureau of Prisons.

The defendant shall not commit another federal, state or local crime.

The defendant shall not unlawfully possess a controlled substance. The defendant shall refrain from any unlawful use of a controlled substance. The defendant shall submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court.

G The above drug testing condition is suspended, based on the court's determination that the defendant poses a low risk of future substance abuse. (Check, if applicable.)

x The defendant shall not possess a firearm, destructive device, or any other dangerous weapon.

x The defendant shall cooperate in the collection of DNA as directed by the probation officer. (Deselect, if inapplicable.)

x The defendant shall register with the state sex offender registration agency in the state where the defendant resides, works, or is a student, as directed by the probation officer. (Check, if applicable.)

G The defendant shall participate in an approved program for domestic violence. (Check, if applicable.)

If this judgment imposes a fine or restitution, it is a condition of supervised release that the defendant pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant must comply with the standard conditions that have been adopted by this court as well as with any additional conditions on the attached page.

STANDARD CONDITIONS OF SUPERVISION

1) the defendant shall not leave the judicial district without the permission of the court or probation officer;
2) the defendant shall report to the probation officer in a manner and frequency directed by the court or probation officer;
3) the defendant shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;
4) the defendant shall support his or her dependents and meet other family responsibilities;
5) the defendant shall work regularly at a lawful occupation, unless excused by the probation officer for schooling, training, or other acceptable reasons;
6) the defendant shall notify the probation officer at least ten days prior to any change in residence or employment, or if such prior notification is not possible, then within five days after such change;
7) the defendant shall refrain from excessive use of alcohol and shall not purchase, possess, use, distribute, import, or manufacture any and all controlled substance and all controlled substance analogues, as defined in 21 U.S.C. § 802, and any paraphernalia related to any controlled substances, except that possession and use of a controlled substance properly prescribed by a licensed medical practitioner is permitted;
8) the defendant shall not frequent places where controlled substances are illegally sold, used, distributed, or administered;
9) the defendant shall not associate with any persons engaged in criminal activity and shall not associate with any person convicted of a felony, unless granted permission to do so by the probation officer;
10) the defendant shall permit a probation officer to visit him or her at any time at home or elsewhere and shall permit confiscation of any contraband observed in plain view of the probation officer;
11) the defendant shall notify the probation officer within seventy-two hours of being arrested or questioned by a law enforcement officer;
12) the defendant shall not enter into any agreement to act as an informer or a special agent of a law enforcement agency without the permission of the court;
13) as directed by the probation officer, the defendant shall notify third parties of risks that may be occasioned by the defendant's criminal record or personal history or characteristics and shall permit the probation officer to make such notifications and to confirm the defendant's compliance with such notification requirement;
14) the defendant shall not possess a firearm, destructive device, or any other dangerous weapon;
15) the defendant shall provide the probation officer with access to any requested financial information; and
16) the defendant shall submit his or her person, and any property, house, residence, vehicle, papers, effects, computer, electronic communications devices, and any data storage devices or media, to search at any time, with or without a warrant, by any federal probation officer, or any other law enforcement officer from whom the Probation Office has requested assistance, with reasonable suspicion concerning a violation of a condition of probation or supervised release or unlawful conduct by the defendant. Any items seized may be removed to the Probation Office or to the office of their designee for a more thorough examination.

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SPECIAL CONDITIONS OF SUPERVISION

1. The defendant shall not have direct or indirect contact with the identified victim known as AC.

2. The defendant shall not have any direct contact with a person under the age of 18 unless it is supervised by a person approved of by the probation officer. The defendant shall not have indirect contact with a person under the age of 18 through another person or through a device (including a telephone, computer, radio, or other means) unless it is supervised by a person approved of by the probation officer. The defendant shall reasonably avoid and remove himself or herself from situations in which the defendant has any other form of contact with a minor.

3. The defendant shall not be in any area in which persons under the age of 18 are likely to congregate, such as school grounds, child care centers, or playgrounds, without the permission of the probation officer.

4. The defendant shall participate in a mental health program, which will include, but will not be limited to, participation in a treatment program for sexual disorders. The program shall be approved by the United States Probation Office.

5. The defendant's supervised release may include examinations using a polygraph, computerized voice stress analyzer, or other similar device to obtain information necessary for supervision, case monitoring, and treatment. The defendant shall answer the questions posed during the examination, subject to his or her right to challenge in a court of law the use of such statements as violations of the defendant's Fifth Amendment rights. In this regard, the defendant shall be deemed to have not waived his or her Fifth Amendment rights. The results of any examinations shall be disclosed to the United States Probation Office and the Court, but shall not be further disclosed without the approval of the Court.

6. The defendant shall contribute to the cost of any evaluation, testing, treatment and/or monitoring services rendered in an amount to be determined by the probation officer based on the defendant's ability to pay and the availability of third party payments.

7. The defendant shall not use or possess any computer or any other device with online capabilities, at any location, except at his or her place of employment, unless the defendant participates in the Computer Restriction and Monitoring Program. The defendant shall permit the United States Probation Office to conduct periodic, unannounced examinations of any computer equipment the defendant uses or possesses, limited to all hardware and software related to online use (e.g., use of the World Wide Web, e-mail, instant messaging, etc.). These examinations may include retrieval and copying of data related to online use, and the viewing of pictures and movies which may be potential violations of the terms and conditions of supervised release from this computer equipment including any internal or external peripherals, internet-capable devices, and data storage media. This computer equipment may be removed to the Probation Office or to the office of their designee for a more thorough examination. The Probation Office may use and/or install any hardware or software system that is needed to monitor the defendant's computer use, subject to the limitations described above.

8. If the defendant's employment requires the use of a computer, the defendant may use a computer in connection with the employment approved by the probation officer, at the defendant's place of employment, provided the defendant notifies his or her employer of: (1) the nature of his or her conviction; and (2) the fact that the defendant's conviction was facilitated by the use of the computer. The Probation Office must confirm the defendant's compliance with this notification requirement.

DEFENDANT'S ACKNOWLEDGMENTOF APPLICABLE CONDITIONS OF SUPERVISION

Upon a finding of a violation of probation or supervised release, I understand that the court may (1) revoke supervision, (2) extend the term of supervision, and/or (3) modify the conditions of supervision.

The conditions of supervision have been read to me. I fully understand the conditions and have been provided a copy of them.

Defendant _____ Date _____

U.S. Probation Officer/Designated Witness _____ Date _____

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	Fine	Restitution
TOTALS	$ 100	$ Waived	$ N/A

G The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

G The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss*	Restitution Ordered	Priority or Percentage

TOTALS $ _____ $ _____

G Restitution amount ordered pursuant to plea agreement $ _____

G The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

G The court determined that the defendant does not have the ability to pay interest and it is ordered that:

G the interest requirement is waived for the G fine G restitution.

G the interest requirement for the G fine G restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT: Vincent Alexis
CASE NUMBER: DNYN513CR000155-001

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties are due as follows:

A X In full immediately; or

B G Lump sum payment of $ _____ due immediately, balance due

G not later than _____ , or
G in accordance with G D, G E, G F, or G G below; or

C G Payment to begin immediately (may be combined with G D, G E, or G G below); or

D G Payment in equal _____ (e.g., weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after the date of this judgment; or

E G Payment in equal _____ (e.g., weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after release from imprisonment to a term of supervision; or

F G Payment during the term of supervised release will commence within _____ (e.g., 30 or 60 days) after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

G G Special instructions regarding the payment of criminal monetary penalties:

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to **Clerk, U.S. District Court, Federal Bldg., 100 S. Clinton Street, P.O. Box 7367, Syracuse, N.Y. 13261-7367**, unless otherwise directed by the court, the probation officer, or the United States attorney. If a victim cannot be located, the restitution paid to the Clerk of the Court for that victim shall be sent to the Treasury, to be retrieved if and when the victim is located.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

G Joint and Several

G Defendant and Co-Defendant Names and Case Numbers (including defendant number), Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

G The Court gives notice that this case involves other defendants who may be held jointly and severally liable for payment of all or part of the restitution ordered herein and may order such payment in the future.

G The defendant shall pay the cost of prosecution.

G The defendant shall pay the following court cost(s):

X The defendant shall forfeit the defendant's interest in the following property to the United States:

The defendant shall forfeit to the United States all right, title, and interest in the items listed in the Preliminary Order of Forfeiture signed by the Court on May 17, 2013.

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal,(5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

United States District Court
for the Northern District of New York

Request for Modifying the Conditions or Term of Supervision with Consent of the Offender
(Probation Form 49, Waiver of Hearing is Attached)

Name of Offender: Vincent Alexis Case Number: 5:13CR00155-001

Name of Sentencing Judicial Officer: Honorable Glenn T. Suddaby, Chief U.S. District Judge

Date of Original Sentence: December 4, 2013

Original Offense: Attempted Travel in Interstate and Foreign Commerce to Engage in Illicit Sexual Conduct

Original Sentence: 97 Months Imprisonment

Type of Supervision: 20 Years Supervised Release Date Supervision Commenced: Pending - May 5, 2020

PETITIONING THE COURT

[ ] To extend the term of supervision for years, for a total term of years.
[X] To modify the conditions of supervision as follows:

The defendant must not view or possess any "visual depiction" (as defined in 18 U.S.C. § 2256), including any photograph, film, picture, or computer or computer-generated image or picture, whether made or produced by electronic, mechanical, or other means, of "sexually explicit conduct" (as defined in 18 U.S.C. § 2256).

CAUSE

On December 4, 2013, the Court sentenced Vincent Alexis to 97 months imprisonment and 20 years supervised release following his plea of guilty to Attempted Travel in Interstate and Foreign Commerce to Engage in Illicit Sexual Conduct in violation of 18 U.S.C. §§ 2423(b) and (e). The defendant is presently serving his sentence with the Federal Bureau of Prisons at FCI Fort Dix. He is scheduled to be released from the Bureau of Prisons on May 5, 2020. The defendant has no ties to the Northern District of New York. He was arrested in the Northern District of New York after attempting to enter Canada in order to meet with a 17-year-old minor to engage in sexual activity with the minor. The defendant has requested to be released to the District of Nevada. The U.S. Probation Office in the District of Nevada is requiring the requested modification of the defendant's conditions of supervised release prior to their acceptance of his supervision.

Alexis is agreeable with this modification and he has signed Probation Form 49, Waiver of Hearing to Modify Conditions. If the Court agrees with this proposed modification, Probation Form 12B and Probation Form 49 will need to be filed with the Clerk's Office. With the exception of the recommended modification, no further action is requested at this time.

Respectfully submitted,

by: M.J. Kester
Michael J. Kester
Supervising U.S. Probation Officer

Date: 3/7/2019

THE COURT ORDERS

[ ] No Action
[ ] The Extension of Supervision as Noted Above
[✓] The Modification of Conditions as Noted Above
[ ] Other

Signature of Judicial Officer

March 7, 2019
Date

PROB 49
(1/89)

UNITED STATES DISTRICT COURT

Northern District of New York

Waiver of Hearing to Modify Conditions of Probation/Supervised Release or Extend Term of Supervision

I have been advised and understand that I am entitled by law to a hearing and assistance of counsel before any unfavorable change may be made in my Conditions of Probation and Supervised Release or my period of supervision being extended. By "assistance of counsel," I understand that I have the right to be represented at the hearing by counsel of my own choosing if I am able to retain counsel. I also understand that I have the right to request the court to appoint counsel to represent me at such a hearing at no cost to myself if I am not able to retain counsel of my own choosing.

I hereby voluntarily waive my statutory right to a hearing and to assistance of counsel. I also agree to the following modification of my Conditions of Probation and Supervised Release or to the proposed extension of my term of supervision:

No Pornography – You must not view or possess any "visual depiction" (as defined in 18 U.S.C. § 2256), including any photograph, film, video, picture, or computer or computer-generated image or picture, whether made or produced by electronic, mechanical, or other means, of "sexually explicit conduct" (as defined in 18 U.S.C. § 2256).

Witness S. Ainsworth
BOP Case Manager

Signed Vincent Alexis
Probationer or Supervised Releasee

AUGUST 24, 2018
Date

MANDATE

N.D.N.Y.
13-cr-155
Suddaby, C.J.

United States Court of Appeals
FOR THE
SECOND CIRCUIT

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 14th day of November, two thousand eighteen.

Present:

Reena Raggi,
Peter W. Hall,
Richard J. Sullivan,
Circuit Judges.

United States of America,

Appellee,

v. 18-1622

Vincent Alexis,

Defendant-Appellant.

Appellant, pro se, moves for leave to proceed in forma pauperis, to compel the submission of a prisoner account statement, and to compel the production of grand jury minutes. Upon due consideration, it is hereby ORDERED that the motions are DENIED and the appeal is DISMISSED because it "lacks an arguable basis either in law or in fact." *Neitzke v. Williams*, 490 U.S. 319, 325 (1989); *see also* 28 U.S.C. § 1915(e).

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk of Court

A True Copy
Catherine O'Hagan Wolfe, Clerk
United States Court of Appeals, Second Circuit

MANDATE ISSUED ON 01/02/2019

16B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Dispensing Practitioner Registration Application

Non-Refundable $300 fee

Rev (06/16/2022)

Type of Application

☑ New Dispensing Location
☐ Dispensing Location Ownership Change (Provide current Dispensing Registration #: _____)
☐ Dispensing Location Address Change (Provide current Dispensing Registration #: _____)

What types of drug(s) will you be dispensing?

☐ Dangerous Drugs (DD) ONLY
☑ Dangerous Drugs (DD) AND Controlled Substances (CS) (Provide your Controlled Substance Registration #: FD8404523)

Is the office or facility from which the practitioner intends to dispense DD/CS wholly owned and operated by the practitioner?

☐ Yes
☑ No (Facility owner(s) must complete the Personal History application at www.bop.nv.gov. Submit this with your application.)

Section 1: Personal Information

First: DAISY Middle: de Gaia Last: de Guzman

Date of Birth: [redacted] SSN or ITIN [redacted] Sex: ☐ M ☑ F ☐ X

Home Address: [redacted] Homeward Way

City: Henderson State: NV Zip: 89011

Telephone: [redacted] Email: [redacted]

Degree: M.D. Practitioner License #: 18593 Specialty: Internal Medicine

(You MUST have a current and active license with your respective BOARD to apply for and maintain a practitioner dispensing registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: Advanced Medical Weight Loss and Wellness Center, INC

Practice Address: 1400 West Horizon Ridge Parkway Suite #: B-213

City: Henderson State: NV Zip: 89012

Telephone: 702-897-9797 Fax: 702-897-9795 Email: Advmed@aol.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		NA ✓

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2+3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Dec 2011	JAN 2013	NJ	NEWARK	ESSEX
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
2:12-CR-389(CCC)	UNITED STATE DISTRICT COURT DNJ			
Reason/Charge				
ANTI KICKBACK STATUE				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
UNITED STATES of AMERICA VS DAISY de GUZMAN				
Name of Business/Industry/Entity				
DAISY de GUZMAN M.D.				

Provide explanation below:

SEE ATTACHED PAGE FOR EXPLANATION and documents

Daisy de Guzman

Original Signature (electronic, copies or stamps not accepted)

April 30, 2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered dispensing practitioner who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

DAISY de Guzman

Print Name (First, Last)

Daisy de Guzman

Original Signature (electronic, copies or stamps not accepted)

April 27, 2023

Date

Board Use Only: Date Processed: _____ Amount: 300.00 CC

Daisy De Guia DE GUZMAN

License Number: 18593

License Type: Medical Doctor

License Status: Active

Initial License Date: Jan-18-2019

Expiration Date: Jun-30-2023

Public Address: 2828 E Lake Mead Blvd

Public City: North Las Vegas

Public State: Nevada

Public ZIP Code: 89030

Public Country: United States

Public Phone Number: 7025512222

Credential: M.D.

Specialties

Specialty
Internal Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
University of Santo Tomas / Manila, Philippines	Medical Doctor Degree	N/A	May-18-1965

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Elizabeth General Hospital / Elizabeth, NJ	Internship	Rotating	Jul-01-1966	Jun-30-1967
Bronx Lebanon Hospital / Bronx, NY	Residency	Internal Medicine	Jul-01-1967	Jun-30-1968
Veterans Administrative Hospital / Manhatten, NY	Residency	Internal Medicine	Jul-01-1968	Jun-30-1969
Bronx Lebanon Hospital / Bronx, NY	Residency	Internal Medicine	Jul-01-1969	Jun-30-1970

Institution	Program Type	Specialty Type	Start Date	End Date
Mount Sinai Hospital / New York City, NY	Fellowship	Internal Medicine	Jul-01-1971	Dec-31-1973

Board Actions

Summary	Attachments
None.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

Supervisor To

Licensee	Relationship	Date of Association
FLANAGAN, Jermaine Kareem	Additional Supervisor	Jan-26-2023

ANSWER TO PAGE 3 NO 2 AND 3

IN DEC.2011,I WAS ONE OF THE 14 NEW JERSEY DOCTORS ACCUSED OF ANTI- KICKBACK STATUE.THE FEDERAL GOVERNMENT SENT A SUPPOSED TO BE MARKETING AGENT FROM A PRIVATE MRI COMPANY AND GAVE ME A MONETARY GIFT AS A GRATITUDE FOR SENDING MRI REQUEST TO THEIR OFFICE,I RECEIVED $1,000.00 IN OCT 2011,$1,500.00 IN NOV 2011 AND ANOTHER $ 1,000.00 IN DEC 2011.

THIS EVENT WAS VIDEOD AND MY LAWYER RECOMMENDED TO PLEAD GUILTY FOR A LESSER OFFENSE.I LOST MY NJ LICENSE FOR 1 YEAR AND WAS SUSPENDED FROM MEDICAID AND MEDICARE FOR 10 YEARS,I WAS REINSTATED BY OFFICE OF INSPECTOR GENERAL IN MARCH 2019

ENCLOSED HEREWITH IS A COPY OF REINSTATEMENT FROM OFFICE OF INSPECTOR GENERAL,NPDB FROM CENTERS OF MEDICARE AND MEDICAID AND NJ MEDICAID.

State of New Jersey
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
PO BOX 712
TRENTON, NJ 08625-0712

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

CAROLE JOHNSON
Commissioner

JENNIFER LANGER JACOBS
Assistant Commissioner

September 22, 2020

Daisy De Guzman, MD
[redacted] Homeward Way
Henderson, NV 89011

Re: Reinstatement Request

Dear Dr. De Guzman,

This is to inform you that you are hereby reinstated to participate in the programs administered in whole or part by the Division of Medical Assistance and Health Services.

Your reinstatement is effective as of the date of this letter. However, please note that this reinstatement letter does not reactivate your New Jersey Medicaid provider number. Rather you must first submit a completed enrollment packet, along with a copy of this letter, to reactivate provider status. Provider Enrollment packets can be found online at www.njmmis.com or by calling the Provider Enrollment Unit at DXC Technology at 609-588-6036 to have an enrollment packet mailed to you.

Sincerely,

Jennifer Langer Jacobs
Assistant Commissioner

c: Kim Ranke, MFD

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Daisy G. De Guzman, M.D.
[redacted] Homeward Way
Henderson, NV 89011

MAR 13 2019

Dear Daisy G. De Guzman:

RE: OI File No. 2-11-40392-9

Your request for the reinstatement of your eligibility to participate as a provider of items and services covered by the title XVIII (Medicare) program has been approved. The reinstatement is effective with the date of this notice.

We have notified the appropriate State agencies of this action. However, the States are not obligated to reinstate you to their programs if they have imposed a longer period of exclusion under their own authority.

We recommend that you contact the Medicare carrier to determine your options for participating in that program.

Although your right to participate in the Federal health care programs has been reinstated effective with the date of this letter, your name will remain on the List of Excluded Individuals/Entities (LEIE) until the next monthly update. You can access the LEIE online at http://oig.hhs.gov/exclusions/index.asp. You should use this letter to demonstrate that your right to participate in the Federal health care programs has been reinstated until your name is removed from the LEIE.

Sincerely,

William T. Echols
Reviewing Official
Health Care Program Exclusions

National Practitioner Data Bank
Health Resources and Services Administration
U.S. Department of Health and Human Services
P.O. Box 10832
Chantilly, VA 20153-0832
https://www.npdb.hrsa.gov

DCN: 5500000191821111
Process Date: 06/15/2022
Page: 1 of 3
DE GUZMAN, DAISY

DE GUZMAN, DAISY

CENTERS FOR MEDICARE AND MEDICAID SERVICES

REVISION TO GOVERNMENT ADMINISTRATIVE ACTION

Date of Action: 02/01/2020

Subsequent Action	Basis for Initial Action
- REINSTATEMENT	- OTHER, SEE SECTION C. OF THE REPORT FOR DETAILS - CRIMINAL CONVICTION

A. REPORTING ENTITY

Entity Name:	CENTERS FOR MEDICARE AND MEDICAID SERVICES
Address:	7500 SECURITY BLVD
	C3-03-14
City, State, Zip:	BALTIMORE, MD 21244-1849
Country:	
Name or Office:	PROVIDERENROLLMENT@CMS.HHS.GOV
Title or Department:	PROVIDERENROLLMENT@CMS.HHS.GOV
Telephone:	(000) 000-0000
Entity Internal Report Reference:	
Type of Report:	REVISION
Related Report Number:	5500000174078262

B. SUBJECT IDENTIFICATION INFORMATION (INDIVIDUAL)

Subject Name:	DE GUZMAN, DAISY
Other Name(s) Used:	
Gender:	FEMALE
Date of Birth:	**/**/****
Organization Name:	
Work Address:	111 MULBERRY ST
City, State, ZIP:	NEWARK, NJ 07102
Organization Type:	
Home Address:	
City, State, ZIP:	
Deceased:	NO
Federal Employer Identification Numbers (FEIN):	
Social Security Numbers (SSN):	***-**-****
Individual Taxpayer Identification Numbers (ITIN):	
National Provider Identifiers (NPI):	
Professional School(s) & Year(s) of Graduation:	
Occupation/Field of Licensure:	PHYSICIAN (MD)
State License Number, State of Licensure:	
Drug Enforcement Administration (DEA) Numbers:	
Unique Physician Identification Numbers (UPIN):	
Name(s) of Health Care Entity (Entities) With Which Subject Is Affiliated or Associated (Inclusion Does Not Imply Complicity in the Reported Action):	
Business Address of Affiliate:	
City, State, ZIP:	
Nature of Relationship(s):	

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CONFIDENTIAL DOCUMENT - FOR AUTHORIZED USE ONLY

ANSWER TO PAGE 3 NO 2 AND 3

IN DEC.2011,I WAS ONE OF THE 14 NEW JERSEY DOCTORS ACCUSED OF ANTI- KICKBACK STATUE.THE FEDERAL GOVERNMENT SENT A SUPPOSED TO BE MARKETING AGENT FROM A PRIVATE MRI COMPANY AND GAVE ME A MONETARY GIFT AS A GRATITUDE FOR SENDING MRI REQUEST TO THEIR OFFICE,I RECEIVED $1,000.00 IN OCT 2011,$1,500.00 IN NOV 2011 AND ANOTHER $ 1,000.00 IN DEC 2011.

THIS EVENT WAS VIDEOD AND MY LAWYER RECOMMENDED TO PLEAD GUILTY FOR A LESSER OFFENSE.I LOST MY NJ LICENSE FOR 1 YEAR AND WAS SUSPENDED FROM MEDICAID AND MEDICARE FOR 10 YEARS,I WAS REINSTATED BY OFFICE OF INSPECTOR GENERAL IN MARCH 2019

ENCLOSED HEREWITH IS A COPY OF REINSTATEMENT FROM OFFICE OF INSPECTOR GENERAL,NPDB FROM CENTERS OF MEDICARE AND MEDICAID AND NJ MEDICAID.

National Practitioner Data Bank
Health Resources and Services Administration
U.S. Department of Health and Human Services
P.O. Box 10832
Chantilly, VA 20153-0832
https://www.npdb.hrsa.gov

DCN: 5500000191821111
Process Date: 06/15/2022
Page: 1 of 3
DE GUZMAN, DAISY

DE GUZMAN, DAISY

CENTERS FOR MEDICARE AND MEDICAID SERVICES

REVISION TO GOVERNMENT ADMINISTRATIVE ACTION

Date of Action: 02/01/2020

Subsequent Action	Basis for Initial Action
- REINSTATEMENT	- OTHER, SEE SECTION C. OF THE REPORT FOR DETAILS - CRIMINAL CONVICTION

A. REPORTING ENTITY

Entity Name:	CENTERS FOR MEDICARE AND MEDICAID SERVICES
Address:	7500 SECURITY BLVD
	C3-03-14
City, State, Zip:	BALTIMORE, MD 21244-1849
Country:	
Name or Office:	PROVIDERENROLLMENT@CMS.HHS.GOV
Title or Department:	PROVIDERENROLLMENT@CMS.HHS.GOV
Telephone:	(000) 000-0000
Entity Internal Report Reference:	
Type of Report:	REVISION
Related Report Number:	5500000174078262

B. SUBJECT IDENTIFICATION INFORMATION (INDIVIDUAL)

Subject Name:	DE GUZMAN, DAISY
Other Name(s) Used:	
Gender:	FEMALE
Date of Birth:	**/**/****
Organization Name:	
Work Address:	111 MULBERRY ST
City, State, ZIP:	NEWARK, NJ 07102
Organization Type:	
Home Address:	
City, State, ZIP:	
Deceased:	NO
Federal Employer Identification Numbers (FEIN):	
Social Security Numbers (SSN):	***-**-****
Individual Taxpayer Identification Numbers (ITIN):	
National Provider Identifiers (NPI):	
Professional School(s) & Year(s) of Graduation:	
Occupation/Field of Licensure:	PHYSICIAN (MD)
State License Number, State of Licensure:	
Drug Enforcement Administration (DEA) Numbers:	
Unique Physician Identification Numbers (UPIN):	
Name(s) of Health Care Entity (Entities) With Which Subject Is Affiliated or Associated (Inclusion Does Not Imply Complicity in the Reported Action):	
Business Address of Affiliate:	
City, State, ZIP:	
Nature of Relationship(s):	

CONFIDENTIAL DOCUMENT - FOR AUTHORIZED USE ONLY

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Daisy G. De Guzman, M.D.
[redacted] Homeward Way
Henderson, NV 89011

MAR 13 2019

Dear Daisy G. De Guzman:

RE: OI File No. 2-11-40392-9

Your request for the reinstatement of your eligibility to participate as a provider of items and services covered by the title XVIII (Medicare) program has been approved. The reinstatement is effective with the date of this notice.

We have notified the appropriate State agencies of this action. However, the States are not obligated to reinstate you to their programs if they have imposed a longer period of exclusion under their own authority.

We recommend that you contact the Medicare carrier to determine your options for participating in that program.

Although your right to participate in the Federal health care programs has been reinstated effective with the date of this letter, your name will remain on the List of Excluded Individuals/Entities (LEIE) until the next monthly update. You can access the LEIE online at http://oig.hhs.gov/exclusions/index.asp. You should use this letter to demonstrate that your right to participate in the Federal health care programs has been reinstated until your name is removed from the LEIE.

Sincerely,

William T. Echols
Reviewing Official
Health Care Program Exclusions

State of New Jersey
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
PO Box 712
TRENTON, NJ 08625-0712

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

CAROLE JOHNSON
Commissioner

JENNIFER LANGER JACOBS
Assistant Commissioner

September 22, 2020

Daisy De Guzman, MD
[redacted] Homeward Way
Henderson, NV 89011

Re: Reinstatement Request

Dear Dr. De Guzman,

This is to inform you that you are hereby reinstated to participate in the programs administered in whole or part by the Division of Medical Assistance and Health Services.

Your reinstatement is effective as of the date of this letter. However, please note that this reinstatement letter does not reactivate your New Jersey Medicaid provider number. Rather you must first submit a completed enrollment packet, along with a copy of this letter, to reactivate provider status. Provider Enrollment packets can be found online at www.njmmis.com or by calling the Provider Enrollment Unit at DXC Technology at 609-588-6036 to have an enrollment packet mailed to you.

Sincerely,

Jennifer Langer Jacobs
Assistant Commissioner

c: Kim Ranke, MFD

17

17A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Y

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

What types of drug(s) will you be prescribing?

☐ Dangerous Drugs ONLY **(Non-Refundable $80 Fee) (PR)**

☒ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V **(Non-Refundable $200 Fee) (CS)**

Select the Controlled Substance Schedules you are applying to prescribe

☒ Schedule I ☒ Schedule II ☐ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Rebecca Middle: Ann Last: Martinez

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Home Address: [redacted] S 2nd Ave

City: Yuma State: AZ Zip Code: 85364

Telephone [redacted] Email:

APRN License #: 865606 Specialty: Family Nurse Practitioner

(A **current license and active-PRESCRIBING status** with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: Naphcare

Practice Address: 911 East Parr Blvd Suite #:

City: Reno State: NV Zip: 89512

Telephone: 775-328-3001 Fax: Email:

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☒ I have at least 2 years or 2,000 hours of clinical experience; OR

☐ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name:

Collaborating Physician Practice Address: Suite #:

City: State: Zip:

Telephone: Fax: Email:

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/16/2001	02/28/2002	DE	Rehoboth	Sussex

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
0111018692	State of Delaware

Reason/Charge
DUI First Offenders Program

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Rebecca Trachtenberg (now Martinez)	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:

My name is Rebecca Martinez. I am including this letter as part of my credentialing. On November 16th, 2001 I was arrested for a DUI in Lewes, DE on highway 1, also known as the Coastal Highway. I was arrested under my maiden name, Rebecca Ann Trachtenberg. I had turned right onto highway 1 from Rehoboth Ave at 1:59am and was very shortly thereafter pulled over by a state policeman. I was determined to be under the influence and arrested for driving under the influence.

This was my first, and last, offence and I therefore qualified for the First Offenders Program (FOP) in Delaware, which is a diversion program for a DUI offence. This renders the arrest a violation only and not a crime and results in no actual conviction according to the Justice of the Peace Court #14. The documentation provided lists the offence as a DUI FOP specifically and not a DUI. I completed the FOP, which required that I attend DUI education classes and the matter was closed on October 17th, 2002. Please let me know if I need to supply any other information or documentation regarding the matter. Thank you.

Original Signature (electronic, copies or stamps not accepted)

Date 6/26/23

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rebecca Ann Martinez

Applicant Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date

Board Use Only: Date Processed: _____ Amount: 200-CC

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rebecca Ann Martinez

Applicant Print Name (First, Last)

R [illegible]

Original Signature (electronic, copies or stamps not accepted)

6/27/23

Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only: Date Processed: _____ Amount: 200-cc

State of Delaware
JUSTICE OF THE PEACE COURT 14
5 E PINE STREET
GEORGETOWN, DE 19947
(302) 856-4657

DISPOSITION RECORD

STATE OF DELAWARE

vs

REBECCA A TRACHTENBERG

Court Case #: 0111018692

Summons # SPR36112

Complaint #

Date of Arrest: 11/16/2001

Chapter 21 Section 4177
Code of the State of Delaware

Offense: DUI FOP

Court: JUSTICE OF THE PEACE COURT 14
Plea: GUILTY
Date of Plea: 02/28/2002

Finding: FIRST OFFENDER OPTION
Date of Finding: 02/28/2002

VCF : $0.00	SUBSTANCE ABUSE:	$0.00	
VRF : $0.00	VIDEOPHONE	: $1.00	
PD : $0.00	ALC	: $0.00	
FINE: $0.00	DELJIS FEE	: $0.00	
COST: $35.00	COURT FEE	: $0.00	
RESTITUTION: $0.00	TRANS FEE	: $0.00	
DNREC: $0.00	POLICE FUND	: $0.00	

I, WILLIAM P WOOD, Justice of the Peace of the State of Delaware, do hereby certify that the above and foregoing is a true and correct copy of the judgment rendered in the above-captioned case, as is of record in the Justice of the Peace Court automated criminal case management system.

IN TESTIMONY WHEREOF, I hereunto set my hand and affix the seal of the said court this 12 day of March, 2012.

WILLIAM P WOOD

Justice of the Peace

JUSTICE OF THE PEACE COURT
STATE OF DELAWARE

State of Delaware
JUSTICE OF THE PEACE COURT 14
5 E PINE STREET
GEORGETOWN, DE 19947
(302) 856-4657

DISPOSITION RECORD - SENTENCE DATA

STATE OF DELAWARE

vs

REBECCA A TRACHTENBERG

Court Case #: 0111018692

Sentence Data

Special Provisions: COMPLETED 17 OCT 2002

I, WILLIAM P WOOD, Justice of the Peace of the State of Delaware, do hereby certify that the above and foregoing is a true and correct copy of the judgment rendered in the above-captioned case, as is of record in the Justice of the Peace Court automated criminal case management system.

IN TESTIMONY WHEREOF, I hereunto set my hand and affix the seal of the said court this 12 day of March, 2012.

WILLIAM P WOOD

WPW

JUSTICE OF THE PEACE COURT
STATE OF DELAWARE

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
8/1/12	02/26/2013	AZ	Tucson	Pima

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
1302155	Arizona Board of Nursing

Reason/Charge
Ethics Violation of the Nurse Practice Act

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Rebecca Hutton	NA

Name of Business/Industry/Entity
NA

Provide explanation below:

My name is Rebecca Martinez. I am a nurse practitioner and I am in recovery from the disease of addiction. I have been in recovery since 2006. In 2012, my husband and I relocated to Arizona. I did not have a good support system or routine in place when I moved here and subsequently had a relapse the summer of 2012. During that relapse my husband convinced me to write prescriptions for narcotics for his use. Although I recommitted to being clean in August of 2012 and have remained clean since then, my husband convinced me to write prescriptions for his medical use on several other occasions in the ensuing six months. I became very concerned about my behavior and his escalating addiction and confided in my family for support. In March of 2013, shortly after I made the family aware of the situation, my mother in law felt compelled to report me for unethical prescribing, and rightly so. During the investigation I chose to disclose to the board of nursing that I have a personal history of addiction because I felt that it was relevant, and the board had a right to know. I officially entered probation on March 23rd of 2014 and successfully completed the term in July of 2017. My license is now in good standing without restrictions.

I have not ever had any issues in my practice with patient care because of my addiction. I have never had an issue with malpractice insurance claims being filed. I currently have no restrictions on my practice. I was able to renew my DEA license in 2020 without incident. In 2015, I voluntarily surrendered both my Pennsylvania and California nursing licenses, in relation to this same incident, as neither state would allow me to complete probation for this infraction in absentia. When I applied for a registered nursing license in the state of Ohio, the board issued an RN license but reprimanded the license based on the past offense in Arizona, there was no new infraction. The reprimand is the lowest form of discipline. The board of nursing of Ohio also issue an NP license for me and I have an active DEA in good standing in that state as well.

Since August of 2012 my recovery has reached a new level of importance and efficacy in my life. As one of Jehovah' s witnesses, I apply bible principles in my life daily and I am committed to being clean in every way. I have a support system of people in the congregation who are also in recovery from addiction or committed to leading a clean life. I have a relapse prevention plan in place. I am truly committed to being honest in all my affairs and taking care of myself. My husband and I separated for several months in 2013 until he could demonstrate that he was dedicated to recovery and until I could address the issues of codependency so I would not make the same mistakes again. I never want to contribute to someone else' s addictive behavior, nor do I want to compromise myself professionally again. Sadly, the disease of addiction claimed my husband' s life on July 8th of 2015 but I can have confidence that I acted with integrity and did not contribute to his demise. Furthermore, I endured that tragedy without relapse and with my community of recovery, successfully.

In addition to the personal strides that I have made in the last 1 years, I also completed both a relapse prevention program and a medical ethics course as part of my consent agreement with the board of

Original Signature (electronic, copies or stamps not accepted)

Date 6/27/23

June 27, 2023

To Whom It May Concern:

My name is Rebecca Martinez. I am a nurse practitioner and I am in recovery from the disease of addiction. I have been in recovery since 2006. In 2012, my husband and I relocated to Arizona. I did not have a good support system or routine in place when I moved here and subsequently had a relapse the summer of 2012. During that relapse my husband convinced me to write prescriptions for narcotics for his use. Although I recommitted to being clean in August of 2012 and have remained clean since then, my husband convinced me to write prescriptions for his medical use on several other occasions in the ensuing six months. I became very concerned about my behavior and his escalating addiction and confided in my family for support. In March of 2013, shortly after I made the family aware of the situation, my mother in law felt compelled to report me for unethical prescribing, and rightly so. During the investigation I chose to disclose to the board of nursing that I have a personal history of addiction because I felt that it was relevant, and the board had a right to know. I officially entered probation on March 23rd of 2014 and successfully completed the term in July of 2017. My license is now in good standing without restrictions. I have not ever had any issues in my practice with patient care because of my addiction. I have never had an issue with malpractice insurance claims being filed. I currently have no restrictions on my practice. I was able to renew my DEA license in 2020 without incident.

In 2015, I voluntarily surrendered both my Pennsylvania and California nursing licenses, in relation to this same incident, as neither state would allow me to complete probation for this infraction in absentia. When I applied for a registered nursing license in the state of Ohio, the board issued an RN license but reprimanded the license based on the past offense in Arizona, there was no new infraction. The reprimand is the lowest form of discipline. The board of nursing of Ohio also issue an NP license for me and I have an active DEA in good standing in that state as well.

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Respectfully,



Rebecca Martinez, RN, MSN, FNP-BC

Doug Ducey
Governor

Joey Ridenour
Executive Director

Arizona State Board of Nursing
4747 North 7th Street, Suite 200
Phoenix. AZ 85014-3655
Phone (602) 771-7800 Fax (602) 771-7882
E-Mail: arizona@azbn.gov
Home Page: http://www.azbn.gov

July 27, 2017

Rebecca Ann Hutton
3411 South Camino Seco 175
Tucson, Arizona 85730

Dear Rebecca Hutton:

CONGRATULATIONS ON COMPLETION OF YOUR ORDER WITH THE ARIZONA STATE BOARD OF NURSING. The Board wishes to take this opportunity to wish you well in your future nursing practice.

Enclosed is the formal termination Order showing that you have completed your agreement with the Arizona State Board of Nursing. Please save this for your records and provide a copy to your employer.

Should you desire a new unstamped license, you must return your stamped license and, in writing, request a new license. If your license is up for renewal you must complete the renewal process instead. If you have any questions, please call me at (602) 771-7811.

Sincerely,

Kathleen Harrington

Kathleen Harrington, RN, MSN-INF
Nurse Practice Consultant
Monitoring Department

:nk

Enclosure

BEFORE THE ARIZONA STATE BOARD OF NURSING

IN THE MATTER OF REGISTERED NURSE LICENSE NO. RN173397 AND ADVANCE PRACTICE LICENSE NO.AP4531 ISSUED TO: REBECCA ANN HUTTON	**ORDER TERMINATING CONSENT AGREEMENT AND** **ORDER NO. 1302115-NUR**

WHEREAS, on March 23, 2014, License No. RN173397 and AP4531 issued to Rebecca Ann Hutton was placed on Probation pursuant to A.R.S. § 32-1663(D); and

WHEREAS, the Board of Nursing duly considered all evidence presented to it concerning Rebecca Ann Hutton compliance with the conditions of said Probation at the Board's regularly scheduled meeting on July 21, 2017; and

WHEREAS, the Board found that Rebecca Ann Hutton has completed all of the Order;

NOW, THEREFORE, it is ordered that the Order of Probation issued March 23, 2014, is hereby terminated.

DATED this 27 day of July, 2017.

Joey Ridenour RN MN FAAN

SEAL

Joey Ridenour, R.N., M.N., F.A.A.N.
Executive Director

JR/:nk

COMMONWEALTH OF PENNSYLVANIA
OFFICE OF GENERAL COUNSEL

William A. Newport
Prosecuting Attorney

wnewport@pa.gov
Prosecution Division

September 10, 2015

Rebecca A. Trachtenberg, C.R.N.P., R.N.
3411 S. Camino Seco #175
Tucson, AZ 85730

RE: *Commonwealth of Pennsylvania, Bureau of Professional and Occupational Affairs v. Rebecca A Trachtenberg, R.N.*, File No.: 14-51-06650, Docket No.: 1328-51-15

Dear Ms. Trachtenberg:

On September 9, 2015, the State Board of Nursing issued an Order adopting the terms of the Consent Agreement in the above-captioned matter. Enclosed is a copy of the Consent Agreement and Order for your records.

The Board's approval of this Consent Agreement completely and finally resolves this matter. Accordingly, this case is now closed.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact me.

Sincerely,

William A. Newport
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State

WAN/cmm
Enclosure: Consent Agreement

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF NURSING

PROTHONOTARY
2015 SEP 10 AM 10: 55
Department of State

Commonwealth of Pennsylvania Bureau of Professional and Occupational Affairs	**File No.:** 14-51-06650
vs.	
Rebecca A. Trachtenberg, C.R.N.P., a/k/a Rebecca Ann Hutton Respondent	**Docket No:** 1328-51-15

CONSENT AGREEMENT AND ORDER

PARTIES

The Commonwealth of Pennsylvania, Department of State, Bureau of Professional and Occupational Affairs ("Commonwealth") and **Rebecca A. Trachtenberg, C.R.N.P., a/k/a Rebecca Ann Hutton** ("Respondent") stipulate as follows in settlement of the above-captioned case.

APPLICABLE LAW

1. This matter is before the State Board of Nursing ("Board") pursuant to Professional Nursing Law, Act of May 22, 1951, P.L. 317, ("Act"), 63 P.S. §§ 211-226, *as amended*; and/or the Act of July 2, 1993, P.L. 345, No. 48 ("ACT 48"), 63 P.S. §§ 2201-2207, *as amended*.

LICENSURE STATUS

2. At all relevant and material times, Respondent held the following license to practice as a certified registered nurse practitioner in the Commonwealth of Pennsylvania: license no. SP008229, which was originally issued on July 26, 2004, and which expired on April 30, 2006; and as a registered nurse license no. RN543464, which was originally issued on February 4, 2003, and which expired on April 30, 2006.

STIPULATED FACTS

3. The Respondent admits that the following allegations are true:

a. Respondent's licenses may be continually reactivated, renewed, or reinstated upon the filing of the appropriate documentation and payment of the necessary fees.

b. Respondent's last known address, as on file with the Board is: 12 Point Circle, Lewes, DE 19958.

c. Respondent's current address is 3411 S. Camino Seco #175, Tucson, AZ 85730.

d. At all relevant and material times, Respondent was authorized to practice as a registered nurse in the State of Arizona, license number RN173397 and certificate number AP4531.

e. On or about May 20, 2013, the Arizona State Board of Nursing ("Arizona Board"), by way of Consent Agreement and Order at Arizona Board Order Number 1302115, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Arizona because Respondent violated A.R.S. §§ 32-1606, 32-1663 (D), 32-1664, A.A.C. § R4-19-403 and R4-19-511(D).

f. A true and correct copy of the Arizona Board's May 20, 2013 Consent Agreement and Order, Arizona Board Order Number 1302115, is attached as **Exhibit** A and is incorporated by reference.

g. Pursuant to the May 20, 2013 Consent Agreement and Order, Respondent's license was suspended with said suspension stayed in favor of probation. See attached **Exhibit A.**

h. Respondent requests that the Board accept the voluntary surrender of her licenses to practice nursing.

i. Respondent agrees, understands and acknowledges that by voluntarily surrendering her licenses to practice nursing that she is forfeiting, relinquishing, and surrendering any and all rights, title and privilege to practice nursing in the Commonwealth of Pennsylvania and all property rights in retaining, renewing and/or reactivating her professional nursing licenses.

j. Respondent agrees, understands and acknowledges that the acceptance of the voluntary surrender of Respondent's licenses by the Board constitutes a reportable disciplinary action of the Board and has the legal effect of a revocation of her/his nursing license. This action is reportable to entities including, but not limited to, the National Practitioner Data Bank, the licensing authority of any state or jurisdiction, governmental entities including federal and state agencies, and any private or public health care facility.

k. Respondent is aware of and understands Respondent's right to have formal charges filed against Respondent and Respondent's right to an administrative hearing in this matter, and the following rights related to that hearing: to be represented by counsel at the hearing; to present witnesses and testimony in defense or in mitigation of any sanction that may be imposed for a violation; to cross-examine witnesses and to challenge evidence presented by the Commonwealth; to present legal arguments by means of a brief; and to take an appeal from any final adverse decision. Nonetheless, Respondent knowingly and voluntarily waives these rights as set forth in paragraph 7 below.

ALLEGED VIOLATIONS

4. The Commonwealth alleges that the Board is authorized to impose a civil penalty under Section 13(b) of the Act, 63 P.S. § 223(b), and/or Section 5(b)(4) of ACT 48, 63 P.S. §2205(b)(4), impose the costs of investigation under Section 5(b)(5) of ACT 48, 63 P.S. § 2205(b)(5), and suspend or revoke, or otherwise restrict Respondent's license under 63 P.S. § 224(a)(6), in that Respondent had a license suspended or revoked or has received other disciplinary action by the proper licensing authority in another state, territory, possession or country.

PROPOSED ORDER

5. The parties, intending to be legally bound, consent to the issuance of the following Order in settlement of this matter:

a. The Board finds that it is authorized to impose a civil penalty under Section 13(b) of the Act, 63 P.S. § 223(b), and/or Section 5(b)(4) of ACT 48, 63 P.S. §2205(b)(4), impose the costs of investigation under Section 5(b)(5) of ACT 48, 63 P.S. § 2205(b)(5), and suspend or revoke, or otherwise restrict Respondent's license under 63 P.S. § 224(a)(6), in that Respondent had a license suspended or revoked or has received other disciplinary action by the proper licensing authority in another state, territory, possession or country.

VOLUNTARY SURRENDER

b. The Board hereby accepts, the **VOLUNTARY SURRENDER** of Respondent's licenses to practice as a certified registered nurse practitioner and registered nurse in the Commonwealth of Pennsylvania, **License Nos. SP008229** and **RN543464**, along with any other licenses, registrations, certificates, approvals, authorizations, or permits (hereinafter referred to collectively as "authorizations to

practice the profession") issued by the Board to Respondent at the time this Consent Agreement is adopted by the Board.

c. Respondent agrees to cease practicing as a certified registered nurse practitioner and registered nurse in the Commonwealth on and after the effective date of this Consent Agreement, and shall not indicate she has any authority to practice the profession in the Commonwealth in any manner whatsoever in the future.

d. The acceptance of Respondent's license by the Board constitutes a reportable disciplinary action of the Board and has the legal effect of a revocation of her nursing licenses. This action is reportable to entities including, but not limited to, the National Practitioner Data Bank, the licensing authority of any state or jurisdiction, governmental entities including federal and state agencies, and any private or public health care facility.

e. Respondent relinquishes all rights, title and privilege to practice nursing in the Commonwealth of Pennsylvania and all property rights in retaining, renewing and/or reactivating her professional nursing licenses in the future.

f. Respondent shall, within ten (10) days of adoption of this Consent Agreement and Order, surrender Respondent's biennial renewal certificate and wallet card (or notarized affidavit of their loss or destruction) by mailing them to:

William A. Newport
Prosecuting Attorney
Bureau of Professional and Occupational Affairs
P.O. Box 69521
Harrisburg, PA 17106-9521

g. Respondent is precluded from applying for reactivation renewal, reissuance or reinstatement of Respondent's licenses without specific authorization from the Board.

h. This case shall be deemed settled and discontinued upon the Board issuing an Order adopting this Consent Agreement.

ADMISSIBILITY OF CONSENT AGREEMENT IN FUTURE PROCEDINGS

6. Respondent agrees that if Respondent is charged with a violation of an Act enforced by this Board in the future, this Consent Agreement and Order shall be admitted into evidence without objection in that proceeding.

ACKNOWLEDGMENT OF NOTICE AND WAIVER OF HEARING

7. Respondent acknowledges the filing and receipt of an Order to Show Cause in this matter. Respondent knowingly and voluntarily waives the right to an administrative hearing in this matter, and to the following rights related to that hearing: to be represented by counsel at the hearing; to present witnesses and testimony in defense or in mitigation of any sanction that may be imposed for a violation; to cross-examine witnesses and to challenge evidence presented by the Commonwealth; to present legal arguments by means of a brief; and to take an appeal from any final adverse decision.

ACKNOWLEDGMENT OF RIGHT TO ATTORNEY

8. Respondent acknowledges that she is aware that she has the right to consult with, and/or be represented by, private legal counsel of Respondent's choosing and at Respondent's expense when reviewing, considering and accepting the terms of this Consent Agreement. To the extent that Respondent is not represented by legal counsel, Respondent has knowingly elected to proceed without the assistance of legal counsel.

WAIVER OF CLAIM OF COMMINGLING AND OTHER CONSTITUTIONAL CLAIMS

9. Respondent expressly waives any constitutional rights and issues, such as commingling of prosecutorial and adjudicative functions by the Board or its counsel, which may arise or have arisen during the negotiation, preparation and/or presentation of this Consent Agreement. Respondent specifically agrees that if the Board rejects this agreement, it may assume that the facts and averments as alleged in this Consent Agreement are true and correct for the limited purpose of recommending a sanction, based on those assumed facts that would be acceptable to the Board before hearing the case. In the event that the Board does assume the facts and averments as alleged in this Consent Agreement are true for purposes of making a recommendation as to an acceptable sanction, such action shall not constitute commingling of prosecutorial and adjudicative functions by the Board or its counsel, and the Respondent expressly waives any constitutional rights and issues related to alleged commingling, bias, or violation of due process rights to have an unbiased and impartial adjudicator in any subsequent hearing. If a hearing is subsequently held, neither this Consent Agreement nor the proposed terms of settlement may be admitted into evidence and any facts, averments, and allegations contained in the Consent Agreement must be proven at hearing unless otherwise separately stipulated. This paragraph is binding on the participants even if the Board does not approve this Consent Agreement.

NO MODIFICATION OF ORDER

10. Respondent agrees, as a condition of entering into this Consent Agreement, not to seek modification at a later date of the Stipulated Order adopting and implementing this Consent Agreement without first obtaining the express written concurrence of the Prosecution Division.

AGREEMENT NOT BINDING ON OTHER PARTIES

11. The Office of General Counsel has approved this Consent Agreement as to form and legality; however, this Consent Agreement shall have no legal effect unless and until the Board issues the stipulated Order.

EFFECT OF BOARD'S REJECTION OF CONSENT AGREEMENT

12. Should the Board not approve this Consent Agreement, presentation to and consideration of this Consent Agreement and other documents and matters by the Board shall not prejudice the Board or any of its members from further participation in the adjudication of this matter. This paragraph is binding on the participants even if the Board does not approve this Consent Agreement.

ENTIRE AGREEMENT

13. This agreement contains the whole agreement between the participants; provided however, that the captions printed in the various provisions of this agreement are for ease of reading only and are not to be interpreted as forming any part of this agreement. There are no other terms, obligations, covenants, representations, statements or conditions, or otherwise, of any kind whatsoever concerning this agreement.

AGREEMENT DOES NOT PREVENT ADDITIONAL DISCIPLINE BASED ON OTHER COMPLAINTS

14. Nothing in this Order shall preclude the Prosecution Division for the Commonwealth from filing charges or the Board from imposing disciplinary or corrective measures for violations or facts not contained in this Consent Agreement;

VERIFICATION OF FACTS AND STATEMENTS

15. Respondent verifies that the facts and statements set forth in this Consent Agreement are true and correct to the best of Respondent's knowledge, information and belief. Respondent understands that statements in this Consent Agreement are made subject to the criminal

penalties of 18 Pa.C.S.A. § 4904 relating to unsworn falsification to authorities.

William A. Newport
Prosecuting Attorney

DATED: 8/24/15

Rebecca A. Trachtenberg
a/k/a Rebecca Ann Hutton
Respondent

DATED: 8/17/15

ARIZONA STATE BOARD OF NURSING

IN THE MATTER OF REGISTERED NURSE LICENSE NO.: RN173397/AP4531 ISSUED TO: **REBECCA ANN HUTTON** RESPONDENT	CONSENT AGREEMENT AND ORDER NO. 1302115

CONSENT AGREEMENT

A complaint charging REBECCA ANN HUTTON (hereinafter "Respondent") with violation of the Nurse Practice Act was received by the Arizona State Board of Nursing (hereinafter "Board"). In the interest of a prompt and speedy settlement of the above-captioned matter, consistent with the public interest, statutory requirements and the responsibilities of the Board, and pursuant to A.R.S. § 41-1092.07 (F) (5), the undersigned parties entered into a Consent Agreement and Order ("Order") as a final disposition of this matter.

Based on the evidence before it, the Board makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. REBECCA ANN HUTTON ("Respondent") holds Board issued registered nurse license no. RN173397 and certificate no. AP4531.

2. On or about February 26, 2013, the Board received a complaint alleging Respondent inappropriately prescribed controlled substances to family members and prescribed controlled substances using the names of family members without their knowledge in the metropolitan Tucson area. Based on the information contained in this complaint, the Board conducted an investigation.

3. From in or around August 2012 through February 2013, Respondent acted unprofessionally and deviated from Standard of Care when she failed to perform a medical exam or maintain a medical record for individuals A.P., D.T., and D.K. for whom she prescribed

EXHIBIT
A

controlled substances, in the Phoenix metropolitan and/or Tucson areas, placing individuals, who were not her patients, at risk for a poor medical outcome.

a. For Patient A.P., Respondent prescribed Soma 350mg #40, Percocet 5.325mg #100, and Percocet 5/325mg #30.

b. For Patient D.T., Respondent prescribed Oxycontin 20mg #20 and Soma 325mg, #15.

c. For Patient D.K., Respondent prescribed Oxycontin 40mg #20, Oxycodone 30mg #50, Oxycodone 30mg #50.

4. On or about August 6, 2012, Respondent acted unprofessionally and deceived the public when she prescribed Oxycontin, a controlled substance, to D.T., a family member who was not a patient of Respondent's, and who had no knowledge a controlled substance had been prescribed in her name.

5. On or about October 15, 2012, Respondent acted unprofessionally and deceived the public when she prescribed Soma 350mg, a controlled substance, for D.T., a family member who was not a patient of Respondent's, and who had no knowledge a controlled substance had been prescribed in her name.

6. On or about February 15, 2013, while employed at a Hospice facility in Phoenix, Arizona, Respondent acted unprofessionally and was counseled by her employer for "violating company policy" when she used a facility printed prescription pad to write a prescription for Soma, a controlled substance, to her social acquaintance, A.P., who is not a patient of the facility and for whom she did not have a medical record.

7. On or about May 14, 2013, Respondent admitted to Board staff that around the time of July 2012, Respondent relapsed on cocaine, and during that time, continued to prescribe controlled substances, placing patients at risk for poor medical outcome.

8 On or about May 14, 2013, Respondent admitted to Board staff that she had written prescriptions for controlled substances, in the Phoenix metropolitan and/or Tucson area, for AP, social acquaintances, and not actual patients, with full knowledge and intent that the controlled substances be diverted and used by her husband, A.H., an individual Respondent knew has a prescription drug addiction.

a. On or about January 31, 2013, prescribed Percocet 5/325mg to A.P.

b. On or about February 13, 2013, prescribed Percocet 5/325mg and Soma 325mg to A.P.

CONCLUSIONS OF LAW

Pursuant to A.R.S. §§ 32-1606, 32-1663 (D), and 32-1664, the Board has subject matter and personal jurisdiction in this matter. (18) "Unprofessional conduct" includes the following whether occurring in this state or elsewhere: (d) Any conduct or practice that is or might be harmful or dangerous to the health of a patient or the public; (g) Willfully or repeatedly violating a provision of this chapter or a rule adopted pursuant to this chapter; (h) Committing an act that deceives, defrauds or harms the public; (j) Violating a rule that is adopted by the board pursuant to this chapter, (effective September 30, 2009); and A.A.C. § R4-19-403 (effective January 31, 2009) (1) A pattern of failure to maintain minimum standards of acceptable and prevailing nursing practice; (3) Failing to maintain professional boundaries or engaging in a dual relationship with a patient, resident, or any family member of a patient or resident; (17) A pattern of using or being under the influence of alcohol, drugs, or a similar substance to the extent that judgment may be impaired and nursing practice detrimentally affected, or while on duty in any health care facility, school, institution, or other work location; (18) Obtaining, possessing, administering, or using any narcotic, controlled substance, or illegal drug in violation of any federal or state criminal law, or in violation of the policy of any health care facility, school,

institution, or other work location at which the nurse practices; (31) Practicing in any other manner that gives the Board reasonable cause to believe the health of a patient or the public may be harmed; and R4-19-511(D) In addition to acts listed under R4-19-403, for a nurse who prescribes or dispenses a drug or device, a practice that is or might be harmful to the health of a patient or the public, includes one or more of the following: (1) Prescribing a controlled substance to one's self or a member of the nurse's family; (5) Prescribing, dispensing, or furnishing a prescription drug or a prescription-only device to a person unless the nurse has examined the person and established a professional relationship, except when the nurse is engaging in one or more of the following: (a) Providing temporary patient care on behalf of the patient's regular treating and licensed health care professional; (b) Providing care in an emergency medical situation where immediate medical care or hospitalization is required by a person for the preservation or health, life, or limb; or (c) Furnishing a prescription drug to prepare a patient for a medical examination. A.R.S. § 32-1663 (D) as defined in A.R.S. § 32-1601 (22) (effective August 2, 2012). 22. "Unprofessional conduct" includes the following whether occurring in this state or elsewhere: (d) Any conduct or practice that is or might be harmful or dangerous to the health of a patient or the public. (g) Willfully or repeatedly violating a provision of this chapter or a rule adopted pursuant to this chapter. (h) Committing an act that deceives, defrauds or harms the public, and (j) Violating a rule that is adopted by the Board pursuant to this chapter.

The conduct and circumstances described in the Findings of Fact constitute sufficient cause pursuant to A.R.S. § 32-1664(N) to revoke, suspend or take other disciplinary action against the license of Respondent to practice as a registered nurse in the State of Arizona.

Respondent admits the Board's Findings of Fact and Conclusions of Law.

In lieu of a formal hearing on these issues, Respondent agrees to issuance of the attached Order and waives all rights to a hearing, rehearing, appeal or judicial review relating to this matter. Respondent further waives any and all claims or causes of action, whether known or unknown, that Respondent may have against the State of Arizona, the Board, its members, offices, employees and/or agents arising out of this matter.

Respondent understands that all investigative materials prepared or received by the Board concerning these violations and all notices and pleadings relating thereto may be retained in the Board's file concerning this matter.

Respondent understands that those admissions are conclusive evidence of a prior violation of the Nurse Practice Act and may be used for purposes of determining sanctions in any future disciplinary matter.

Respondent understands the right to consult legal counsel prior to entering into this Consent Agreement and such consultation has either been obtained or is waived.

Respondent understands that this Consent Agreement is effective upon its acceptance by the Board and by Respondent as evidenced by the respective signatures thereto. Respondent's signature obtained via facsimile shall have the same effect as an original signature. Once signed by Respondent, the Agreement cannot be withdrawn without the Board's approval or by stipulation between Respondent and the Board's designee. The effective date of this Order is the date the Consent Agreement is signed by the Board and by Respondent. If the Consent Agreement is signed on different dates, the later date is the effective date.

Rebecca Hutton
Respondent

Dated: 3/23/2014

HUTTON, REBECCA: SES/ss

ARIZONA STATE BOARD OF NURSING
Joey Ridenour RN MN FAAN

Joey Ridenour, R.N., M.N., F.A.A.N.
Executive Director

Dated: MAY 20, 2013

HUTTON, REBECCA; SES/ss

ORDER

In view of the above Findings of Fact, Conclusions of Law and the consent of Respondent, the Board hereby issues the following Order:

A. Respondent's consent to the terms and conditions of the Order and waiver of public hearing are accepted.

B. Respondent's registered nurse license number RN173397 and advanced practice certificate number AP4531 is hereby **suspended**; however, the **suspension is stayed** for as long as Respondent remains in compliance with this Order. During the stay of the suspension, Respondent's registered nurse license number RN173397 and Advanced Practice certificate number AP4531 is placed on probation for at minimum, 18 months, followed by standard probation for 18 months. Prior to termination of this Order, Respondent shall work as a nurse practitioner for a minimum of twenty-four months (not less than sixteen hours a week).

C. If Respondent is non-compliant with any of the terms of the Order during the 18-month stayed suspension period, the stay of the suspension shall be lifted and Respondent's license shall be automatically suspended for a minimum period of 18 months. Except as provided in paragraphs 7 (Drug Testing) and 14 (Quarterly Reports) of this Order, the Board or its designee, in its sole discretion, shall determine noncompliance with the stayed portion of the Order. With the exception of the provisions identified in Paragraphs 7 (Drug Testing) and 14

(Quarterly Reports). Respondent waives any and all rights to any further review, hearing, rehearing or judicial review of any suspension imposed pursuant to this paragraph.

D. If Respondent is noncompliant with any of the terms of the Order during the 18-month probation portion of the Order, Respondent's noncompliance shall be reviewed by the Board for consideration of possible further discipline on Respondent's nursing license.

E. If Respondent is convicted of a felony, Respondent's license shall be automatically revoked for a period of five years. Respondent waives any and all rights to a hearing, rehearing or judicial review of any revocation imposed pursuant to this paragraph.

F. This Order becomes effective upon the Board and Respondent's acceptance of the Order. The effective date is the date the Order is signed by the Board and Respondent. If Order is signed on different dates, the later date is the effective date.

G. At any time Respondent is required by terms of the Order to provide a copy of the Order to another individual or facility the Respondent must provide all pages of the Order.

H. The probation is subject to the following terms and conditions:

TERMS OF PROBATION
(Stayed Suspension and Standard Probation)

1. Stamping of License

Within three (3) days of the effective date of this Order, Respondent shall submit her license to the Board. Respondent's license shall be stamped "Probation" and returned to Respondent. While this Order is in effect, if the Board issues any certificates or licenses authorized by statute, except a nursing assistant certificate, such certificate or license shall also be stamped "**PROBATION.**" Respondent is not eligible for a multistate "Compact" license.

2. Nursing Ethics

Within thirty (30) days from the effective date of this Order Respondent shall make an appointment to undergo a nursing ethics course or begin nursing ethics counseling by a Board-approved treatment professional. If Respondent chooses to fulfill this stipulation by participation in counseling, Respondent shall execute the appropriate release of information form(s) to allow the counselor to communicate information to the Board or its designee. Prior to beginning the course or counseling, Respondent shall furnish a copy of this Consent Agreement and Order to include Findings of Fact and Conclusions of Law to the counselor or course director. Respondent shall cause the course director or counselor to notify the Board in writing within thirty days of entry into the course or therapy, and to verify in that same letter receipt of the Consent Agreement and Order to include Findings of Fact.

Respondent shall undergo and continue treatment or course attendance until the course director or treatment professional determines and reports to the Board in writing and on letterhead, that treatment is no longer considered necessary or the course has been successfully completed by the Respondent. During the duration of the course of counseling Respondent shall have the treatment professional or course director provide written reports to the Board every three months. The Board reserves the right to amend this Order based on the recommendations of the course director or treatment professional.

3. Substance Use Disorder Evaluation

On September 18, 2013 and again on December 4, 2013, Respondent was evaluated by Jacquelyn St. Germaine, PhD., a Board-approved evaluator. Prior to the evaluation, Dr. St. Germaine was provided with a copy of the Board's investigative report as well as other documents. Respondent executed the appropriate release of information forms to allow Dr. St. Germaine to communicate with the Board or its designee. The report from Dr. St. Germaine included a history of substance abuse, past treatment, present status of recovery and participation

in recovery activities, and recommendations for on-going treatment. Respondent will complete all recommendations as recommended by Dr. St. Germaine.

If recommended, Respondent shall enroll any recommended treatment or therapy within thirty (30) days of being notified by the Board of the recommendations from the evaluator. Respondent shall cause the program facilitator to inform the Board, in writing, verifying enrollment in the program. Prior to entry into any recommended therapy, Respondent shall provide a copy of this Consent Agreement and Order to include Findings of Fact and Conclusions of Law, and Order to the program facilitator. Respondent shall immediately execute the appropriate release of information form(s) to allow the facilitator to communicate information with the Board or its designee. Respondent shall participate in treatment or therapy until the Board receives verification from the facilitator in writing that Respondent has successfully completed the treatment requirements. During participation in treatment Respondent shall cause the provider or program facilitator to submit to the Board, in writing on a Board-approved form, evidence of satisfactory attendance, participation, discharge and successful completion of the program. Such reports are due beginning on the first quarterly reporting date after entry into treatment or therapy program and quarterly thereafter, according to schedule, and until verification of successful completion of the program has been received by the Board.

4. Relapse Prevention Therapy

Within thirty (30) days of the effective date of this Order, Respondent shall enter a Board approved Relapse Prevention Therapy Program. Respondent shall immediately execute the appropriate release of information form(s) to allow the facilitator to communicate information to the Board or its designee, and Respondent shall immediately provide a copy of this Consent Agreement and Order to include Findings of Fact and Conclusions of Law to the

facilitator. Within seven days of entering treatment, Respondent shall cause the facilitator to submit to the Board written verification of Respondent's enrollment in the Program, and verification of receipt of Respondent's entire Consent Agreement. Thereafter, Respondent shall cause the facilitator to provide quarterly reports to the Board according to the quarterly reporting schedule assigned to Respondent. Respondent shall continue undergoing treatment until the facilitator provides written notification to the Board, indicating that treatment is no longer needed. The Board reserves the right to amend the Order based on recommendation(s) of treating professional(s).

5. Nurse Recovery Group

Within seven (7) days of the effective date of this Order, Respondent shall enroll in a Board-acceptable Nurse Recovery Group if a group is available within forty miles. Respondent shall sign release of information forms allowing the group facilitator to inform the Board, in writing and on letterhead, of Respondent's entry and progress in the group. Respondent shall attend a Nurse Recovery Group once per week and have no "Unexcused" absences or "No call/No show" occurrences.

6. Participation in AA/NA

(a) Within seven (7) days of the effective date of this Order and throughout the term of this Order, Respondent shall participate at least two times weekly, in Alcoholics Anonymous (AA), Narcotics Anonymous (NA), or an equivalent program and shall provide to the Board, in writing on Board-approved forms verifying attendance within 7 days of assigned quarterly reporting due dates. The first report is due by the end of the first month after the effective date of the Order, and quarterly thereafter according to the assigned reporting dates.

(b) Respondent must obtain a temporary sponsor if participating in a twelve-step program within 30 of the effective date of this Order and a permanent sponsor within 60days

of the effective date of the Order. Respondent shall maintain a sponsor relationship throughout the terms of this Order. Failure to comply with stipulations as enumerated in sections (a) and (b) shall be considered as noncompliance with the terms of the Order.

7. Drug Testing

Respondent has received a copy of the Board's policy entitled "Guidelines For Non-Compliance With Drug Testing – Monitoring And CANDO Departments" dated May 21, 2013 ("Policy"), and agrees to abide by the terms and conditions set forth in the Policy.

Within seven (7) days of the effective date of this Order, Respondent shall enroll in a program that meets Board approved criteria for random drug testing. Drug testing may include testing of urine, hair follicle, nail, saliva or blood as determined by the Board or the Board's designee.

For random urine drug testing, Respondent shall submit a urine specimen a minimum of twice per month for a minimum period of 18 months. Thereafter, Respondent shall submit a urine specimen a minimum of once per month for the duration of the Order, and may be required to submit a specimen more frequently as determined by the Board or its designee.

For random hair testing, Respondent shall submit to hair testing that includes a health professional's panel of drugs to be tested at minimum, quarterly, and may be required to submit a specimen more frequently as determined by the Board or its designee. The first hair test must be submitted within thirty (30) days of the effective date of this Order and then quarterly thereafter.

Respondent shall provide written notification to the drug testing laboratory and the Board's designee of his/her unavailability to test before the unavailability occurs.

Within seven (7) days of a missed drug test due to an unexpected illness, Respondent must provide the Board or the Board's designee with written documentation from a medical provider stating that the medical provider personally examined Respondent on the day of the

requested drug test and that Respondent was not physically able to report to the laboratory for drug testing.

The Board's designee will immediately notify Respondent's employer of any drug test positive for an unauthorized drug. If Respondent tests positive for an unauthorized drug, misses a drug test or fails to submit a specimen suitable for drug testing, the Board or Board's designee may direct Respondent to cease practicing pending further determination by the Board or the Board's designee; and Respondent shall not return to practice until receiving written authorization from the Board or the Board's designee. During the Stayed Suspension period, if so investigated, reviewed and substantiated, testing positive for an unauthorized drug, failing to submit to a drug test or failing to submit a specimen suitable for drug testing, shall be considered as noncompliance with the terms of the Order, and the stay of suspension shall be lifted and Respondent's license automatically suspended. **If Respondent contests the lifting of the stay as it relates to this paragraph, Respondent shall request in writing, within 10 days of being notified of the automatic suspension of licensure, that the matter be placed on the Board agenda for the Board to review and determine if the automatic suspension of Respondent's license was supported by substantial evidence. If the written request is received within ten (10) days of a regularly scheduled Board meeting, the request will NOT be heard at that meeting, but will be heard at the NEXT regularly scheduled Board meeting. Pending the Board's review, Respondent's license shall be reported as suspended – under review. Respondent may not work in any capacity involving nursing licensure pending the Board's review. The Board's decision and Order shall not be subject to further review.**

During the standard eighteen month probation period of the Order, if so investigated, reviewed and substantiated, testing positive for an unauthorized drug, failing to submit to a drug

test or failing to submit a specimen suitable for drug testing, shall be considered as noncompliance with the terms of the Order.

Failing to submit to a drug test on a day when a drug test has been requested by the Board, its designee, an employer, or the laboratory constitutes a violation of this Agreement for which Respondent may not request further review/investigation by the Board's designee.

Violations of this Agreement for which Respondent may request further review/investigation by the Board's designee during the standard eighteen month probation include:

(1) A drug test positive for an unauthorized drug;

(2) Failing to submit a specimen suitable for drug testing, including a substituted or adulterated specimen.

Respondent may submit a written request to the Board's designee requesting further review/investigation within five days of being notified of the violation, and include the reason(s) for the violation in the request. Board staff may then investigate the reason(s) for the violation, including obtaining a written verification of Respondent's drug testing results from the Toxicologist or Medical Review Officer affiliated with the drug testing laboratory.

8. Abstain from Alcohol Use

Respondent shall abstain completely from the personal use of alcoholic beverages.

9. Abstain From Unauthorized Drug Use/Proof of Prescription/One Medical Provider

Respondent shall abstain completely from the personal use or possession of controlled substances, as defined in the State Controlled Substances Act, and dangerous drugs as defined by law, or any drugs requiring a prescription.

Orders prohibiting Respondent from personal use or possession of controlled substances or dangerous drugs do not apply to medications lawfully prescribed to Respondent for a bona fide illness or condition by a medical provider. During the duration of this Order, Respondent shall select one medical provider to coordinate her health care needs and to be aware of all prescriptions utilized by Respondent. Respondent shall immediately submit to that provider a copy of this Consent Agreement and Order to include the Findings of Fact and Conclusions of Law and shall execute all release of information form(s) as required by the Board or its designee. The medical provider shall, within one week of the effective date of the consent agreement, inform the Board, in writing, of knowledge of Respondent's Order and provide a list of medications prescribed for Respondent. DURING THE DURATION OF THE CONSENT AGREEMENT, RESPONDENT SHALL CAUSE ALL PROVIDERS TO NOTIFY THE BOARD OF ANY ADDITIONAL MEDICATIONS ORDERED BY THE PROVIDER. THE NOTIFICATION SHALL BE MADE IN WRITING WITHIN ONE WEEK OF THE PROVIDER'S ISSUANCE OF THE PRESCRIPTION.

If Respondent has a lawful prescription for a narcotic or mood-altering drug, Respondent shall cause her prescribing provider to submit monthly reports to the Board by the 30th day of each month regarding the continued need for the prescribed narcotic or mood-altering medications. The Board or its designee may, at any time, request the provider to document the continued need for prescribed medications. Respondent shall keep a written record of medications taken, including over-the-counter drugs, and produce such record upon request by the Board or its designee.

10. Pharmacy Profiles

Throughout the duration of this Order, Respondent shall use only one pharmacy from which to obtain her prescriptions. Within thirty (30) days of the effective date of the Consent

Agreement, Respondent shall submit in writing to the Board the name of every pharmacy and/or facility from which Respondent is currently obtaining prescription medications, and shall submit the name of the pharmacy from which she chooses to obtain future prescriptions. Throughout the duration of the Order, Respondent must inform the Board in writing within 7 days of any additions or changes in pharmacies from which Respondent obtains medications. Respondent shall submit a copy of all pharmacy profiles to the Board on a quarterly basis according to the assigned reporting due dates, and upon request from the Board or its designee. The first report shall be due on the first quarterly due date after the effective date of this Order.

11. Relapse Prevention Evaluation

Eighteen (18) months prior to the termination of the Order or as requested by the Board or its designee, Respondent shall be evaluated by a Board approved evaluator with expertise in substance use disorders and recovery maintenance. If recommended by the evaluator, Respondent shall enter, participate regularly and successfully complete a relapse prevention program, or any other recommendations as designated by the evaluator; Respondent shall enroll in a relapse prevention program or other recommended therapy within 30 days of being notified by the Board or its designee of the recommendations from the evaluator.

Respondent shall cause the program facilitator to inform the Board in writing verifying enrollment in the program. Prior to entry into a relapse prevention program or any type of other recommended therapy, Respondent shall provide a copy of this Consent Agreement and Order to include Findings of Fact and Conclusions of Law, and Order to the program facilitator. Respondent shall immediately execute the appropriate release of information form(s) to allow the facilitator to communicate information with the Board or its designee. Respondent shall participate in the relapse prevention program or therapy until the Board receives verification from the facilitator in writing that Respondent has successfully completed the program. During

participation in the program Respondent shall cause the program facilitator to provide to the Board, in writing on a Board-approved form, evidence of satisfactory attendance, participation, discharge and successful completion of the program. Such reports are due beginning on the first quarterly reporting date after entry into the relapse prevention program and quarterly thereafter, according to schedule, for the remainder of the probationary period or verification of successful completion of the program.

12. Notification of Practice Settings

Any setting in which Respondent accepts employment, which requires RN licensure, shall be provided with a copy of the entire Order within three (3) calendar days of the effective date of this Order and must confirm, in writing, their ability to provide Respondent with the supervision as required by this Order. Thereafter, any setting in which Respondent accepts employment, which requires RN licensure shall be provided with a copy of the entire Order on or before the date of hire and within three (3) calendar days of hire must confirm, in writing, their ability to provide Respondent with the supervision as required by this Order.. In the event Respondent is attending a nursing program, Respondent shall provide a copy of the entire Consent Agreement and Order to the Program Director. Respondent shall cause the Program Director to inform the Board, in writing and on school letterhead, acknowledgment of the program's receipt of a copy of the Consent Agreement and Order and the program's ability to comply with the conditions of probation during clinical experiences.

13. Chart Review

Prior to accepting employment as an advanced practice family nurse practitioner, Respondent shall identify and provide the name to the Board of a nationally certified family nurse practitioner of same or higher educational level (auditor) or Board approved physician to conduct chart audits of Respondent's patients on a monthly basis. For the first 12 months while working in a position which

requires advanced practice certification, Respondent shall cause the previously identified nationally certified family nurse practitioner of same or higher educational level or Board approved physician to audit 50% of the records of persons Respondent has provided care to during the prior 30 days and review of prescriber's (Respondent's) Controlled Substance Pharmacy Program profile. The audit shall include a review and confirmation of appropriate assessment, diagnosis, treatment plan, and medications prescribed. Review should also include prescription profiles, appropriate controlled substance prescribing and adhering to pain agreement. For the first 12 months while working in a position which requires advanced practice certification, Respondent shall cause the auditor to provide to the Board, in writing, a summary of the random chart audit to contain a minimum of 50% of Respondent's patients and 100% controlled substance prescription review by a Nationally Certified FNP with same or higher education level or Board approved physician by the 30th of each month. For the second 12 months, Respondent may have 25% of Respondent's patients and 100% controlled substance audited instead of 50%, and then for the duration Respondent may have 10% audited of Respondent's patients and 100% controlled substance instead of 25%.

14. Quarterly Reports

Within thirty (30) days of the effective date of this Order, and quarterly thereafter, Respondent shall cause **every** employer Respondent has worked for to submit to the Board, in writing, quarterly employer evaluations on the Board-approved form including 100% controlled substance prescription review by a Nationally certified FNP with the same or higher education level or by a Board approved physician. In the event Respondent is not employed in nursing or attending school during any quarter or portion thereof, Respondent shall submit to the Board, in writing, a self-report describing other employment or activities on the Board-approved form.

Receipt of confirmation of employment disciplinary action, including written counseling(s), suspension, termination or resignation in lieu of termination from a place of

employment, any of which pertains to improper patient care, unsafe practice, inappropriate medication removal or administration, sub-standard documentation, or impairment on duty, positive drug test showing evidence of any drug other than an authorized drug, and/or refusal to submit to an employer requested drug screen/testing, shall be investigated by Board staff and reviewed and substantiated by the Board's designee. If so investigated, reviewed and substantiated, the employment disciplinary action shall be considered as noncompliance with the terms of the Order, and the stay of suspension shall be lifted and Respondent's license automatically suspended. **If Respondent contests the lifting of the stay as it relates to this paragraph, Respondent shall request in writing, within 10 days of being notified of the automatic suspension of licensure, that the matter be placed on the Board agenda for the Board to review and determine if the automatic suspension of Respondent's license was supported by substantial evidence. If the written request is received within ten (10) days of a regularly scheduled Board meeting, the request will NOT be heard at that meeting, but will be heard at the NEXT regularly scheduled Board meeting. Pending the Board's review, Respondent's license shall be reported as suspended – under review. Respondent may not work in any capacity involving nursing licensure pending the Board's review. The Board's decision and Order shall not be subject to further review.**

Failure to provide employer evaluations or if not working in nursing, self-reports, within seven days of the reporting date is noncompliance with this Order and is not subject to further review.

15. Practice Under On-Site Supervision

While Respondent is working as a registered nurse, Respondent shall practice as a registered nurse only under the on-site supervision by a Nationally certified FNP with the same or higher education level or a Board approved physician who is in good standing with the Board.

On-site supervision is defined as having a registered nurse present in the building while Respondent is on duty. While Respondent is working for Optum United Healthcare conducting history and physical examinations in a home setting, this on-site supervision does not apply; instead, Respondent shall communicate regularly by telephone with her supervisor, her supervisor shall conduct regular review of Respondent's work by accompanying Respondent to the history and physical examinations that Respondent conducts, and her supervisor shall provide quarterly reports to the Board about Respondent's compliance with the Consent Agreement and Order.

The supervising nurse or Board approved physician shall have read this Consent Agreement and Order to include the Findings of Fact and Conclusions of Law, and Order, and shall provide input on Respondent's employer evaluations to the Board. The supervising nurse or Board approved physician shall be primarily one person, who may periodically delegate to other qualified personnel, who shall also have read this Consent Agreement and Order to include Findings of Fact, Conclusions of Law. In the event that the assigned supervising nurse or Board approved physician is no longer responsible for the supervision required by this paragraph, Respondent shall cause her new supervising nurse or Board approved physician to inform the Board, in writing and on employer letterhead, acknowledgment of the new supervisor's receipt of a copy of this Consent Agreement and Order to include the Findings of Fact and Conclusions of Law and the new supervising nurse or Board approved physician's agreement to comply with the conditions of probation within ten days of assignment of a new supervising nurse.

16. Acceptable Hours of Work

Respondent shall work only the day or evening shift. Evening shift is defined as a shift that ends prior to midnight. Within a 14-day period Respondent shall not work more than 84 scheduled hours.

Respondent may work three 12-hour shifts in one seven day period and four 12-hour shifts in the other seven-day period, but Respondent may not work more than 3 consecutive 12-hour shifts during this probationary period. Respondent shall not work 2 consecutive 8 hour shifts within a 24 hour period or be scheduled to work 16 hours within a 24 hour period.

17. Registry Work Prohibited

Respondent may not work for a nurse's registry, home health, traveling nurse agency, any other temporary employing agencies, float pool, or position that requires on-call status, unless employed by Optum United Healthcare as described in section 15 (Practice Under On-Site Supervision) above. In no event is Respondent permitted to write prescriptions in this capacity.

18. Out of State Practice/Residence

Before any out-of-state practice or residence can be credited toward fulfillment of these terms and conditions, out-of-state practice or residence must first be approved by the Board prior to leaving the state. If Respondent fails to receive such approval before leaving the state, none of the time spent out of state will be credited to the fulfillment of the terms and conditions of this Order.

19. Release of Information Forms

Respondent shall sign all release of information forms as required by the Board or its designee and return them to the Board within 10 days of the Board's written request. Failure to provide for the release of information, as required by this paragraph constitutes non-compliance with this Order.

20. Interview with the Board or its Designee

Respondent shall appear in person or telephonically for interviews with the Board or its designee upon request at various intervals and with at least two (2) day notice.

21. Renewal of License

In the event Respondent's registered nurse license is scheduled to expire while this Order is in effect, Respondent shall apply for renewal of the license, pay the applicable fee, and otherwise maintain qualification to practice nursing in Arizona.

22. Change of Employment/Personal Address/Telephone Number

Respondent shall notify the Board, in writing, within 7 days of any change in nursing employment, personal address or telephone number. Changes in nursing employment include the acceptance, resignation or termination of employment.

23. Obey All Laws

Respondent shall obey all laws/rules governing the practice of nursing in this state and obey all federal, state and local criminal laws. Respondent shall report to the Board, within 10 days, any misdemeanor or felony arrest or conviction.

24. Costs

Respondent shall bear all costs of complying with this Order.

25. Violation of Probation

If during the stayed suspension portion of the Order, if Respondent is noncompliant with the terms of the Order in any way, the stay of suspension shall be lifted and Respondent's license shall be automatically suspended for a minimum period of 18 months. If during the standard probation portion of the Order, Respondent is noncompliant with the terms of the Order in any respect, the Board staff may notify the Respondent's employer of the noncompliance. Additionally, the Board may revoke probation and take further disciplinary action for noncompliance with this agreement after affording Respondent notice and the opportunity to be heard. If a complaint or petition to revoke probation is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

26. Voluntary Surrender of License

Respondent may, at any time this order is in effect, voluntarily request surrender of her license.

27. Completion of Order

When Respondent has 9 months left in the probationary period Respondent's compliance will be reviewed by the Board's designee. If Respondent has demonstrated full compliance with all terms of the Order, Respondent will be eligible to participate in a "step-down" component of the Order where reports from AA and Nurse Recovery Group will no longer be required.

Respondent is not eligible for early termination of this Order. Upon successful completion of the terms of the Order, Respondent shall request formal review by the Board, and after formal review by the Board, Respondent's nursing license may be fully restored by the appropriate Board action if compliance with this Order has been demonstrated.

ARIZONA STATE BOARD OF NURSING

SEAL

Joey Ridenour RN MN FAAN

Joey Ridenour, R.N., M.N., F.A.A.N.
Executive Director

Dated: MAY 20, 2013

COPY mailed and e-mailed this 10th day of April, 2014 to:

Kathleen Lambert, Esq.
2905 N Longhorn Drive
Tucson, AZ 85749-9755
klambert3@qwestoffice.net

Rebecca Ann Hutton
3411 S. Camino Seco #175,
Tucson, AZ 85730
rebeccatrac@gmail.com

By: T. Smith

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF NURSING

Commonwealth of Pennsylvania Bureau of Professional and Occupational Affairs	**File No.: 14-51-06650**
vs.	
Rebecca A. Trachtenberg, C.R.N.P., a/k/a Rebecca Ann Hutton Respondent	**Docket No: 1328-51-15**

ORDER

AND NOW, this 9th day of September, 2015, the **STATE BOARD OF NURSING** ("Board") adopts and approves the foregoing Consent Agreement and incorporates the terms of paragraph 5, which shall constitute the Board's Order and is now issued in resolution of this matter.

This Order shall take effect immediately.

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

Ian J. Harlow
Commissioner

BY ORDER:
STATE BOARD OF NURSING

Kristin Malady, RN, BSN
Chair

For the Commonwealth:

William A. Newport, Esquire
2601 North Third Street
P. O. Box 69521
Harrisburg, PA 17106-9521

For the Respondent:

Rebecca A. Trachtenberg, C.R.N.P
a/k/a Rebecca Ann Hutton
3411 S. Camino Seco #175
Tucson, AZ 85730

Date of mailing: September 10, 2015

ARIZONA STATE BOARD OF NURSING

IN THE MATTER OF REGISTERED NURSE LICENSE NO.: RN173397/AP4531 ISSUED TO: **REBECCA ANN HUTTON** RESPONDENT	CONSENT AGREEMENT AND ORDER NO. 1302115

CONSENT AGREEMENT

A complaint charging REBECCA ANN HUTTON (hereinafter "Respondent") with violation of the Nurse Practice Act was received by the Arizona State Board of Nursing (hereinafter "Board"). In the interest of a prompt and speedy settlement of the above-captioned matter, consistent with the public interest, statutory requirements and the responsibilities of the Board, and pursuant to A.R.S. § 41-1092.07 (F) (5), the undersigned parties entered into a Consent Agreement and Order ("Order") as a final disposition of this matter.

Based on the evidence before it, the Board makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. REBECCA ANN HUTTON ("Respondent") holds Board issued registered nurse license no. RN173397 and certificate no. AP4531.

2. On or about February 26, 2013, the Board received a complaint alleging Respondent inappropriately prescribed controlled substances to family members and prescribed controlled substances using the names of family members without their knowledge in the metropolitan Tucson area. Based on the information contained in this complaint, the Board conducted an investigation.

3. From in or around August 2012 through February 2013, Respondent acted unprofessionally and deviated from Standard of Care when she failed to perform a medical exam or maintain a medical record for individuals A.P., D.T., and D.K. for whom she prescribed

controlled substances, in the Phoenix metropolitan and/or Tucson areas, placing individuals, who were not her patients, at risk for a poor medical outcome.

a. For Patient A.P., Respondent prescribed Soma 350mg #40, Percocet 5.325mg #100, and Percocet 5/325mg #30.

b. For Patient D.T., Respondent prescribed Oxycontin 20mg #20 and Soma 325mg, #15.

c. For Patient D.K., Respondent prescribed Oxycontin 40mg #20, Oxycodone 30mg #50, Oxycodone 30mg #50.

4. On or about August 6, 2012, Respondent acted unprofessionally and deceived the public when she prescribed Oxycontin, a controlled substance, to D.T., a family member who was not a patient of Respondent's, and who had no knowledge a controlled substance had been prescribed in her name.

5. On or about October 15, 2012, Respondent acted unprofessionally and deceived the public when she prescribed Soma 350mg, a controlled substance, for D.T., a family member who was not a patient of Respondent's, and who had no knowledge a controlled substance had been prescribed in her name.

6. On or about February 15, 2013, while employed at a Hospice facility in Phoenix, Arizona, Respondent acted unprofessionally and was counseled by her employer for "violating company policy" when she used a facility printed prescription pad to write a prescription for Soma, a controlled substance, to her social acquaintance, A.P., who is not a patient of the facility and for whom she did not have a medical record.

7. On or about May 14, 2013, Respondent admitted to Board staff that around the time of July 2012, Respondent relapsed on cocaine, and during that time, continued to prescribe controlled substances, placing patients at risk for poor medical outcome.

8 On or about May 14, 2013, Respondent admitted to Board staff that she had written prescriptions for controlled substances, in the Phoenix metropolitan and/or Tucson area, for AP, social acquaintances, and not actual patients, with full knowledge and intent that the controlled substances be diverted and used by her husband, A.H., an individual Respondent knew has a prescription drug addiction.

a. On or about January 31, 2013, prescribed Percocet 5/325mg to A.P.

b. On or about February 13, 2013, prescribed Percocet 5/325mg and Soma 325mg to A.P.

CONCLUSIONS OF LAW

Pursuant to A.R.S. §§ 32-1606, 32-1663 (D), and 32-1664, the Board has subject matter and personal jurisdiction in this matter. (18) "Unprofessional conduct" includes the following whether occurring in this state or elsewhere: (d) Any conduct or practice that is or might be harmful or dangerous to the health of a patient or the public; (g) Willfully or repeatedly violating a provision of this chapter or a rule adopted pursuant to this chapter; (h) Committing an act that deceives, defrauds or harms the public; (j) Violating a rule that is adopted by the board pursuant to this chapter, (effective September 30, 2009); and A.A.C. § R4-19-403 (effective January 31, 2009) (1) A pattern of failure to maintain minimum standards of acceptable and prevailing nursing practice; (3) Failing to maintain professional boundaries or engaging in a dual relationship with a patient, resident, or any family member of a patient or resident; (17) A pattern of using or being under the influence of alcohol, drugs, or a similar substance to the extent that judgment may be impaired and nursing practice detrimentally affected, or while on duty in any health care facility, school, institution, or other work location; (18) Obtaining, possessing, administering, or using any narcotic, controlled substance, or illegal drug in violation of any federal or state criminal law, or in violation of the policy of any health care facility, school,

institution, or other work location at which the nurse practices; (31) Practicing in any other manner that gives the Board reasonable cause to believe the health of a patient or the public may be harmed; and R4-19-511(D) In addition to acts listed under R4-19-403, for a nurse who prescribes or dispenses a drug or device, a practice that is or might be harmful to the health of a patient or the public, includes one or more of the following: (1) Prescribing a controlled substance to one's self or a member of the nurse's family; (5) Prescribing, dispensing, or furnishing a prescription drug or a prescription-only device to a person unless the nurse has examined the person and established a professional relationship, except when the nurse is engaging in one or more of the following: (a) Providing temporary patient care on behalf of the patient's regular treating and licensed health care professional; (b) Providing care in an emergency medical situation where immediate medical care or hospitalization is required by a person for the preservation or health, life, or limb; or (c) Furnishing a prescription drug to prepare a patient for a medical examination. A.R.S. § 32-1663 (D) as defined in A.R.S. § 32-1601 (22) (effective August 2, 2012). 22. "Unprofessional conduct" includes the following whether occurring in this state or elsewhere: (d) Any conduct or practice that is or might be harmful or dangerous to the health of a patient or the public. (g) Willfully or repeatedly violating a provision of this chapter or a rule adopted pursuant to this chapter. (h) Committing an act that deceives, defrauds or harms the public, and (j) Violating a rule that is adopted by the Board pursuant to this chapter.

The conduct and circumstances described in the Findings of Fact constitute sufficient cause pursuant to A.R.S. § 32-1664(N) to revoke, suspend or take other disciplinary action against the license of Respondent to practice as a registered nurse in the State of Arizona.

Respondent admits the Board's Findings of Fact and Conclusions of Law.

In lieu of a formal hearing on these issues, Respondent agrees to issuance of the attached Order and waives all rights to a hearing, rehearing, appeal or judicial review relating to this matter. Respondent further waives any and all claims or causes of action, whether known or unknown, that Respondent may have against the State of Arizona, the Board, its members, offices, employees and/or agents arising out of this matter.

Respondent understands that all investigative materials prepared or received by the Board concerning these violations and all notices and pleadings relating thereto may be retained in the Board's file concerning this matter.

Respondent understands that those admissions are conclusive evidence of a prior violation of the Nurse Practice Act and may be used for purposes of determining sanctions in any future disciplinary matter.

Respondent understands the right to consult legal counsel prior to entering into this Consent Agreement and such consultation has either been obtained or is waived.

Respondent understands that this Consent Agreement is effective upon its acceptance by the Board and by Respondent as evidenced by the respective signatures thereto. Respondent's signature obtained via facsimile shall have the same effect as an original signature. Once signed by Respondent, the Agreement cannot be withdrawn without the Board's approval or by stipulation between Respondent and the Board's designee. The effective date of this Order is the date the Consent Agreement is signed by the Board and by Respondent. If the Consent Agreement is signed on different dates, the later date is the effective date.

_____

Respondent

Dated:_____

HUTTON, REBECCA; SES/ss

ARIZONA STATE BOARD OF NURSING

_____

Joey Ridenour, R.N., M.N., F.A.A.N.
Executive Director

Dated:_____

HUTTON, REBECCA; SES/ss

ORDER

In view of the above Findings of Fact, Conclusions of Law and the consent of Respondent, the Board hereby issues the following Order:

A. Respondent's consent to the terms and conditions of the Order and waiver of public hearing are accepted.

B. Respondent's registered nurse license number RN173397 and advanced practice certificate number AP4531 is hereby **suspended**; however, the **suspension is stayed** for as long as Respondent remains in compliance with this Order. During the stay of the suspension, Respondent's registered nurse license number RN173397 and Advanced Practice certificate number AP4531 is placed on probation for at minimum, 18 months, followed by standard probation for 18 months. Prior to termination of this Order, Respondent shall work as a nurse practitioner for a minimum of twenty-four months (not less than sixteen hours a week).

C. If Respondent is non-compliant with any of the terms of the Order during the 18-month stayed suspension period, the stay of the suspension shall be lifted and Respondent's license shall be automatically suspended for a minimum period of 18 months. Except as provided in paragraphs 7 (Drug Testing) and 14 (Quarterly Reports) of this Order, the Board or its designee, in its sole discretion, shall determine noncompliance with the stayed portion of the Order. With the exception of the provisions identified in Paragraphs 7 (Drug Testing) and 14

(Quarterly Reports), Respondent waives any and all rights to any further review, hearing, rehearing or judicial review of any suspension imposed pursuant to this paragraph.

D. If Respondent is noncompliant with any of the terms of the Order during the 18-month probation portion of the Order, Respondent's noncompliance shall be reviewed by the Board for consideration of possible further discipline on Respondent's nursing license.

E. If Respondent is convicted of a felony, Respondent's license shall be automatically revoked for a period of five years. Respondent waives any and all rights to a hearing, rehearing or judicial review of any revocation imposed pursuant to this paragraph.

F. This Order becomes effective upon the Board and Respondent's acceptance of the Order. The effective date is the date the Order is signed by the Board and Respondent. If Order is signed on different dates, the later date is the effective date.

G. At any time Respondent is required by terms of the Order to provide a copy of the Order to another individual or facility the Respondent must provide all pages of the Order.

H. The probation is subject to the following terms and conditions:

TERMS OF PROBATION
(Stayed Suspension and Standard Probation)

1. Stamping of License

Within three (3) days of the effective date of this Order, Respondent shall submit her license to the Board. Respondent's license shall be stamped "Probation" and returned to Respondent. While this Order is in effect, if the Board issues any certificates or licenses authorized by statute, except a nursing assistant certificate, such certificate or license shall also be stamped "**PROBATION.**" Respondent is not eligible for a multistate "Compact" license.

2. Nursing Ethics

Within thirty (30) days from the effective date of this Order Respondent shall make an appointment to undergo a nursing ethics course or begin nursing ethics counseling by a Board-approved treatment professional. If Respondent chooses to fulfill this stipulation by participation in counseling, Respondent shall execute the appropriate release of information form(s) to allow the counselor to communicate information to the Board or its designee. Prior to beginning the course or counseling, Respondent shall furnish a copy of this Consent Agreement and Order to include Findings of Fact and Conclusions of Law to the counselor or course director. Respondent shall cause the course director or counselor to notify the Board in writing within thirty days of entry into the course or therapy, and to verify in that same letter receipt of the Consent Agreement and Order to include Findings of Fact.

Respondent shall undergo and continue treatment or course attendance until the course director or treatment professional determines and reports to the Board in writing and on letterhead, that treatment is no longer considered necessary or the course has been successfully completed by the Respondent. During the duration of the course of counseling Respondent shall have the treatment professional or course director provide written reports to the Board every three months. The Board reserves the right to amend this Order based on the recommendations of the course director or treatment professional.

3. Substance Use Disorder Evaluation

On September 18, 2013 and again on December 4, 2013, Respondent was evaluated by Jacquelyn St. Germaine, PhD., a Board-approved evaluator. Prior to the evaluation, Dr. St. Germaine was provided with a copy of the Board's investigative report as well as other documents. Respondent executed the appropriate release of information forms to allow Dr. St. Germaine to communicate with the Board or its designee. The report from Dr. St. Germaine included a history of substance abuse, past treatment, present status of recovery and participation

in recovery activities, and recommendations for on-going treatment. Respondent will complete all recommendations as recommended by Dr. St. Germaine.

If recommended, Respondent shall enroll any recommended treatment or therapy within thirty (30) days of being notified by the Board of the recommendations from the evaluator. Respondent shall cause the program facilitator to inform the Board, in writing, verifying enrollment in the program. Prior to entry into any recommended therapy, Respondent shall provide a copy of this Consent Agreement and Order to include Findings of Fact and Conclusions of Law, and Order to the program facilitator. Respondent shall immediately execute the appropriate release of information form(s) to allow the facilitator to communicate information with the Board or its designee. Respondent shall participate in treatment or therapy until the Board receives verification from the facilitator in writing that Respondent has successfully completed the treatment requirements. During participation in treatment Respondent shall cause the provider or program facilitator to submit to the Board, in writing on a Board-approved form, evidence of satisfactory attendance, participation, discharge and successful completion of the program. Such reports are due beginning on the first quarterly reporting date after entry into treatment or therapy program and quarterly thereafter, according to schedule, and until verification of successful completion of the program has been received by the Board.

4. Relapse Prevention Therapy

Within thirty (30) days of the effective date of this Order, Respondent shall enter a Board approved Relapse Prevention Therapy Program. Respondent shall immediately execute the appropriate release of information form(s) to allow the facilitator to communicate information to the Board or its designee, and Respondent shall immediately provide a copy of this Consent Agreement and Order to include Findings of Fact and Conclusions of Law to the

facilitator. Within seven days of entering treatment, Respondent shall cause the facilitator to submit to the Board written verification of Respondent's enrollment in the Program, and verification of receipt of Respondent's entire Consent Agreement. Thereafter, Respondent shall cause the facilitator to provide quarterly reports to the Board according to the quarterly reporting schedule assigned to Respondent. Respondent shall continue undergoing treatment until the facilitator provides written notification to the Board, indicating that treatment is no longer needed. The Board reserves the right to amend the Order based on recommendation(s) of treating professional(s).

5. Nurse Recovery Group

Within seven (7) days of the effective date of this Order, Respondent shall enroll in a Board-acceptable Nurse Recovery Group if a group is available within forty miles. Respondent shall sign release of information forms allowing the group facilitator to inform the Board, in writing and on letterhead, of Respondent's entry and progress in the group. Respondent shall attend a Nurse Recovery Group once per week and have no "Unexcused" absences or "No call/No show" occurrences.

6. Participation in AA/NA

(a) Within seven (7) days of the effective date of this Order and throughout the term of this Order, Respondent shall participate at least two times weekly, in Alcoholics Anonymous (AA), Narcotics Anonymous (NA), or an equivalent program and shall provide to the Board, in writing on Board-approved forms verifying attendance within 7 days of assigned quarterly reporting due dates. The first report is due by the end of the first month after the effective date of the Order, and quarterly thereafter according to the assigned reporting dates.

(b) Respondent must obtain a temporary sponsor if participating in a twelve-step program within 30 of the effective date of this Order and a permanent sponsor within 60days

of the effective date of the Order. Respondent shall maintain a sponsor relationship throughout the terms of this Order. Failure to comply with stipulations as enumerated in sections (a) and (b) shall be considered as noncompliance with the terms of the Order.

7. Drug Testing

Respondent has received a copy of the Board's policy entitled "Guidelines For Non-Compliance With Drug Testing – Monitoring And CANDO Departments" dated May 21, 2013 ("Policy"), and agrees to abide by the terms and conditions set forth in the Policy.

Within seven (7) days of the effective date of this Order, Respondent shall enroll in a program that meets Board approved criteria for random drug testing. Drug testing may include testing of urine, hair follicle, nail, saliva or blood as determined by the Board or the Board's designee.

For random urine drug testing, Respondent shall submit a urine specimen a minimum of twice per month for a minimum period of 18 months. Thereafter, Respondent shall submit a urine specimen a minimum of once per month for the duration of the Order, and may be required to submit a specimen more frequently as determined by the Board or its designee.

For random hair testing, Respondent shall submit to hair testing that includes a health professional's panel of drugs to be tested at minimum, quarterly, and may be required to submit a specimen more frequently as determined by the Board or its designee. The first hair test must be submitted within thirty (30) days of the effective date of this Order and then quarterly thereafter.

Respondent shall provide written notification to the drug testing laboratory and the Board's designee of his/her unavailability to test before the unavailability occurs.

Within seven (7) days of a missed drug test due to an unexpected illness, Respondent must provide the Board or the Board's designee with written documentation from a medical provider stating that the medical provider personally examined Respondent on the day of the

requested drug test and that Respondent was not physically able to report to the laboratory for drug testing.

The Board's designee will immediately notify Respondent's employer of any drug test positive for an unauthorized drug. If Respondent tests positive for an unauthorized drug, misses a drug test or fails to submit a specimen suitable for drug testing, the Board or Board's designee may direct Respondent to cease practicing pending further determination by the Board or the Board's designee; and Respondent shall not return to practice until receiving written authorization from the Board or the Board's designee. During the Stayed Suspension period, if so investigated, reviewed and substantiated, testing positive for an unauthorized drug, failing to submit to a drug test or failing to submit a specimen suitable for drug testing, shall be considered as noncompliance with the terms of the Order, and the stay of suspension shall be lifted and Respondent's license automatically suspended. **If Respondent contests the lifting of the stay as it relates to this paragraph, Respondent shall request in writing, within 10 days of being notified of the automatic suspension of licensure, that the matter be placed on the Board agenda for the Board to review and determine if the automatic suspension of Respondent's license was supported by substantial evidence. If the written request is received within ten (10) days of a regularly scheduled Board meeting, the request will NOT be heard at that meeting, but will be heard at the NEXT regularly scheduled Board meeting. Pending the Board's review, Respondent's license shall be reported as suspended – under review. Respondent may not work in any capacity involving nursing licensure pending the Board's review. The Board's decision and Order shall not be subject to further review.**

During the standard eighteen month probation period of the Order, if so investigated, reviewed and substantiated, testing positive for an unauthorized drug, failing to submit to a drug

test or failing to submit a specimen suitable for drug testing, shall be considered as noncompliance with the terms of the Order.

Failing to submit to a drug test on a day when a drug test has been requested by the Board, its designee, an employer, or the laboratory constitutes a violation of this Agreement for which Respondent may not request further review/investigation by the Board's designee.

Violations of this Agreement for which Respondent may request further review/investigation by the Board's designee during the standard eighteen month probation include:

(1) A drug test positive for an unauthorized drug;

(2) Failing to submit a specimen suitable for drug testing, including a substituted or adulterated specimen.

Respondent may submit a written request to the Board's designee requesting further review/investigation within five days of being notified of the violation, and include the reason(s) for the violation in the request. Board staff may then investigate the reason(s) for the violation, including obtaining a written verification of Respondent's drug testing results from the Toxicologist or Medical Review Officer affiliated with the drug testing laboratory.

8. Abstain from Alcohol Use

Respondent shall abstain completely from the personal use of alcoholic beverages.

9. Abstain From Unauthorized Drug Use/Proof of Prescription/One Medical Provider

Respondent shall abstain completely from the personal use or possession of controlled substances, as defined in the State Controlled Substances Act, and dangerous drugs as defined by law, or any drugs requiring a prescription.

Orders prohibiting Respondent from personal use or possession of controlled substances or dangerous drugs do not apply to medications lawfully prescribed to Respondent for a bona fide illness or condition by a medical provider. During the duration of this Order, Respondent shall select one medical provider to coordinate her health care needs and to be aware of all prescriptions utilized by Respondent. Respondent shall immediately submit to that provider a copy of this Consent Agreement and Order to include the Findings of Fact and Conclusions of Law and shall execute all release of information form(s) as required by the Board or its designee. The medical provider shall, within one week of the effective date of the consent agreement, inform the Board, in writing, of knowledge of Respondent's Order and provide a list of medications prescribed for Respondent. DURING THE DURATION OF THE CONSENT AGREEMENT, RESPONDENT SHALL CAUSE ALL PROVIDERS TO NOTIFY THE BOARD OF ANY ADDITIONAL MEDICATIONS ORDERED BY THE PROVIDER. THE NOTIFICATION SHALL BE MADE IN WRITING WITHIN ONE WEEK OF THE PROVIDER'S ISSUANCE OF THE PRESCRIPTION.

If Respondent has a lawful prescription for a narcotic or mood-altering drug, Respondent shall cause her prescribing provider to submit monthly reports to the Board by the 30th day of each month regarding the continued need for the prescribed narcotic or mood-altering medications. The Board or its designee may, at any time, request the provider to document the continued need for prescribed medications. Respondent shall keep a written record of medications taken, including over-the-counter drugs, and produce such record upon request by the Board or its designee.

10. Pharmacy Profiles

Throughout the duration of this Order, Respondent shall use only one pharmacy from which to obtain her prescriptions. Within thirty (30) days of the effective date of the Consent

Agreement, Respondent shall submit in writing to the Board the name of every pharmacy and/or facility from which Respondent is currently obtaining prescription medications, and shall submit the name of the pharmacy from which she chooses to obtain future prescriptions. Throughout the duration of the Order, Respondent must inform the Board in writing within 7 days of any additions or changes in pharmacies from which Respondent obtains medications. Respondent shall submit a copy of all pharmacy profiles to the Board on a quarterly basis according to the assigned reporting due dates, and upon request from the Board or its designee. The first report shall be due on the first quarterly due date after the effective date of this Order.

11. Relapse Prevention Evaluation

Eighteen (18) months prior to the termination of the Order or as requested by the Board or its designee, Respondent shall be evaluated by a Board approved evaluator with expertise in substance use disorders and recovery maintenance. If recommended by the evaluator, Respondent shall enter, participate regularly and successfully complete a relapse prevention program, or any other recommendations as designated by the evaluator; Respondent shall enroll in a relapse prevention program or other recommended therapy within 30 days of being notified by the Board or its designee of the recommendations from the evaluator.

Respondent shall cause the program facilitator to inform the Board in writing verifying enrollment in the program. Prior to entry into a relapse prevention program or any type of other recommended therapy, Respondent shall provide a copy of this Consent Agreement and Order to include Findings of Fact and Conclusions of Law, and Order to the program facilitator. Respondent shall immediately execute the appropriate release of information form(s) to allow the facilitator to communicate information with the Board or its designee. Respondent shall participate in the relapse prevention program or therapy until the Board receives verification from the facilitator in writing that Respondent has successfully completed the program. During

participation in the program Respondent shall cause the program facilitator to provide to the Board, in writing on a Board-approved form, evidence of satisfactory attendance, participation, discharge and successful completion of the program. Such reports are due beginning on the first quarterly reporting date after entry into the relapse prevention program and quarterly thereafter, according to schedule, for the remainder of the probationary period or verification of successful completion of the program.

12. Notification of Practice Settings

Any setting in which Respondent accepts employment, which requires RN licensure, shall be provided with a copy of the entire Order within three (3) calendar days of the effective date of this Order and must confirm, in writing, their ability to provide Respondent with the supervision as required by this Order. Thereafter, any setting in which Respondent accepts employment, which requires RN licensure shall be provided with a copy of the entire Order on or before the date of hire and within three (3) calendar days of hire must confirm, in writing, their ability to provide Respondent with the supervision as required by this Order.. In the event Respondent is attending a nursing program, Respondent shall provide a copy of the entire Consent Agreement and Order to the Program Director. Respondent shall cause the Program Director to inform the Board, in writing and on school letterhead, acknowledgment of the program's receipt of a copy of the Consent Agreement and Order and the program's ability to comply with the conditions of probation during clinical experiences.

13. Chart Review

Prior to accepting employment as an advanced practice family nurse practitioner, Respondent shall identify and provide the name to the Board of a nationally certified family nurse practitioner of same or higher educational level (auditor) or Board approved physician to conduct chart audits of Respondent's patients on a monthly basis. For the first 12 months while working in a position which

requires advanced practice certification, Respondent shall cause the previously identified nationally certified family nurse practitioner of same or higher educational level or Board approved physician to audit 50% of the records of persons Respondent has provided care to during the prior 30 days and review of prescriber's (Respondent's) Controlled Substance Pharmacy Program profile. The audit shall include a review and confirmation of appropriate assessment, diagnosis, treatment plan, and medications prescribed. Review should also include prescription profiles, appropriate controlled substance prescribing and adhering to pain agreement. For the first 12 months while working in a position which requires advanced practice certification, Respondent shall cause the auditor to provide to the Board, in writing, a summary of the random chart audit to contain a minimum of 50% of Respondent's patients and 100% controlled substance prescription review by a Nationally Certified FNP with same or higher education level or Board approved physician by the 30th of each month. For the second 12 months, Respondent may have 25% of Respondent's patients and 100% controlled substance audited instead of 50%, and then for the duration Respondent may have 10% audited of Respondent's patients and 100% controlled substance instead of 25%.

14. Quarterly Reports

Within thirty (30) days of the effective date of this Order, and quarterly thereafter, Respondent shall cause **every** employer Respondent has worked for to submit to the Board, in writing, quarterly employer evaluations on the Board-approved form including 100% controlled substance prescription review by a Nationally certified FNP with the same or higher education level or by a Board approved physician. In the event Respondent is not employed in nursing or attending school during any quarter or portion thereof, Respondent shall submit to the Board, in writing, a self-report describing other employment or activities on the Board-approved form.

Receipt of confirmation of employment disciplinary action, including written counseling(s), suspension, termination or resignation in lieu of termination from a place of

employment, any of which pertains to improper patient care, unsafe practice, inappropriate medication removal or administration, sub-standard documentation, or impairment on duty, positive drug test showing evidence of any drug other than an authorized drug, and/or refusal to submit to an employer requested drug screen/testing, shall be investigated by Board staff and reviewed and substantiated by the Board's designee. If so investigated, reviewed and substantiated, the employment disciplinary action shall be considered as noncompliance with the terms of the Order, and the stay of suspension shall be lifted and Respondent's license automatically suspended. **If Respondent contests the lifting of the stay as it relates to this paragraph, Respondent shall request in writing, within 10 days of being notified of the automatic suspension of licensure, that the matter be placed on the Board agenda for the Board to review and determine if the automatic suspension of Respondent's license was supported by substantial evidence. If the written request is received within ten (10) days of a regularly scheduled Board meeting, the request will NOT be heard at that meeting, but will be heard at the NEXT regularly scheduled Board meeting. Pending the Board's review, Respondent's license shall be reported as suspended – under review. Respondent may not work in any capacity involving nursing licensure pending the Board's review. The Board's decision and Order shall not be subject to further review.**

Failure to provide employer evaluations or if not working in nursing, self-reports, within seven days of the reporting date is noncompliance with this Order and is not subject to further review.

15. Practice Under On-Site Supervision

While Respondent is working as a registered nurse, Respondent shall practice as a registered nurse only under the on-site supervision by a Nationally certified FNP with the same or higher education level or a Board approved physician who is in good standing with the Board.

On-site supervision is defined as having a registered nurse present in the building while Respondent is on duty. While Respondent is working for Optum United Healthcare conducting history and physical examinations in a home setting, this on-site supervision does not apply; instead, Respondent shall communicate regularly by telephone with her supervisor, her supervisor shall conduct regular review of Respondent's work by accompanying Respondent to the history and physical examinations that Respondent conducts, and her supervisor shall provide quarterly reports to the Board about Respondent's compliance with the Consent Agreement and Order.

The supervising nurse or Board approved physician shall have read this Consent Agreement and Order to include the Findings of Fact and Conclusions of Law, and Order, and shall provide input on Respondent's employer evaluations to the Board. The supervising nurse or Board approved physician shall be primarily one person, who may periodically delegate to other qualified personnel, who shall also have read this Consent Agreement and Order to include Findings of Fact, Conclusions of Law. In the event that the assigned supervising nurse or Board approved physician is no longer responsible for the supervision required by this paragraph, Respondent shall cause her new supervising nurse or Board approved physician to inform the Board, in writing and on employer letterhead, acknowledgment of the new supervisor's receipt of a copy of this Consent Agreement and Order to include the Findings of Fact and Conclusions of Law and the new supervising nurse or Board approved physician's agreement to comply with the conditions of probation within ten days of assignment of a new supervising nurse.

16. Acceptable Hours of Work

Respondent shall work only the day or evening shift. Evening shift is defined as a shift that ends prior to midnight. Within a 14-day period Respondent shall not work more than 84 scheduled hours.

Respondent may work three 12-hour shifts in one seven day period and four 12-hour shifts in the other seven-day period, but Respondent may not work more than 3 consecutive 12-hour shifts during this probationary period. Respondent shall not work 2 consecutive 8 hour shifts within a 24 hour period or be scheduled to work 16 hours within a 24 hour period.

17. Registry Work Prohibited

Respondent may not work for a nurse's registry, home health, traveling nurse agency, any other temporary employing agencies, float pool, or position that requires on-call status, unless employed by Optum United Healthcare as described in section 15 (Practice Under On-Site Supervision) above. In no event is Respondent permitted to write prescriptions in this capacity.

18. Out of State Practice/Residence

Before any out-of-state practice or residence can be credited toward fulfillment of these terms and conditions, out-of-state practice or residence must first be approved by the Board prior to leaving the state. If Respondent fails to receive such approval before leaving the state, none of the time spent out of state will be credited to the fulfillment of the terms and conditions of this Order.

19. Release of Information Forms

Respondent shall sign all release of information forms as required by the Board or its designee and return them to the Board within 10 days of the Board's written request. Failure to provide for the release of information, as required by this paragraph constitutes non-compliance with this Order.

20. Interview with the Board or its Designee

Respondent shall appear in person or telephonically for interviews with the Board or its designee upon request at various intervals and with at least two (2) day notice.

21. Renewal of License

In the event Respondent's registered nurse license is scheduled to expire while this Order is in effect, Respondent shall apply for renewal of the license, pay the applicable fee, and otherwise maintain qualification to practice nursing in Arizona.

22. Change of Employment/Personal Address/Telephone Number

Respondent shall notify the Board, in writing, within 7 days of any change in nursing employment, personal address or telephone number. Changes in nursing employment include the acceptance, resignation or termination of employment.

23. Obey All Laws

Respondent shall obey all laws/rules governing the practice of nursing in this state and obey all federal, state and local criminal laws. Respondent shall report to the Board, within 10 days, any misdemeanor or felony arrest or conviction.

24. Costs

Respondent shall bear all costs of complying with this Order.

25. Violation of Probation

If during the stayed suspension portion of the Order, if Respondent is noncompliant with the terms of the Order in any way, the stay of suspension shall be lifted and Respondent's license shall be automatically suspended for a minimum period of 18 months. If during the standard probation portion of the Order, Respondent is noncompliant with the terms of the Order in any respect, the Board staff may notify the Respondent's employer of the noncompliance. Additionally, the Board may revoke probation and take further disciplinary action for noncompliance with this agreement after affording Respondent notice and the opportunity to be heard. If a complaint or petition to revoke probation is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

26. Voluntary Surrender of License

Respondent may, at any time this order is in effect, voluntarily request surrender of her license.

27. Completion of Order

When Respondent has 9 months left in the probationary period Respondent's compliance will be reviewed by the Board's designee. If Respondent has demonstrated full compliance with all terms of the Order, Respondent will be eligible to participate in a "step-down" component of the Order where reports from AA and Nurse Recovery Group will no longer be required.

Respondent is not eligible for early termination of this Order. Upon successful completion of the terms of the Order, Respondent shall request formal review by the Board, and after formal review by the Board, Respondent's nursing license may be fully restored by the appropriate Board action if compliance with this Order has been demonstrated.

ARIZONA STATE BOARD OF NURSING

SEAL

_____

Joey Ridenour, R.N., M.N., F.A.A.N.
Executive Director

Dated:

COPY mailed and e-mailed this day of , 2014 to:

Kathleen Lambert, Esq.
2905 N Longhorn Drive
Tucson, AZ 85749-9755
klambert3@qwestoffice.net

Rebecca Ann Hutton
3411 S. Camino Seco #175,
Tucson, AZ 85730
rebeccatrac@gmail.com

By: _____

Ohio Board of Nursing

CONSENT AGREEMENT

BETWEEN

REBECCA ANN LEON, RN, APPLICANT

AND

OHIO BOARD OF NURSING

BASIS FOR ACTION

[redacted]

EFFECTIVE DATE

MS. HUTTON understands that this Consent Agreement is subject to ratification by the Board prior to signature by the Board President and shall become effective upon the last date of signature below.

REBECCA HUTTON, RN APPLICANT — DATE: 23/10/26

LAURA LEE KRABILL, MBA, RN — DATE:
President, Ohio Board of Nursing

BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: REBECCA ANN HUTTON a.k.a. REBECCA ANN TRACHTENBERG a.k.a. REBECCA TRACHTENBERG Registered Nurse License No. 645757 Nurse Practitioner Certificate No. 15318 Nurse Practitioner Furnishing Certificate No. 15318 Respondent.	Case No. 2015-589

DECISION AND ORDER

Pursuant to Title 16 of the California Code of Regulations, section 1403, the attached Stipulated Settlement is hereby adopted by the Board of Registered Nursing as its Decision and Order in the above-entitled matter.

This Decision shall become effective on May 6, 2015.

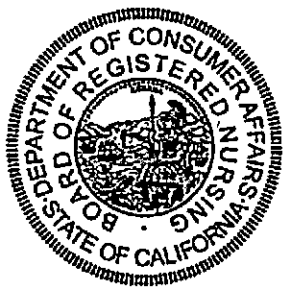
IT IS SO ORDERED this 6th day of May, 2015.

Louise R. Bailey
Louise R. Bailey, M.Ed., RN
Executive Officer
Board of Registered Nursing
Department of Consumer Affairs
State of California

I hereby certify the foregoing to be a true copy of the documents on file in our office.

BOARD OF REGISTERED NURSING

Louise R. Bailey, M.Ed., RN
Executive Officer



KAMALA D. HARRIS
Attorney General of California
LINDA K. SCHNEIDER
Senior Assistant Attorney General
DIANN SOKOLOFF
Supervising Deputy Attorney General
State Bar No. 161082
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, CA 94612-0550
Telephone: (510) 622-2212
Facsimile: (510) 622-2270
Attorneys for Complainant

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **REBECCA ANN HUTTON, AKA.** **REBECCA ANN TRACHTENBERG, AKA.** **REBECCA TRACHTENBERG** **[redacted]South Camino Seco, Unit [redacted]** **Tucson, AZ 85730** **Registered Nurse License No. 645757** **Nurse Practitioner Certificate No. 15318** **Nurse Practitioner Furnishing Certificate No. 15318** Respondent.	Case No. 2015-589 **STIPULATED SURRENDER OF LICENSE AND ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Louise R. Bailey, M.Ed., RN (Complainant) is the Executive Officer of the Board of Registered Nursing. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Diann Sokoloff, Supervising Deputy Attorney General.

2. Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg (Respondent) is representing herself in this proceeding and has chosen not to exercise her right to be represented by counsel.

3. On or about September 30, 2004, the Board of Registered Nursing issued Registered Nurse License No. 645757 to Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg (Respondent). The Registered Nurse License expired on April 30, 2012, and has not been renewed.

4. On or about October 1, 2004, the Board of Registered Nursing issued Nurse Practitioner Certificate No. 15318 to Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg (Respondent). The Nurse Practitioner Certificate expired on April 30, 2012, and has not been renewed.

5. On or about May 19, 2005, the Board of Registered Nursing issued Nurse Practitioner Furnishing Certificate No. 15318 to Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg (Respondent). The Nurse Practitioner Certificate expired on April 30, 2012, and has not been renewed.

JURISDICTION

6. Accusation No. 2015-589 was filed before the Board of Registered Nursing (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on February 17, 2015. Respondent timely filed her Notice of Defense contesting the Accusation. A copy of Accusation No. 2015-589 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, and understands the charges and allegations in Accusation No. 2015-589. Respondent also has carefully read, and understands the effects of this Stipulated Surrender of License and Order.

8. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel, at her own expense; the right to confront and cross-examine the witnesses against her; the right to

present evidence and to testify on her own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

10. Respondent admits the truth of each and every charge and allegation in Accusation No. 2015-589, agrees that cause exists for discipline and hereby surrenders her Registered Nurse License No. 645757, Nurse Practitioner Certificate No. 15318, and Nurse Practitioner Furnishing Certificate No. 15318 for the Board's formal acceptance.

11. Respondent understands that by signing this stipulation she enables the Board to issue an order accepting the surrender of her Registered Nurse License, Nurse Practitioner Certificate, and Nurse Practitioner Furnishing Certificate without further process.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Registered Nursing. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Registered Nursing may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent. By signing the stipulation, Respondent understands and agrees that she may not withdraw her agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

14. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS HEREBY ORDERED that Registered Nurse License No. 645757, Nurse Practitioner Certificate No. 15318, and Nurse Practitioner Furnishing Certificate No. 15318 issued to Respondent Rebecca Ann Hutton, aka. Rebecca Ann Trachtenberg aka. Rebecca Trachtenberg, are surrendered and accepted by the Board of Registered Nursing.

1. The surrender of Respondent's Registered Nurse License, Nurse Practitioner Certificate, and Nurse Practitioner Furnishing Certificate and the acceptance of the surrendered license and certificates by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board of Registered Nursing.

2. Respondent shall lose all rights and privileges as a registered nurse, nurse practitioner, and nurse practitioner furnisher in California as of the effective date of the Board's Decision and Order.

3. Respondent shall cause to be delivered to the Board her pocket license and certificates, if one was issued, her wall certificates on or before the effective date of the Decision and Order.

4. If Respondent ever files an application for licensure or a petition for reinstatement in the State of California, the Board shall treat it as a petition for reinstatement. Respondent must comply with all the laws, regulations and procedures for reinstatement of a revoked license in effect at the time the petition is filed, and all of the charges and allegations contained in

Accusation No. 2015-589 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the petition.

5. If and when Respondent's license and certificates are reinstated, she shall pay to the Board costs associated with its investigation and enforcement pursuant to Business and Professions Code section 125.3 in the amount of $950.00. Respondent shall be permitted to pay these costs in a payment plan approved by the Board. Nothing in this provision shall be construed to prohibit the Board from reducing the amount of cost recovery upon reinstatement of the license.

6. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation, No. 2015-589 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

7. Respondent shall not apply for licensure or petition for reinstatement for two (2) years from the effective date of the Board of Registered Nursing's Decision and Order.

ACCEPTANCE

I have carefully read the Stipulated Surrender of License and Order. I understand the stipulation and the effect it will have on my Registered Nurse License, and Nurse Practitioner and Nurse Practitioner Furnishing Certificates. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Registered Nursing.

DATED: 4/22/15

R Hutton

REBECCA ANN HUTTON, AKA, REBECCA ANN TRACHTENBERG AKA. REBECCA TRACHTENBERG
Respondent

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ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Registered Nursing of the Department of Consumer Affairs.

Dated: 4/23/15

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA SCHNEIDER
Senior Assistant Attorney General

DIANN SOKOLOFF
Supervising Deputy Attorney General
Attorneys for Complainant

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KAMALA D. HARRIS
Attorney General of California
LINDA K. SCHNEIDER
Senior Assistant Attorney General
DIANN SOKOLOFF
Supervising Deputy Attorney General
State Bar No. 161082
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, CA 94612-0550
Telephone: (510) 622-2212
Facsimile: (510) 622-2270
Attorneys for Complainant

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **REBECCA ANN HUTTON a.k.a.** **REBECCA ANN TRACHTENBERG a.k.a.** **REBECCA TRACHTENBERG** **329 Ramona Avenue** **El Cerrito, CA 94530** **Registered Nurse License No. 645757** **Nurse Practitioner Certificate No. 15318** **Nurse Practitioner Furnishing Certificate No. 15318** Respondent.	Case No. 2015-589 **ACCUSATION**

Complainant alleges:

PARTIES

1. Louise R. Bailey, M.Ed., RN (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Registered Nursing (Board), Department of Consumer Affairs.

2. On or about September 30, 2004, the Board issued Registered Nurse License Number 645757 to Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg (Respondent). The Registered Nurse License expired on April 30, 2012, and has not been renewed.

3. On or about October 1, 2004, the Board issued Nurse Practitioner Certificate Number 15318 to Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg (Respondent). The Nurse Practitioner Certificate expired on April 30, 2012, and has not been renewed.

4. On or about May 19, 2005, the Board issued Nurse Practitioner Furnishing Certificate Number 15318 to Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg (Respondent). The Nurse Practitioner Furnishing Certificate expired on April 30, 2012, and has not been renewed.

JURISDICTION

5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Section 2750 of the Code states:

"Every certificate holder or licensee, including licensees holding temporary licenses, or licensees holding licenses placed in an inactive status, may be disciplined as provided in this article [Article 3 of the Nursing Practice Act (Bus. & Prof Code, § 2700 et seq.)]. As used in this article, "license" includes certificate, registration, or any other authorization to engage in practice regulated by this chapter. The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted therein."

7. Section 2764 of the Code states:

"The lapsing or suspension of a license by operation of law or by order or decision of the board or a court of law, or the voluntary surrender of a license by a licentiate shall not deprive the board of jurisdiction to proceed with any investigation of or action or disciplinary proceeding against such license, or to render a decision suspending or revoking such license."

STATUTORY PROVISION

8. Section 2761 of the Code states:

"The board may take disciplinary action against a certified or licensed nurse or deny an application for a certificate or license for any of the following:

"(a) Unprofessional conduct, which includes, but is not limited to, the following:

. . .

"(4) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action against a health care professional license or certificate by another state or territory of the United States, by any other government agency, or by another California health care professional licensing board. A certified copy of the decision or judgment shall be conclusive evidence of that action."

COST RECOVERY

9. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated.

CAUSE FOR DISCIPLINE
(Unprofessional Conduct – Out of State Discipline)
(Bus. & Prof. Code, §§2761, subd. (a)(4))

10. Respondent has subjected her Registered Nurse License to disciplinary action for unprofessional conduct in that on or about May 20, 2013, in *In the Matter of Registered Nurse License No.: RN173397/AP4531 Issued to Rebecca Ann Hutton, Respondent in Consent Agreement and Order No. 1302115*, the Arizona Board of Nursing (Arizona Board) entered a Consent Agreement and Order suspending Respondent's registered nurse license. According to the Arizona Board's Order, on or about August 2012 through February 2013, Respondent acted unprofessionally and deviated from the Standard of Care in her performance, maintenance of records, prescription of controlled substances, and for violating hospital policies. Respondent admitted these allegations. On May 14, 2013, Respondent admitted to the Board that around July 2012, Respondent relapsed on cocaine and during that time, continued to prescribe controlled substances, placing patients at risk for poor medical outcome. The Arizona Board stayed the

suspension on Respondent's registered nursing license and placed Respondent on probation for a minimum of 36 months. During this probation period, the Arizona Board ordered Respondent to attend a nursing ethics course; enter an approved Relapse Prevention Therapy Program; enroll in a Nurse Recovery Group; participate in Alcoholics Anonymous, Narcotics Anonymous, or an equivalent program; and adhere to various other terms and conditions as outlined in the Order.

DISCIPLINARY CONSIDERATIONS

11. In determining the level of discipline to be imposed in this matter, if any, Complainant further alleges that on or about February 28, 2002, in a criminal matter entitled, "*State of Delaware vs. Rebecca A. Trachtenberg*", in the State of Delaware, Justice of the Peace Court 14, Court Case No. 0111018692, Respondent was convicted of driving under the influence of alcohol. Respondent was required to enroll in a First Offender Program and pay various fees and fines.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Registered Nursing issue a decision:

1. Revoking or suspending Registered Nurse License Number 645757, issued to Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg.

2. Revoking or suspending Nurse Practitioner Certificate Number 15318, issued to Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg.

3. Revoking or suspending Nurse Practitioner Furnishing Certificate Number 15318, issued to Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg.

4. Ordering Rebecca Ann Hutton, also known as Rebecca Ann Trachtenberg, also known as Rebecca Trachtenberg to pay the Board of Registered Nursing the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section

125.3;

5. Taking such other and further action as deemed necessary and proper.

DATED: January 20, 2015

for LOUISE R. BAILEY, M.ED., RN
Executive Officer, Board of Registered Nursing
Department of Consumer Affairs
State of California
Complainant

Nevada State Board of Pharmacy

985 Damonte Ranch Pkwy #206 • Reno • NV 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
E-mail: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

Date: July 7, 2023

To: Rebecca Ann Martinez
907 S 2nd Avenue
Yuma, AZ 85364

Enclosed please find your application sent to the Nevada State Board of Pharmacy.

The application is being returned for the following reason(s):

- ☐ **Information Discrepancy**: the answers provided in section ____ of the application does not match your criminal background check. Please resubmit an application correctly answering the questions in section ____ of the application and provide a signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement, or other disposition for any affirmative answer in section ____ of the application.

- ☒ **Missing Documents**: a signed statement of explanation for each event and/or a copy of all documents that identify the circumstance or contain an order, agreement, or other disposition for the question(s) answered affirmatively in section 6 was not provided. Please resubmit an application with the required documents.

- ☐ **Missing Information**: the highlighted fields in the enclosed application was not completed. Please complete the highlighted fields and resubmit your application.

- ☐ **Incorrect Application**: you completed and submitted an outdated application. Please complete and submit the updated enclosed application.

- ☐ **Missing Fingerprint Submission:** Each person required to submit fingerprints pursuant to NRS 639.500 must submit a complete set of fingerprints by contacting a local law enforcement agency for fingerprinting, sign the Nevada Department of Public Safety's "Fingerprint Background Waiver" Form attached and return it together with the completed fingerprint card and a cashier's check or money order in the amount of $40.25 made payable to "Nevada State Board of Pharmacy"

Please contact us If you have any questions.
Sincerely,

Nevada State Board of Pharmacy

Nevada State Board of
NURSING
Primary Source License Verification

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

REBECCA ANN MARTINEZ

Thursday, July 20 2023 08:01:48 AM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active– *ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing– *ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

Active Prescribing -D– *ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing verifying that they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MARTINEZ, REBECCA ANN	RN	865606	Inactive	03/17/2023	05/08/2023	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MARTINEZ, REBECCA ANN	RN	865606	Active	05/08/2023	03/26/2025	NO

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MARTINEZ, REBECCA ANN	APRN-CNP	865606	Active Prescribing - CII	06/26/2023	03/26/2025	NO

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 03/26/2025
  - Original Issuance Date: 06/26/2023
  - Current Issue Date: 06/26/2023
  - Certification expiration date: 02/29/2024

License type information

17B

TM

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

What types of drug(s) will you be prescribing?

☐ Dangerous Drugs ONLY (Non-Refundable $80 Fee) (PR)

☑ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V (Non-Refundable $200 Fee) (CS)

Select the Controlled Substance Schedules you are applying to prescribe

☐ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Camilo Middle: Andres Last: Murillo

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: 3436 sw 23 ter

City: Miami State: Fl Zip Code: 33145

Telephone: 305-812-2208 Email: cammurillo71@Gmail.com

APRN License #: 860881 Specialty: Family/Individual across the life

(A current license and active-PRESCRIBING status with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: Direct Primary Care Coconut Grove

Practice Address: 3436 sw 23 ter Suite #:

City: Miami State: Fl Zip: 33145

Telephone: 305-812-2208 Fax: 305-390-4659 Email: cammurillo71@Gmail.com

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☑ I have at least 2 years or 2,000 hours of clinical experience; OR

☐ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name:

Collaborating Physician Practice Address: Suite #:

City: State: Zip:

Telephone: Fax: Email:

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
See Attachment	See Attachments	FL	Miami	Dade
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
See Attachments		See Attachments		
Reason/Charge				
"				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
"				
Name of Business/Industry/Entity				
"				

Provide explanation below:

See Attachments and packet of paperwork provided.

Original Signature (electronic, copies or stamps not accepted)

05-20-23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Camilo Murillo

Applicant Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05-20-2023

Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only: Date Processed: _____ Amount: $200-CK-4143

November 23, 2020(Originally in system)
January 14, 2021(Updated)

State of Nevada
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521

Re: Camilo Andres Murillo
License #: Florida RN9420080
License #: Illinois 041506215
DOB: [redacted]
Last 4 Social Security #[redacted]

To whom it may concern:

I have worked in a Healthcare setting since 2002 after graduating as a medical assistant, I started at the University of Miami as a receptionist at the Sylvester Cancer Center. Here are some of the accomplishments I have made as a Healthcare professional and encountered thousands of patients during my career without compromising care.

- License Practical Nurse 01/16/2008
-Registered Nurse 10/26/2015 Miami Dade College
-Emergency Medical Technician 07/11/2016 Miami Dade College
-Bachelor Science Nursing 06/27/17 Broward College
-Master Science Nursing "Family Nurse Practitioner" 08/07/2020 University of Miami

Explanation of arrest:

-1/15/01 SELL OF CANNABIS; This is a duplicate charge which was dismissed (See attachments provided)
-07/21/00 DUI; I was 18 years old, not even 2 months out of high school, Guilty; completed the program and all requirements (See attachments) completion of program.
-11/03/00 CANNABIS SELL; This charge is over 20 years old; it was poor judgement in my youth and received a with hold adjudication which is not a conviction.
-11/29/00 CRIMINAL MISCHIEF; This was originally filed as a felony charge (F00038091) then reduced to a misdemeanor (M01000297) which was not prosecuted and dismissed.
-05/14/02 DISORDERLY INTOXICATION; Withhold adjudication, not a conviction.
-06/18/10 RECKLESS DRIVING; Withhold adjudication, not a conviction
*All WITH HOLDS, NOLLE PROS, NO ACTIONS, DISMISSED are not ADJUDICATIONS OF

GUILT.

I have attached the following:

- Dispositions of all criminal record
- Miami Dade Police Department "Letter of Copy not on file"
- Dockets of the duplicate Cannabis sales
- Florida Board of Nursing Exemption and Exemption for Licensure in compact states
- Traffic Disposition of DUI
- Transcripts of highest nursing degree received.

Best regards,
Camilo Andres Murillo FLORIDA License #RN9420080 / #APRN11010959

3436 SW 23 Ter
Miami, FL 33145
[redacted]

Miami-Dade Police Department
Central Records Bureau
9105 NW 25th Street
Miami, Florida 33172-1505

miamidade.gov

Date: January 10, 2020

To Whom It May Concern:

A name search of the Miami-Dade Police Department (MDPD) arrest records under the name of:
Name: **MURILLO, CAMILO ANDRES**
Race/Sex: **W/M** Date of Birth: [redacted]
AKA:
MDPD Criminal Identification Number: **679481**
☐ No Local Record
☐ Criminal Registration Only/No Local Record

☒ Local Felony Arrest Record(s)
☒ Copy on File
☒ Copy Not on File

☒ For Case Disposition Contact: (305) 275-1155
Felony Division
1351 NW 12 Street
Miami, Florida 33125

☒ Local Misdemeanor Arrest Records(s)
☒ Copy on File
☐ Copy Not on File

☒ For Case Disposition Contact: (305) 275-1155
Misdemeanor Division
1351 NW 12 Street
Miami, Florida 33125

☒ Local Traffic Arrest Records(s)
☒ Copy on File
☒ Copy Not on File

☒ For Case Disposition Contact: (305) 275-1111
Traffic Division
1351 NW 12 Street, Room 124
Miami, Florida 33125

☐ Other Local Agency Arrest Records(s)

☐ Civil Division (305) 275-1155
73 W. Flagler Street
Miami, Florida 33142

Case Numbers:
F00-038091 M01-000297 *F00-035444 B02-026311 M02-001783 F02-023357 F10-018078 0987-FOT M18-018567 *394654-W
Comments:
***COPY NOT ON FILE**

Date: **1/10/2020** Researched by (Name/Title): **G. CHERENFANT, PRT1/9564**
Print and Sign ID/Badge#

Date: **1/10/2020** Prepared by (Name/Title): **J. FLOYD, PRT1/8711**
Print and Sign ID/Badge#

MIAMI DADE COUNTY, FL RECORDS BUREAU

NOTE: Not valid unless the seal of the MDPD is affixed. The MDPD is prohibited from disclosing the existence of juvenile criminal history information, as well as records that have been sealed or expunged. Therefore, if "No Local Record" is indicated, there remains the possibility that juvenile, sealed or expunged records may be associated with the above name that cannot be disclosed. There is also the possibility that an adult or juvenile may have been arrested in a jurisdiction other than Miami-Dade County. The Florida Department of Law Enforcement may disclose information related to criminal history for certain licensing and employment purposes as provided by law. They may be contacted at 1-800-342-0820.

IN THE CIRCUIT AND COUNTY COURTS OF THE ELEVENTH JUDICIAL CIRCUIT OF FLORIDA

IN AND FOR MIAMI-DADE COUNTY

I, HARVEY RUVIN, CLERK OF THE CIRCUIT AND COUNTY COURT OF THE ELEVENTH JUDICIAL CIRCUIT OF FLORIDA, IN AND FOR MIAMI-DADE COUNTY, DO HEREBY CERTIFY THAT A DILIGENT EXAMINATION OF THE FELONY, MISDEMEANOR AND NON CRIMINAL VIOLATION FILES AND RECORDS IN MY OFFICE REGARDING:

NAME: MURILLO, CAMILO ANDRES
DATE OF BIRTH: [redacted]
RACE: WHITE SEX: MALE
YEARS RESEARCHED: 2000 - 2019

INDICATES THE FOLLOWING:

CASE NUMBER	CITATION/ ARREST / FILE DATE	CHARGES	DISPOSITION	DISPO DATE
MURILLO, CAMILO ANDRES				
M18018567	07/02/2018	BATTERY	NOLLE PROS	02/11/2019
		DISORDERLY INTOX	NOLLE PROS	02/11/2019
MURILLO, CAMILO ANDRES				
B02026311	05/14/2002	DISORDERLY INTOX	WH ADJ / CTS	07/22/2008
MURILLO, CAMILO ANDRES				
M01000297	11/29/2000	CRIM MIS/200-1000	NOLLE PROS	05/02/2001
MURILLO, CAMILO ANDRES				
F00038091	11/29/2000	CRIM MIS/1000+	REDUCED/TRN CNTY C	01/03/2001
MURILLO, CAMILO ANDRES				
F00035444	11/03/2000	CANN/SELL/DEL/PSNW/I	WH ADJ-PROB SP CON	01/03/2001
		PROBATION VIOLATION	DISMISSED	10/01/2001
		CANN/SELL/DEL/PSNW/I	NO ACTION	12/04/2000
MURILLO, CAMILO		AKA*		
F02023357	08/07/2002	BATTERY/AGGRAVATED	NO ACTION	09/06/2002
		ASSAULT/AGGRAVATED	NO ACTION	09/06/2002
MURILLO, CAMILO A		AKA*		
M02001783	01/01/2002	PETIT LARCENY, THEFT	WH ADJ-SUSP ENT SE	02/14/2002
MURRILLO, CAMILO		AKA*		
F10018078	06/18/2010	FLEE/ELUDE PO	WH ADJ-PROB SP CON	09/22/2010
		RECK DRVG/PROP/PERS	WH ADJ-SUSP ENT SE	09/22/2010

PAGE: 001

CIRCUIT AND COUNTY COURTS CLERK IN GOD WE TRUST MIAMI-DADE COUNTY, FLORIDA

****

PURSUANT TO FLORIDA RULES OF COURT, RULE 2.430, COURT RECORDS THAT ARE NOT PERMANENTLY RECORDED MAY BE UNAVAILABLE, OR DISPOSED OF BY THE CLERK, IN ACCORDANCE WITH THE APPLICABLE RETENTION SCHEDULE REQUIRED BY SAID RULE. (10 YEARS FOR FELONY, MISDEMEANOR AND CRIMINAL TRAFFIC VIOLATIONS IN WHICH THE DEFENDANT WAS ADJUDICATED NOT GUILTY).
PLEASE SEE FLORIDA RULES OF COURT, RULE 2.430, FOR A COMPLETE LISTING OF RECORDS RETENTION REQUIREMENTS.

WITNESS MY HAND AND THE SEAL OF THE COURT AT MIAMI, MIAMI-DADE COUNTY, FLORIDA, THIS 09 DAY OF DECEMBER, 2019.

HARVEY RUVIN, CLERK
CIRCUIT AND COUNTY COURTS
IN AND FOR MIAMI-DADE COUNTY, FLORIDA

PAGE: 002

BY: _____ DEPUTY CLERK

TYOSHO BENNETT 22969

Deputy Clerk of the Circuit Court
of the Eleventh Judicial Circuit
of Florida, In and for Dade County

CIRCUIT CRIMINAL DIVISION | IN THE CIRCUIT COURT OF THE
RENWAH
PRINTED DOCKET - FELONY | ELEVENTH JUDICIAL CIRCUIT OF
CASE ACTION SUMMARY | FLORIDA IN AND FOR DADE COUNTY

CASE NO: F00035444 IDS: 0619743 CIN: 0679481 POLICE CASE NO: 3081853Z
STATE CSE: 132000CF03544400001XX FILE LOC: 10 RECORD CENTER BOX# 254 201
DEFENDANT: MURILLO CAMILO ANDRES
ADDRESS: [redacted] SW 23 TER MIAMI FL 33145
PERSONAL INFORMATION IMPORTANT DATES
DOB: [redacted] RACE: W SEX: M ARREST: 11/03/2000 ARR: 01/03/2001
EYES: BRO HEIGHT: 510 FILED: 11/06/2000 TRIAL:
HAIR: BLK WEIGHT: 220 INFO: 12/04/2000 CLOSED: 01/03/2001
JUDGE: RODRIGUEZ ROSA BOOKED: 11/04/2000
SECTION: F004 SPEEDY REQ: 04/27/2001
ATTORNEY: BRANDOW JOHN ATTY TYPE: PDEF
WARRANT: ISSUED: ARR-OFCR: -1- 4835
COURTROOM: LOCATION: FUTURE HEARING: TYPE: OTH HRG:

CHARGES	T	D	DESCRIPTION	DISPOSITION	DATE	PL	TL
893.13(1)(A)2	F	3	CANN/SELL/DEL/PSNW/I	WH ADJ-PROB SP COND	01/03/2001	NB	B
948.061	Z	0	PROBATION VIOLATION	DISMISSED	10/01/2001		
893.13(1)(A)2	F	3	CANN/SELL/DEL/PSNW/I	NO ACTION	12/04/2000		

SEQ	DATE	PROGRESS OF CASE
63	10/24/2001	COURT FEE PAYMENT 116.48 RECEIPT # 0335297
62	10/12/2001	TRIAL PROS. ASSIGNED: ROBINS, CARI
61	10/10/2001	MOTION TO TERMINATE PROBATION/COMMUNITY CONTROL
		FILED 10/10/2001 ORAL
		SET FOR 10/10/2001 AT 09:57 GRANTED
60	10/09/2001	WRITE-IN HEARING RECORDED ON 10/09/2001 AT 09:00
59	10/09/2001	REPORT RE: PROBATION
		SET FOR 10/10/2001 AT 09:00
58	10/01/2001	AMENDED AFFIDAVIT OF VIOLATION OF PROBATION
57	10/01/2001	VIOLATION OF PROBATION AFFIDAVIT FILED
56	10/01/2001	00002 2/ 948.061 PROBATION VIOLATION
		DISP/DISMISSED -MODIFIED/REMOVED
55	10/01/2001	MOTION TO WAIVE COST OF SUPERVISION
		FILED 10/01/2001 ORAL
		SET FOR 10/01/2001 AT 09:43 GRANTED
54	09/28/2001	REPORT RE: PROB/COM CONTROL VIOL
		SET FOR 10/01/2001 AT 09:00
53	09/24/2001	COURT NOTICE ISSUED. HEARING DATE 09/28/2001 TYPE R
52	09/21/2001	REPORT RE: PROB/COM CONTROL VIOL
		SET FOR 09/28/2001 AT 09:00
51	09/17/2001	COURT NOTICE ISSUED. HEARING DATE 09/21/2001 TYPE R
50	09/14/2001	TRIAL PROS. ASSIGNED: RAMSINGH, RON
49	09/14/2001	REPORT RE: PROB/COM CONTROL VIOL
		SET FOR 09/21/2001 AT 09:00
48	09/13/2001	PSYCHOLOGICAL EVALUATION
		SONIA RUIZ,PSY
47	09/03/2001	COURT NOTICE ISSUED. HEARING DATE 09/14/2001 TYPE R
46	09/03/2001	COURT NOTICE ISSUED. HEARING DATE 09/13/2001 TYPE R
45	08/31/2001	REPORT RE: PROB/COM CONTROL VIOL
		SET FOR 09/14/2001 AT 09:00

* * * CONTINUED ON NEXT PAGE * * *

44	08/31/2001	REPORT RE: EVALUATION
		SET FOR 09/13/2001 AT 09:00
43	08/31/2001	TRIAL PROS. ASSIGNED: ASA, DIVISION
42	08/31/2001	ORDER APPOINTING EXPERT TO DETERMINE COMPETENCY
		DR.SONIA RUIZ
41	08/30/2001	PROBATION WARRANT ISSUED: 08/30/2001 SERVED 08/30/2001
40	08/30/2001	BOOKING DATE
39	08/30/2001	ARREST DATE
38	08/30/2001	LETTER FROM:-
		MARIO MURILLO
37	08/30/2001	VIOLATION OF PROBATION AFFIDAVIT FILED
36	04/19/2001	COURT FEE PAYMENT 67.21 RECEIPT # 0335627
35	02/09/2001	COURT FEE PAYMENT 284.31 RECEIPT # 0338336
34	02/05/2001	NOTICE OF FAILURE TO PAY SENT
32	01/08/2001	FINDING OF GUILT/ORDER W/H ADJUDICATION & SPECIAL CONDITIONS
		COSTS, PROBATION
		BOOK 19448 PAGE 2283
31	01/08/2001	BK 19448 PG 2283-84
30	01/08/2001	DEFENSE ATTY PDEF/PUBLIC DEFENDER APPOINTMENT, AS
29	01/04/2001	DISCHARGE CERTIFICATE ISSUED
		S10197781
33	01/03/2001	FINGERPRINTS FILED
		BOOK 19448 PAGE 2285
28	01/03/2001	SENTENCING GUIDELINES SCORE SHEET
27	01/03/2001	ORDER OF PROBATION
26	01/03/2001	TRIAL PROS. ASSIGNED: SERCUS, JULIE
25	01/03/2001	MEMORANDUM OF COSTS
		AMOUNT 468.00
24	01/03/2001	PUBLIC DEFENDER APPLICATION FEE/AFFIDAVIT
		TO BE PAID IN FULL
		AMOUNT 40.00
23	01/03/2001	DESCRIPTION ASSESSED PAID BALANCE
		CRT FACILTY 150.00 150.00 0.00
		CRIME STOPPE 20.00 20.00 0.00
		LOC CRIM JUS 200.00 200.00 0.00
		CRM COMP TR 50.00 50.00 0.00
		STATE LETTF 3.00 3.00 0.00
		COUNTY LETTF 2.00 2.00 0.00
		JUV ASSESSM 3.00 3.00 0.00
		INSOLV APPL 40.00 40.00 0.00
		TOTAL: 468.00 468.00 0.00
		LAST ASSESSED: 01/03/2001 LAST PAYMENT: 10/24/2001
22	01/03/2001	CLOSING JUDGE PINEIRO, ROBERTO M
21	01/03/2001	02910 MOORE, JAMES SNC AMT/ 10000
		DISCHARGED 01/03/2001
		POWER/S10197781
20	12/21/2000	COURT NOTICE ISSUED. HEARING DATE 01/03/2001 TYPE R
19	12/21/2000	COURT NOTICE ISSUED. HEARING DATE 01/03/2001 TYPE A
18	12/20/2000	TRIAL PROS. ASSIGNED: ASA, DIVISION
17	12/20/2000	REPORT RE: TRIAL DATE
		SET FOR 01/03/2001 AT 09:00
16	12/20/2000	ARRAIGNMENT HEARING SCHEDULED FOR 01/03/2001 AT 09:00
14	12/08/2000	COURT NOTICE ISSUED. HEARING DATE 12/20/2000 TYPE A
15	12/07/2000	DISCOVERY RESP: STATE'S DEMAND FOR DISCOVERY & DEMAND FOR AL
13	12/07/2000	TRIAL PROS. ASSIGNED: ASA, DIVISION
12	12/07/2000	ARRAIGNMENT HEARING SCHEDULED FOR 12/20/2000 AT 09:00

* * * CONTINUED ON NEXT PAGE * * *

11	12/04/2000	INFORMATION FILED
10	11/28/2000	COURT NOTICE ISSUED. HEARING DATE 12/07/2000 TYPE A
7	11/27/2000	ARRAIGNMENT HEARING SCHEDULED FOR 12/07/2000 AT 09:00
9	11/22/2000	
8	11/22/2000	COURT NOTICE ISSUED. HEARING DATE 12/04/2000 TYPE A
6	11/08/2000	
5	11/08/2000	INTAKE PROS. ASSIGNED: STROZIER, MICHAEL
4	11/06/2000	BOND RECEIVED
		POWER/RECEIPT #S10197781
3	11/06/2000	COURT NOTICE ISSUED. HEARING DATE 11/21/2000 TYPE A
2	11/04/2000	02910 MOORE, JAMES SNC AMT/ 10000
		ISSUED 11/04/2000
		POWER/S10197781
1	11/04/2000	ARRAIGNMENT HEARING SCHEDULED FOR 11/21/2000 AT 09:00

* * * END OF REPORT * * *

STATE OF FLORIDA COUNTY OF DADE

DEC 31 2007

746

Cin#679481

COMPLAINT/ARREST AFFIDAVIT

11/29/00

DR/I# Number: 13.01.033995 — ☒ Felony ☐ Misdemeanor ☐ Traffic ☐ Juvenile ☐ Warrant

Jail No: 00-96739

Police Case No:

IDB No:

Agency Code: 60

Municipal P.D. Det. ID No:

MDPD Records and ID No: 679481

Court Case No:

DEFENDANT'S NAME: Last: Murillo First: Camilo Middle:

DOB: [redacted]

Sex: M Race: W Ethnic: Height: 509 Weight: 190 Hair: BAO Eyes: BAO

LOCAL ADDRESS: [redacted] SW 23 Terr — Street City State Zip — Phone — Alias: NONE

PERMANENT ADDRESS: Street City State Zip — Phone — Address Source: ☒ Verbal ☐ Voter's I.D. ☐ Driver's License ☐ Other

BUSINESS ADDRESS: Street City State Zip — Phone — Occupation — Place of Birth

DRIVER'S LICENSE NO: State — Social Security No: — Scars, Tattoos, Unique Physical Features: N.V

Weapon Seized? Type ☐ Yes ☐ No — Arrest Date mo/day/yr: 12/20/2000 — Arrest Time: 0900 ☒ A.M. ☐ P.M. — Arrest Location (include name of business): B.G.B 6-4 — GRID

If Def. has Concealed Weapons Permit, PERMIT # W- — For Robbery, Burglary, F/A Viol: Suspected History of drug involvement? ☐ Yes ☒ No — No. Cases Cleared — Influence of Drugs ☐ Yes ☐ No ☐ Unk. — Influence of Alcohol ☐ Yes ☐ No ☐ Unk. — Citizen — Native Type ☐ City ☐ State ☐ Florida ☐ Out of State

CO-DEFENDANTS: 1. Last First Middle — DOB mo/day/yr — ☐ In Custody ☐ Felony ☐ Juvenile ☐ At Large ☐ Misdemeanor

2. Last First Middle — DOB mo/day/yr — ☐ In Custody ☐ Felony ☐ Juvenile ☐ At Large ☐ Misdemeanor

CODE — DRUG ACTIVITY: S. Sell N. Nar. B. Buy P. Poss. R. Smuggle D. Deliver T. Traffic E. Use K. Dispense/Dist. F. Other M. Manufacture/Produce/Cultivate — DRUG TYPE: B. Barbiturate C. Cocaine H. Hallucinogen M. Marijuana O. Opium/Deriv. P. Paraphernalia/Equipment S. Synthetic U. Unknown Z. Other

SIGNAL: ☐ 100 ☐ 150 ☐ 200 ☐ 250 ☐ 300 ☐ 400

	CHARGES	Arrest	Type	Counts	STATUTE	DV	GANG	PCA	FAS	DW	PW	WCIT	VIOLATION OF SECT.
1	CAIN/SELL/DEL/BRGLY			1									F000354444 ✓
2													
3													OF THE 2000 OF
4													

The undersigned certifies and swears that he has just and reasonable grounds to believe, and does believe that the above named Defendant

On the WED day of DEC. 20 2000 9:00 ☒ A.M. ☐ P.M. (Time) B.G.B 6-4 (Location, include name of business)

committed the following violation of law: Narrative, (Be specific)

Δ Taken into Custody - NO Bond - 1/4

Con 4/NCB

PEB B. PINERO 1

PAGE ____ OF ____

Hold for Other Agency: Agency ____ Verified by ____

I Swear that this above Statement is correct and true to the best of my knowledge and belief

Officer's Name (Print): Angela Jones

Officer's Signature: Angela Jones 12.20.00

PR 0143 60

Complainant's Name — Court ID Number/Loc. Code

Rev. 1/97

☐ HOLD FOR BOND HEARING. DO NOT BOND OUT (Officer Must Appear at Bond Hearing)

Sworn to and subscribed before me the undersigned authority, this ____ day of ____

Deputy of the Court or Notary Public

☐ I understand that should I willfully fail to appear before the court as required by this notice to appear that I may be held in contempt of court and a warrant for my arrest shall be issued. Furthermore, I agree that notice concerning the time, date, and place of all court hearings should be sent to the above address. I agree that it is my responsibility to notify Clerk of the Court (Juveniles notify Family Division Juvenile Section) anytime that my address changes.

☐ You need not appear in court, but must comply with the instructions on the reverse side hereof.

Signature of Defendant / Juvenile and Parents or Guardian

MDPD RECORDS COPY

MIAMI DADE P.D. RECORDS BUREAU DADE COUNTY, FL

THIS IS A TRUE COPY OF AN ORIGINAL DOCUMENT ON FILE WITH THE MIAMI-DADE POLICE DEPARTMENT MIAMI, FLORIDA 33172

SIGNATURE — 1/10/20 DATE

Transport Officer (s) _____/_____ ID# _____-_____ Dept# _____ Taken To _____

Transport Officer (s) _____/_____ ID# _____-_____ Dept# _____ Taken To _____

Transport Officer (s) _____/_____ ID# _____-_____ Dept# _____ Taken To _____

Does defendant have any signs/complaints of injury? ☐ Yes ☐ No Indicate any signs or complaints of injury regardless whether they happened prior to, during, or after arrest, or whether they have any connection to the arrest at all.
(If Yes, complete below data/notify supervisor.)

Explain: _____

_____

_____

_____ Name and Rank of Supervisor Notified: _____

Defendants Vehicle

YEAR	MAKE	MODEL	TAG	STATE	VIN	COLOR

OWNER/DRIVER/DESIGNEE RELEASE FORM & DISCLAIMER OF LIABILITY

Owner/Driver/Designee (O/D/D) must read and sign disclaimer of liability if vehicle is left at scene, or removed, or released to O/D/D at scene.

Released to: _____/_____ Left on Scene? ☐ YES ☐ NO

(Print Name - Signature) D/L # State

The undersigned certifies that he/she is the legal owner/driver/designee of the vehicle described above. In consideration of being permitted to leave the vehicle mentioned at the location mentioned, or removed, or released, the undersigned hereby releases and discharges Miami-Dade County and all of its agents and employees for any damage to, or damage caused, theft of, or theft from, the vehicle described above.

_____ _____

Signature of Owner/Driver/Designee Signature of Officer Witnessing ID #

IF YOUR VEHICLE IS PARKED MORE THAN 48 HOURS, IT IS SUBJECT TO BE REMOVED.

MIAMI DADE COUNTY, FL RECORDS BUREAU

MIAMI-DADE COUNTY
CORRECTIONS AND REHABILITATION DEPARTMENT
JAIL BOOKING RECORD

CTN 6794X1

00 96739

PHOTO



INT

[redacted]

JAIL NUMBER	DEFENDANT NAME	RACE	SEX	DATE OF BIRTH
0000**96739**	MONTILLA, CAMILO ANDRES	W	M	[redacted]

ADDRESS		HEIGHT	WEIGHT	HAIR	EYES	SOCIAL SECURITY NUMBER
[redacted] SW 22[illegible] TERR		5-09	190	BLK	BRO	

CITY AND STATE	RESIDENCE	FOR	TO	BOOKED DATE	CELL LOCATION
MIAMI FL	CITY	01285	0823	12/29/00	7B1

COURT CASE NUMBER	PRINT	ARREST LOCATION
F00-038091	Y	2700 SW 24 AVE 06197431067948

DATE	SEQ	INPUT NUMBER	CHARGE DESCRIPTION / PENALTIES	NO	CASE / WARR. NUMBER	BOND AMOUNT
12/29/00	1	0063300110	CRIMINAL MISCHIEF/$1,000 OR MORE		F00-038091	5000
			OUT ON FELONY BOND		F00 35444	
			Chg#2 added per Jones #0143. C4R/05 #4137			
12/20/00			Cannabis Sell/DEL/Posn W/Int	TC	F0035444	
		Chg#3	added per Jones #0143. C4R/05 #4137			

DISPOSITIONS

11/29 chg 1) F00-38091 Arr 12/20 Pinero
Reset P/C Hearing 11/30/00 PM Cal — Klein/0104
11/30 chg 1) F00-38091 - Reset PM cal 11/30 Klein/0814
11/30 chg 1) F00-38091 BND $5,000. — Klein/0104
DEC 07 2000 00-38091 Cont 12/20 - NO Bond - Pinero 4/0143
DEC 08 2000 00-38091 CONT. 12/20/00 — Pinero Em 3046
DEC 20 2000 00-38091, 00-35444 Cont 1/4/01 — Pinero 4/0143
JAN 03 2001 00-38091, [redacted] Bind down to misd. Criminal → MOL 297

COMMENTS

11/30 F00-35444 - 1 H/O for chg Pinero on 12/1/00 AM cal

AKA'S

Chg #1

RELEASED CJS

MOTHER'S MAIDEN NAME

FATHER'S NAME

RELEASE INFO

BOND AMOUNT 500-

BONDSMAN NAME STATE

BONDING COMPANY SNEC

PASS NUMBER

RELEASED BY

DATE OF RELEASE JAN 03 2001

TIME OF RELEASE 1255

POWER NUMBER 55-235825

MIAMI DADE P.C. RECORDS BUREAU DADE COUNTY, FL

THIS IS A REDACTED COPY OF AN ORIGINAL DOCUMENT ON FILE WITH THE MIAMI DADE POLICE DEPARTMENT MIAMI, FLORIDA 33172

SIGNATURE

1/10/20
DATE

I HEREBY AUTHORIZE THE SHERIFF, HIS JAILER, OR DEPUTIES TO OPEN AND INSPECT ALL MAIL MATTER OR PACKAGES WHICH MAY BE ADDRESSED TO ME AS LONG AS I AM A PRISONER IN HIS CUSTODY.

11/28/00
DATE

X Camilo Murillo
PRISONER'S SIGNATURE

DATE	NO	CHARGES	CPC	FSS/CASE/WARR	BOND

DATE	DISPOSITIONS
	mischief. Bond set at $500 — Pinero #0113 00-35444 Pled Guilty w/A Adj. Sent to ONE Probation. — Pena Pinero #0113

MIAMI DADE P.D.
RECORDS
BUREAU
DADE COUNTY, FL

COMPLAINT/ARREST AFFIDAVIT

OBTS Number: | ☐ Felony ☐ Misdemeanor ☐ Traffic ☐ Juvenile ☐ Warrant | Jail No: 72475 | Police Case No: 485824-Z

DTS No. | Agency Code: 30 | Municipal P.D. Det. ID No. | Municipal Prosecutor ID No: 699481 | Court Case No.

DEFENDANT'S NAME: Last: MURILLO | First: CAMILO | Middle: ANDRES | DOB mo/day/yr: [redacted] | Sex: M | Race: W | Ethnic | Height: 5'10" | Weight: 200 | Hair: BR | Eyes: BR

LOCAL ADDRESS: [redacted] SW 23 Ter | Street | City: MIAMI | State: FL | Zip: 33145 | [redacted] | Alias

PERMANENT ADDRESS: S/A LOCAL | Street | City | State | Zip | Phone | Address Source: ☒ Verbal ☐ Voter's I.D. ☐ Driver's License ☐ Other

BUSINESS ADDRESS: PHILLIES 1601 NW 72 AVE | Street | City: MIAMI | State: FL | Zip: 33126 | Phone: (305) 592-2552 | Occupation: PAINTER, CONST. AGENT | Place of Birth: FL

DRIVER'S LICENSE NO. | State | Social Security No. [redacted] | Scars, Tattoos, Unique Physical Features: TATTOO L-ARM R-LEG

Weapon Seized? Type ☐ Yes ☐ No | Arrest Date mo/day/yr: 08/30/01 | Arrest Time: 3:00 ☐ A.M. ☐ P.M. | Arrest Location (include name of business): 3436 SW 23 Ter (Pal 1455)

If Def. has Concealed Weapons Permit, PERMIT # W-N/A | For Robbery, Burglary, F/A Viol: Suspected history of drug involvement? ☐ Yes ☐ No | No. Cases Cleared: 1 | Influence of Drugs ☐ Yes ☐ No ☐ Unk. | Influence of Alcoh. ☐ Yes ☐ No ☐ Unk. | Citizenship: US | Resid. ☐ City ☐ Florida ☐ Out of State | Date

CO-DEFENDANTS: 1. Last | First: N | Middle | DOB mo/day/yr: __/__/__ | ☐ In Custody ☐ Felony ☐ Misd. ☐ At Large

2. Last | First: A | Middle | DOB mo/day/yr: __/__/__ | ☐ In Custody ☐ Felony ☐ Misd. ☐ At Large

CODE — DRUG ACTIVITY: N. N/A, P. Possess, S. Sell, B. Buy, T. Traffic, R. Smuggle, D. Deliver, E. Use, K. Dispense/Distribute, Z. Other, M. Manufacture/Produce/Cultivate | DRUG TYPE: N. N/A, A. Amphetamine, B. Barbiturate, C. Cocaine, E. Heroin, H. Hallucinogen, M. Marijuana, O. Opium/Deriv., S. Synthetic, P. Paraphernalia: Equipment, U. Unknown, Z. Other

CHARGES	Activity	Type	Counts	STATUTE	O.V.	A.C.	CAPIAS	I.W.	W.W.	PHOTO	VIOLATION OF SPEA
1. CAN./SALE/POSS	N	N	1							PW/F-00-35444	21-81
2. V.O.P.	N	N	1								
3.											
4.											OF THE CODE OF MIAMI DADE

The undersigned certifies and swears that he has/had reasonable grounds to believe, and does believe that the above named Defendant on the 30 day of AUGUST 2001 2:00 ☒ A.M. ☐ P.M. (Time) 3436 SW 23 Ter. (Location, Include name of business)

committed the following violation of law. Narrative. (Be specific)

ISSUED 8/30/01

DC # 01-5861 NO BOND

PAGE 1 OF 1

Held for Other Agency | Agency | Verified by

I Swear (or affirm) the above Statement is correct and true to the best of my knowledge and belief.

YOUNG

Officer's Name (Print)

Officer's Signature

MIAMI DADE P.D. RECORDS BUREAU DADE COUNTY, FL

Badge/ID Number/Loc. Code: H020 68

Agency Name

☐ HOLD FOR BOND HEARING. DO NOT BOND OUT (Officer Must Appear at Bond Hearing)

Sworn to and subscribed before me, the undersigned authority, this 30 day of AUGUST 2001

Deputy of the Clerk or Notary Public

MDPD RECORDS COPY

☐ I understand that should I willfully fail to appear before the court as required by this notice to appear that I may be held in contempt of court and a warrant for my arrest shall be issued. Furthermore, I agree that notice concerning the time, date and place of all court hearings should be sent to the above address. I agree that it is my responsibility to notify Clerk of the Court (Juveniles notify Family Division Juvenile Section) of any change of my address.

☐ You need not appear in court, but must comply with the instructions on the reverse side hereof.

Signature of Defendant / Juvenile and Parent or Guardian

THIS IS A REDACTED COPY OF AN ORIGINAL DOCUMENT ON FILE WITH THE MIAMI-DADE POLICE DEPARTMENT MIAMI, FLORIDA 33172

SIGNATURE 1/10/20 DATE

Transport Officer (s) Young / _____ ID# 7000 - _____ Dept# 30 Taken To DCJ.

Transport Officer (s) _____ / _____ ID# _____ - _____ Dept# _____ Taken To _____

Transport Officer (s) _____ / _____ ID# _____ - _____ Dept# _____ Taken To _____

Does defendant have any signs/complaints of injury? ☐ Yes ☒ No Indicate any signs or complaints of injury regardless whether they happened prior to, during, or after arrest, or whether they have any connection to the arrest at all.
(If Yes, complete below data/notify supervisor.)

Explain: _____

_____

_____

_____ _____ Name and Rank of Supervisor Notified: _____

JUVENILES ONLY: MDPD JUVENILE ID NUMBER: J-

Defendants Vehicle

YEAR	MAKE	MODEL	TAG	STATE	VIN	COLOR
			N/A			

OWNER/DRIVER/DESIGNEE RELEASE FORM & DISCLAIMER OF LIABILITY

Owner/Driver/Designee (O/D/D) must read and sign disclaimer of liability if vehicle is left at scene, or removed, or released to O/D/D at scene.

Released to: _____ / _____ Left on Scene? ☐ YES ☐ NO
(Print Name - Signature) D/L # State

The undersigned certifies that he/she is the legal owner/driver/designee of the vehicle described above. In consideration of being permitted to leave the vehicle mentioned at the location mentioned, or removed, or released, the undersigned hereby releases and discharges Metropolitan Dade County and all of its agents and employees for any damage to, or damage caused, theft of, or theft from, the vehicle described above.

_____ _____
Signature of Owner/Driver/Designee Signature of Officer Witnessing

IF YOUR VEHICLE IS PARKED MORE THAN 48 HOURS, IT IS SUBJECT TO BE REMOVED.

MIAMI-DADE P.D. RECORDS BUREAU DADE COUNTY, FL

204

MIAMI-DADE COUNTY
CORRECTIONS AND REHABILITATION DEPARTMENT
JAIL BOOKING RECORD

679481

01 72423



RIGHT THUMB PRINT



JAIL NUMBER	DEFENDANT NAME	RACE	SEX	DATE OF BIRTH
010072473	MURILLO, CAMILO ANDRES	W	M	[redacted]

ADDRESS	HEIGHT	WEIGHT	HAIR	EYES	SOCIAL SECURITY NUMBER
[redacted] SW 23 TERR	510	200	BLK	BRO	[redacted]

CITY AND STATE	RESIDENCE	TOT	TU	BOOKED DATE	CELL LOCATION
MIAMI FL	DADE	15:00	1540	08/30/01	PT2CA

COURT CASE NUMBER	PRINT	ARREST LOCATION
	Y	3436 SW 22 TERR #0619743

DATE	SEQ.	INPUT NUMBER	CHARGE DESCRIPTION/PENALTIES	NO.	CASE/WARR NUMBER	BOND AMOUNT
08/30/01	1		VOP/CANN SALE POSS	FW	F00-035444	NO BOND

DISPOSITIONS

8/31/01 F00-35444 - Ct. 9/13 Rpt. Pineiro 1400 1584
9/13/01 00-35444 - cont 9/14/01 rpt-Pineiro — BS
9/14/01 00-35444 - cont 9/21/01 rpt-Pineiro — NBND
9/21/01 00-35444 - cont 9/28/01 rpt-Pineiro AH4496
9/28/01 00-35444 - cont 10/1/01 rpt-Pineiro
10/1/01 00-35444 - probation reinstated-Pineiro — VB404

COMMENTS

RELEASED
CJS

AKA'S

PROB REINSTATED

MOTHERS MAIDEN NAME		BOND AMOUNT	BONDSMAN NAME	BONDSMAN #
FATHERS NAME	RELEASE	BONDING COMPANY		PASS NUMBER
		RELEASED BY: CR	DATE OF RELEASE: OCT 01 2001	TIME OF RELEASE: 1120

MIAMI DADE PD RECORDS BUREAU DADE COUNTY, FL

THIS IS A REDACTED COPY OF AN ORIGINAL DOCUMENT ON FILE WITH THE MIAMI-DADE POLICE DEPARTMENT MIAMI, FLORIDA 33172

SIGNATURE 11/10/20 DATE

I HEREBY AUTHORIZE THE SHERIFF, HIS JAILER, OR DEPUTIES TO OPEN AND INSPECT ALL MAIL MATTER OR PACKAGES WHICH MAY BE ADDRESSED TO ME AS LONG AS I AM A PRISONER IN HIS CUSTODY.

DATE

Carlos Miller

PRISONER'S – SIGNATURE

DATE	NO	CHARGES	CPC	FSS/CASE/WARR	BOND

DATE	DISPOSITIONS

MIAMI DADE P.D.
RECORDS BUREAU
DADE COUNTY, FL

IN THE COUNTY COURT OF THE ELEVENTH JUDICIAL CIRCUIT IN AND FOR MIAMI-DADE COUNTY, FLORIDA www.miami-dadeclerk.com

TRAFFIC DIVISION

CLERK'S CERTIFICATE

THE STATE OF FLORIDA VS.

CAMILO A MURILLO

Defendant

DL Number M640101821660 State FL Date of Birth 05/06/1982 Case Number 394654W

ISSUE DATE: 07/21/2000 (●) No Accident ( ) Accident STATUTE #: 316.193

(●) COURT DESCRIPTION :

Disposition Date: 07/27/2000

PLEA:
- ( ) Guilty
- ( ) NOT Guilty
- (●) Nolo Contedere

FINDING:
- (●) Guilty
- ( ) NOT Guilty

ADJUDICATION:
- ( ) NOT Guilty
- ( ) Dismissed
- ( ) Nolle Prosse
- (●) Adjudication of Guilt
- ( ) Adjudication Withheld

( ) STATUTORY DISPOSITION:

Disposition Date:
- ( ) Admitted Infraction by Payment of Civil Penalty pursuant to F.S. 318.14 (4)
- ( ) Did not contest the infraction and elected a statutory Driver Improvement Course; Adjudication was withheld pursuant to FS318.14 (9)
- ( ) Adjudication was withheld pursuant to FS318.14 (10) (a)
- ( ) Dismissed by Clerk pursuant to statutory compliance

(●) COURT REQUIREMENTS: (●) Completed by Defendant ( ) Not Completed by Defendant

(●) SENTENCE:

(●) Probation:	6 months	( ) High Risk Traffic School	
(●) Fine/Cost:	$664.75	(●) DUI Program	
( ) Jail Time:		( ) TASC Program	
( ) Hours Traffic School:		( ) Alcoholic Anonymous	
( ) DL Suspended/Revoked:		(●) Victim Impact Panel	
(●) Community Service Hours:	50 HOURS	( ) Suspend Entry of Sentence	
( ) Court Order Restitution:		( ) Interlock Device	
( ) Other			

( ) After a diligent search of Miami-Dade County records, we are unable to locate:
- ( ) Any information on the above named defendant.
- ( ) The above styled case was not (an) _____ offense.
- ( ) The above styled case has been destroyed in compliance with Florida retention schedules
- ( ) The sentencing information is no longer available.
- ( ) The offense cited in the above styled case has been decriminalized.

This is to certify that the information above is true and correct.

Witness my Hand and Official Seal this 9 day of December , 2019 .

Harvey Ruvin

HARVEY RUVIN
CLERK OF COURTS

By: Deputy Clerk Sandra M Pierre-Louis

12/9/2019
Date

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Vision: To be the Healthiest State in the Nation

January 15, 2020

Camilo Andres Murillo
3436 Sw 23 Ter
Miami, FL 33145

RE: Exemption application for Registered Nurse License No. 9420080

Dear Mr. Murillo:

This letter is to acknowledge receipt of your application for exemption. Enclosed (by mail only) is a copy of your criminal history report. This document is confidential and may not be used for any purpose other than your personal review. If you chose to mail your criminal history report back to the department, your criminal history report may therefor become subject to public disclosure. You are required to provide documentation for each item highlighted in the report:

Our records indicate that we have not received your Livescan results within 90 days of your application. If you have already had your electronic fingerprinting (Livescan) completed, please allow 24-72 hours for receipt of your results. The Department of Health cannot accept hard copy (paper) fingerprint cards.

All applicants for exemption must have electronic fingerprinting completed by a Florida Department of Law Enforcement (FDLE) approved provider. For a list of approved providers and a list of Frequently Asked Questions visit our website at: http://www.flhealthsource.gov/bgs-providers.

You will need to provide the Livescan provider with an ORI (Originating Agency) number. Applicants who use the incorrect ORI number may have their background check results misdirected. Our office will not be able to retrieve misdirected results and this will delay the processing of your application. Your ORI number is: EDOH4420Z. Email a confirmation to mqa.backgroundscreen@flhealth.gov once completed.

Provide arrest reports for all disqualifying offenses. You may obtain these documents by contacting the arresting agency. If documents are not available due to record retention policies, have the arresting agency provide you with a letter, on their letterhead, stating there is no information available.

You must provide all available full court dispositions, regardless of adjudication, to show the outcome of each case. Court documents can be obtained from the Clerk of the Court in the jurisdiction where the offense occurred. If documents are not available due to record retention policies, have the Clerk of Court provide you with a letter, on their letterhead, stating there is no information available.

Provide written documentation that you have completed your sentence requirements, including any probation or confinement. You may obtain a copy of this documentation by contacting the Department of Corrections. The documentation must include the start date of the sentence, end date of the sentence, and show that all conditions were met.

Provide proof of completion of fines, restitution, or other court ordered sanctions for each offense. This documentation can be obtained from the Clerk of Court in the county in which the offense occurred. This must include the date in which the payment/completion of the sanction was satisfied. If the clerk is unable to locate the documents associated with any offense, an official letter from the agency stating the reason is required.

Provide a typed letter detailing the events of all disqualifying offenses listed on your background report. If the offense involved battery or assault, the explanation must include your relationship with the parties involved and their age at the time the offense occurred.

To eliminate further delays, return a copy of this letter along with the required item(s) to:

Florida Department of Health
Attn: Cassie Hurley
4052 Bald Cypress Way, Bin BSU - 01
Tallahassee, FL 32399-3260

If you no longer wish to pursue the application process, please email or fax a written statement indicating your intent to withdraw the application.

If you have any questions, you may contact our office at (850) 488-0595, or e-mail mqa.backgroundscreen@flhealth.gov.

Sincerely,

Cassie Hurley

Cassie Hurley
Government Analyst II
Background Screening and
Practitioner Notification Services

3839

50071492 Sex ###-##
Student ID SSN

09/21/2020

Murillo, Camilo Andres

UNIVERSITY OF MIAMI

MIAMI

CORAL GABLES, FLORIDA 33124

Other Institutions Attended

Broward College Central
225 East Las Olas Boulevard
Ft Lauderdale, FL 33301
Miami Dade College Kendall
11011 South West 104Th Street
Miami, FL 33176
Mattia College
13926 Sw 47Th St
Miami, FL 33175

External Degrees

Broward College Central
BACHELOR OF SCIENCE IN NURSING 06/27/2017
Miami Dade College Kendall
ASSOCIATE OF ARTS 04/30/2016
Mattia College
ASSOCIATE OF SCIENCE 08/28/2015

Beginning of Graduate Record

Spring 2018

Graduate Nursing
Nursing Major
Family Nurse Practitioner Track

Course	Course Title	Attempted	Earned	Grade	Qty Pts
NUR 601	ADV PHARMACOLOGY	3.000	3.000	B	9.000
Instructor:	Martin Zdanowicz				
NUR 612	PHYSIOL/PATHOPHYSI	3.000	3.000	B	9.000
Instructor:	Johis Ortega Sandra Giraldo-Perez				

			Earned Credits	Graded Credits	Qty Pts
UM Semester GPA	3.000	UM Semester Totals	6.000	6.000	18.000
UM Cum GPA	3.000	UM Cumulative Totals	6.000	6.000	18.000

Summer 2018

Graduate Nursing
Nursing Major
Family Nurse Practitioner Track

Course	Course Title	Attempted	Earned	Grade	Qty Pts
NUR 609	PROF ADV PRAC NURN	2.000	2.000	A+	8.000
Instructor:	Martha Maldonado				
NUR 613	HLTH ASSM DIAG REA	3.000	3.000	B+	9.900
Instructor:	Patricia Briones				
NUR 630	RES EVD-BAS PRACT	3.000	3.000	A	12.000
Instructor:	Brian McCabe				

			Earned Credits	Graded Credits	Qty Pts
UM Semester GPA	3.738	UM Semester Totals	8.000	8.000	29.900
UM Cum GPA	3.421	UM Cumulative Totals	14.000	14.000	47.900

Fall 2018

Graduate Nursing
Nursing Major
Family Nurse Practitioner Track

Course	Course Title	Attempted	Earned	Grade	Qty Pts
NUR 608	CNCPT ADV PRAC NUR	3.000	3.000	A	12.000
Instructor:	Brenda Owusu				
NUR 628	ADULT GERON I	5.000	5.000	B	15.000
Instructor:	Juan Gonzalez				

			Earned Credits	Graded Credits	Qty Pts
UM Semester GPA	3.375	UM Semester Totals	8.000	8.000	27.000
UM Cum GPA	3.405	UM Cumulative Totals	22.000	22.000	74.900

Spring 2019

Graduate Nursing
Nursing Major
Family Nurse Practitioner Track

Course	Course Title	Attempted	Earned	Grade	Qty Pts
NUR 623	MATERNAL CHILD HLTH	5.000	5.000	B+	16.500
Instructor:	Kenya Snowden Giselle Garcia Rivero				
NUR 631	ADULT GERON II	4.000	4.000	A	16.000
Instructor:	Patricia Briones				

			Earned Credits	Graded Credits	Qty Pts
UM Semester GPA	3.611	UM Semester Totals	9.000	9.000	32.500
UM Cum GPA	3.465	UM Cumulative Totals	31.000	31.000	107.400

Summer 2019

Graduate Nursing
Nursing Major
Family Nurse Practitioner Track

Course	Course Title	Attempted	Earned	Grade	Qty Pts
NUR 647	AD PRAC NUR INTEGR	6.000	6.000	B-	16.200
Instructor:	Juan Gonzalez				

			Earned Credits	Graded Credits	Qty Pts
UM Semester GPA	2.700	UM Semester Totals	6.000	6.000	16.200

STUDENT COPY - NOT OFFICIAL

3840

50071492 Sex ###-##
Student ID SSN

Murillo, Camilo Andres

UNIVERSITY OF MIAMI

MIAMI

CORAL GABLES, FLORIDA 33124

09/21/2020

UM Cum GPA	3.341	UM Cumulative Totals	37.000	37.000	123.600

READMITTED - SUMMER 2020

Summer 2020

Graduate Nursing
Nursing Major
Family Nurse Practitioner Track

Course	Course Title	Attempted	Earned	Grade	Qty Pts
NUR 647	AD PRAC NUR INTEGR	6.000	6.000	B+	19.800
Instructor:	Juan Gonzalez				

			Earned Credits	Graded Credits	Qty Pts
UM Semester GPA	3.300	UM Semester Totals	6.000	6.000	19.800
UM Cum GPA	3.335	UM Cumulative Totals	43.000	43.000	143.400

Degrees Awarded

Degree: MASTER OF SCIENCE IN NURSING
Confer Date: 08/07/2020
Nursing Major

End of Undergraduate & Graduate

STUDENT COPY - NOT OFFICIAL

MURILLO, CAMILO
3436 SW 23RD TER
MIAMI, FL 33145-3023

1 : 3
504/525

10000070 2/001043-1/1 n

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
MM6437431	01-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	MLP-NURSE PRACTITIONER	04-20-2021

MURILLO, CAMILO
3436 SW 23RD TER
MIAMI, FL 33145-3023

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D C 20537

Registered activity within schedule is restricted by your state.

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
MM6437431	01-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	MLP-NURSE PRACTITIONER	04-20-2021

MURILLO, CAMILO
3436 SW 23RD TER
MIAMI, FL 33145-3023

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Form DEA-223 (9/2016)

Nevada State Board of NURSING
Primary Source License Verification

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

CAMILO ANDRES MURILLO

Tuesday, June 06 2023 10:02:16 AM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active *– ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing *– ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII *– ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to protocol with a collaborative physician.*

Active Prescribing-CII-COLL *– ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provide his/her current protocol with a collaborative physician.*

Active Prescribing -D *– ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-

Active Prescribing – CII –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, an provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing ve they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MURILLO, CAMILO ANDRES	RN	860881	Inactive	10/21/2022	01/10/2023	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MURILLO, CAMILO ANDRES	APRN-CNP	860881	Inactive	12/13/2022	01/12/2023	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 01/12/2023
  - Original Issuance Date: 12/13/2022
  - Current Issue Date: 12/13/2022
  - Certification expiration date: 12/25/2025

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MURILLO, CAMILO ANDRES	RN	860881	Active	01/10/2023	05/06/2024	NO

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MURILLO, CAMILO ANDRES	APRN-CNP	860881	Active Prescribing - CII	01/12/2023	05/06/2024	NO

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 05/06/2024
  - Original Issuance Date: 01/12/2023
  - Current Issue Date: 01/12/2023
  - Certification expiration date: 12/25/2025

License type information

- **RN:** Registered Nurse
- **PN:** Practical Nurse (aka Licensed Practical Nurse (LPN), Vocational Nurse (VN), Licensed Vocational Nurse (LVN))
- **CNP:** Certified Nurse Practitioner
- **CNS:** Clinical Nurse Specialist
- **CNM:** Certified Nurse Midwife
- **CRNA:** Certified Registered Nurse Anesthetist

18

Renewal Application
Controlled Substance

Application Fee : $200.00
Convenience Fee : $10.00
License Number : CS27126
License Type : Controlled Substance
New Expiration Date : 10/31/2024

Personal Information

First Name : RAYMOND

Middle (initial only) : BRADBURY

Last Name : GRABER

License # : CS27126

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA : Desert Valley Dental

Military Address :

Street : 3665 Lakeside Dr

Country : United States

City : RENO

State : Nevada

Zip : 89509

Practice Phone : (775) 329-5437

Practice Fax : (775) 815-1553

Email Address : [redacted]

Sex : Male

Practice License Number:

Specialty:

Child Support Information – Check appropriate answer

- I am **NOT SUBJECT** to a court order for the support of a child.
- I am **SUBJECT** to a court order for the support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.
- I am **SUBJECT** to a court order for the support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount pursuant to the order.

Military Service Information

Have you ever served on active duty in the Armed Forces of the United States and separated from such service under condition other than dishonorable — Yes / No

Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable — Yes / No

Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the National Oceanic and Atmospheric Administration of the United States in the capacity of the commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? — Yes / No

DEA Registration

Document Name	Document Type	Date	Link	Action
DEA Registration	NV DEA Certificate	02/15/2023	Document Details	

Document Name :

Document Type : NV DEA Certificate

Document :

Drop file here to upload or click here to browse and select file(s) to upload.

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Acknowledgement and Declaration

By signing and submitting this renewal application, I certify that: 1. My DEA certificate is ACTIVE and reflects my current NV practicing address, 2. I hold an active Nevada license with my professional licensing board, and 3. I have an active Nevada Prescription Monitoring Program (PMP) account.

It is a violation of Nevada Statute to falsify this application and sanctions will be imposed for misrepresentation. I hereby certify that I have read this application. I certify that all statements made are true and correct.

Signature : Raymond Graber

Date Of Application : 02/15/2023

Please type only the First and Last Name that are listed at the top of the page.

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2022 to 10/31/2024	License Renewal Fee	$200.00
	Convenience Fee	$10.00
	Late Fee	$100.00
	Total :	**$310.00**

Fee and Payment

Payment Method : Credit / Debit Card

Application Fees : 200

Reinstatement Fee : 0

Transaction Fee : 10

Late Fees : 100

Reference Number : 64206415869

InvoiceDate : 02/15/2023

Paid

Pay & Submit

Legal Information

1. Since your last renewal or recent licensure have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license? ● Yes No

After my arrest on August 27, 2022 described in my answer to question #2, I voluntarily entered into a ASAM Level I outpatient treatment with Eddie Miller, LCDAC on September 16, 2022. Since that time I have been attending regular individual counseling sessions in addition to attendance at AA meetings. In addition to counseling, Ms. Miller also requires me to submit to random drug/alcohol screens. I have attached a current status report from Ms. Miller. At the time of my arrest, I voluntarily ceased practicing dentistry until my counselor and I determined that I was in the right place to resume practice. I have recently began practicing again with the agreement of Ms. Miller and I remain actively engaged in my recovery and am complying with all requirements requested of me. I have not prescribed any controlled substances during the time of my CS license being non-renewed.

Document Name	Document Type	Date	Link	Action
Dr Graber progress	Legal - Question 1	02/15/2023	Document Details	

Document Name :

Document Type : Legal - Question 1

Document :

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2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state? ● Yes No

On November 4, 2022, I was charged with one count of misdemeanor Possession of a Drug Not to Be Introduced into Interstate Commerce in violation of NRS 454.351 in Carson City Justice Court. The charge related to an arrest on August 27, 2022. (Please note, I was initially charged with felony Possession of a Schedule I or II Controlled Substance which the prosecutor moved to dismiss on November 3, 2022 and which was dismissed by the Court on November 7, 2022).
On January 11, 2023, I entered a plea of guilty to the misdemeanor charge. No conviction has been entered and sentencing has been deferred until January 2024. If I comply with all terms of the Court during that time which include a substance abuse evaluation, 9 to 12 months of substance abuse counsel; prohibition of possession or consumption of alcohol, illegal drugs, narcotics medications (unless prescribed and approved), then the charges will be dismissed and no conviction will be entered.

Document Name	Document Type	Date	Link	Action
Misdo Criminial Complaint_Graber	Legal - Question 2	02/15/2023	Document Details	
ORDER SETTING HEARINGS, AND CONDITIONS	Legal - Question 2	02/15/2023	Document Details	

Document Name :

Document Type : Legal - Question 2

Document :

Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

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Criminal Action :

State : Nevada

Date : 01/11/2023

Case # : 22CR012061CRF

County : Carson City

Court : Carson City Justice Court

Miller Counseling
104 W Telegraph St.
Carson City, NV 89703
(775)434-7200
emillercounseling@att.net

January 28, 2023

Progress Letter
RE: Dr. Raymond Graber
Birth Date: [redacted]

To Whom it May Concern,

This letter is being sent to confirm that Dr. Raymond Graber voluntarily participated in a substance abuse evaluation and enrolled in substance abuse counseling with Miller Counseling on September 16, 2022. Dr. Graber has been attending ASAM Level 1 Outpatient counseling for the last five months and has attended a total of 18 sessions. Dr. Graber has an extremely positive attitude in sessions, he attends AA meetings, is reading Rational Recovery and exploring new paths to recovery. He appears to be taking his sobriety seriously. Dr. Graber has submitted to eleven random Urine Drug Screens with Miller Counseling and has tested negative on all occasions.

Dr. Graber's prognosis is good at the present time due to his ability to accept accountability for his situation, his willingness to participate in treatment and his desire to make positive changes in his life. Dr. Graber reports his number one goal is long-term sobriety and he is willing to do whatever is in the best of his patients and his career.

If you have any questions, please feel free to contact this agency at (775)434-7200.

Respectfully submitted,

Eddie Miller
Certified Alcohol and Drug Counselor
CADC #00269-C

This notice accompanies a disclosure of information concerning a client in alcohol and drug abuse treatment, made to you with the consent of such client. This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making further disclosures of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of this information to criminally investigate or prosecute an alcohol of drug abuse patient.

FILED
2022 NOV -4 PM 1:22

Carson City District Attorney's Office
JASON D. WOODBURY
DISTRICT ATTORNEY
GARRIT S. PRUYT
Chief Deputy District Attorney
Nevada Bar No.: 13228
GPruyt@carson.org
885 East Musser Street, Suite 2030
Carson City, NV 89701
Telephone (775) 887-2072
Facsimile (775) 887-2129
Representing State of Nevada

Office of the District Attorney
Carson City, Nevada
885 East Musser Street, Suite 2030, Carson City, NV 89701
Tel: (775) 887-2072 Fax (775) 887-2129

IN THE CARSON CITY JUSTICE COURT

IN AND FOR CARSON CITY, STATE OF NEVADA

STATE OF NEVADA,

Plaintiff,

v.

RAYMOND BRADBURY GRABER, III,

Defendant.

Case No. 22CR0206 1C RF

Dept. No. II

CRIMINAL COMPLAINT

Garrit S. Pruyt, Chief Deputy District Attorney for Carson City, Nevada, complains and declares, upon information, belief and/or personal knowledge, that RAYMOND BRADBURY GRABER, III, the Defendant, above-named, at Carson Township, in Carson City, State of Nevada, has committed the crime(s) of: POSSESSION OF A DRUG NOT TO BE INTRODUCED INTO INTERSTATE COMMERCE, a violation of NRS 454.351, a Misdemeanor, in the manner following:

///

Count I

POSSESS DRUG NOT TO BE INTRODUCED INTO INTERSTATE COMMERCE

(MISDEMEANOR - NRS 454.351)

That the Defendant, Raymond Bradbury Graber, III, on or about August 27, 2022, at Carson Township, in Carson City, State of Nevada, Defendant did willfully and unlawfully possess, procure, obtain, process, produce, derive, manufacture, sell, offers for sale, gives away or otherwise furnishes any drug which may not be lawfully introduced into interstate commerce under the Federal Food, Drug and Cosmetic Act, to wit: Defendant did possess and have within his dominion and a control approximately 3.15 grams of cocaine, all of which occurred at or near 5650 South Carson Street, Carson City, State of Nevada.

All of which is contrary to the form of the Statutes in such cases made and provided and against the peace and dignity of the State of Nevada. Said Complainant declares under penalty of perjury under the law of the State of Nevada that the foregoing is true and correct and prays that the Defendant may be dealt with according to law.

DATED this 3rd day of November, 2022.

GARRIT S. PRUYT
Chief Deputy District Attorney
Nevada Bar No. 13228

Office of the District Attorney
Carson City, Nevada
885 East Musser Street, Suite 2030, Carson City, NV 89701
Tel: (775) 887-2072 Fax (775) 887-2129

THE CARSON CITY JUSTICE AND MUNICIPAL COURT
ORDER SETTING HEARINGS, AND CONDITIONS OF RELEASE FROM JAIL

DEFENDANT: GRABER, RAYMOND BRADBURY, III

COURT CASE #: **22 CR 01206 1C RF** ORIGINATING CASE #: **22-5289** LANGUAGE SPOKEN: **ENGLISH** STATUS: **OPEN**

PROSECUTING ATTORNEY: **CARSON CITY DISTRICT ATTORNEY** DEFENSE ATTORNEY: **ALLISON JOFFEE**

COURT HEARING INFORMATION

ARRAIGNMENT	Tuesday, January 11, 2022	8:30 am	=	NO HEARING HELD
ARRAIGNMENT	Wednesday, December 14, 2022	8:30 am	=	CONTINUED
ARRAIGNMENT	Wednesday, January 11, 2023	8:30 am	=	ARRAIGNMENT HEARING HELD WITH
STATUS REVIEW HEARING	Wednesday, January 24, 2024	8:30 am	=	NOT RESULTED

CHARGE AND SENTENCE INFORMATION

CHARGE 454.351 - POSSESS DRUG NOT TO BE INTRODUCED INTO INTERSTATE COMMERCE

PLEA: 01/11/2023 - GUILTY

DISPOSITION: 01/11/2023 - DEFERRED SENTENCING ONE YEAR JAIL:

CONDITIONS

REQUIREMENTS	DUE DATE		COMPLETED
		OBEY ALL LAWS	
		SUBMIT TO SEARCH & SEIZURE WITH OR WITHOUT CAUSE FOR ALCOHOL, ILLEGAL DRUGS, MARIJUANA AND/OR ANY PRODUCTS CONTAINING THC, ILLEGAL DRUGS(INCLUDING ANY AND ALL SYNTHETIC CANNABINOIDS), DRUG PARAPHERNALIA; ANY NARCOTIC MEDICATIONS, EVEN IF PRESCRIBED BY A PHYSICIAN, MUST BE APPROVED BY DEPT OF ALTERNATIVE SENTENCING PRIOR TO TAKING.	
12 MONTH(S)	2/5/2024	SUBSTANCE ABUSE COUNSELING 9 TO 12 MONTHS	
1 ENROLLMENT	2/5/2024	PROOF OF ENROLLMENT REQUIRED	
	1/11/2024	COURT MONITORED SENTENCE	
		DO NOT POSSESS OR CONSUME ANY ALCOHOL, ILLEGAL DRUGS, MARIJUANA AND/OR ANY PRODUCTS CONTAINING THC, ILLEGAL DRUGS (INCLUDING ANY AND ALL SYNTHETIC CANNABINOIDS), DRUG PARAPHERNALIA, ANY NARCOTIC MEDICATIONS, EVEN IF PRESCRIBED BY A PHYSICIAN, MUST BE APPROVED BY DEPT OF ALTERNATIVE SENTENCING PRIOR TO TAKING.	
		MONTHLY REPORTS DUE 5TH OF EACH MONTH	
1 EVALUATION	2/3/2023	SUBSTANCE ABUSE EVALUATION; RECEIVE THE EVALUATION, ENSURE THAT THE COURT RECEIVES IT BY THE DUE DATE ORDERED AND FOLLOW ALL OF THE EVALUATOR'S RECOMMENDATIONS.	

ADDITIONAL CASE INFORMATION

SRH REGARDIN DEFERRED SENTENCE

19

19A

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – October 12, 2023

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.162; NRS 453.163; NRS 639.070; NRS 639.23916

REGULATIONS relating Governor Lombardo's Executive Order 003-2023. Changes in these regulations streamline and clarify licensing requirements while ensuring public safety; and providing other matters properly relating thereto.

Executive Order 003-2023

SECTION 1

Every executive branch department, agency, board and commission shall undertake a comprehensive review of the regulations subject to its enforcement. On or before, May 1, 2023, each department, agency, board and commission shall provide a report to the Governor's office detailing how the regulation subject to its enforcement can be streamlined, clarified, reduced or otherwise improved to ensure those regulations provide for the general welfare of the State without unnecessarily inhibiting economic growth.

SECTION 2:

As part of its report, every executive branch department, agency, board and commission shall provide a list of not less than ten (10) regulations recommended for removal, ranking them in descending order of priority.

NAC 639.215 Application for license to operate pharmacy: Appearance of applicant before Board; execution on behalf of partnership or corporation; payment of expenses for special meeting of Board. (NRS 639.070**,** 639.231**)**

1. An applicant for a license to operate a pharmacy in the State of Nevada [~~must~~] ***may be required to*** appear before the Board in support of the application and must receive instructions relative to the pharmacy laws if the applicant:
   (a) Is applying for a license to operate a pharmacy in this State for the first time;
   (b) Responded affirmatively to any of the questions on the application regarding his or her character or competency;
   (c) Is applying for the licensure of a pharmacy located outside the State that will be shipping compounded parenteral products into this State; or
   (d) Is requested to do so by the Board.
2. If an applicant who is required to appear before the Board is:
   (a) A partnership, all partners must appear.
   (b) A corporation, a designated representative of the corporation must appear. If the designated representative is not an officer of the corporation, a letter authorizing him or her to appear on behalf of the corporation that is signed by an officer of the

corporation must be submitted with the application. Documentation of the status of the person signing the letter of authorization must be submitted with the application.

3. If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation. Documentation of the status of the person signing the application must be submitted with the application.

4. A special meeting of the Board will not be called for the purpose of considering an application for a license to operate a pharmacy until the applicant has paid the Executive Secretary sufficient money to defray all expenses of the meeting.

NAC 639.272 Requirements for registration certificate. (NRS 639.070**,** 639.1373**)**

1. The application of a physician assistant for:
   (a) A registration certificate to prescribe controlled substances, poisons, dangerous drugs and devices or to prescribe poisons, dangerous drugs and devices; or
   (b) A registration certificate to prescribe and dispense controlled substances, poisons, dangerous drugs and devices or to prescribe and dispense poisons, dangerous drugs and devices, must be in writing and filed with the Executive Secretary.

2. Each application for a registration certificate to prescribe controlled substances, poisons, dangerous drugs and devices or to prescribe poisons, dangerous drugs and devices must include:
   (a) The name, address, social security number and telephone number of the applicant;
   (b) A copy of the license issued by the Board of Medical Examiners or certificate issued by the State Board of Osteopathic Medicine that authorizes the applicant to prescribe controlled substances, poisons, dangerous drugs and devices or to prescribe poisons, dangerous drugs and devices;
   (c) The name, address and telephone number of the applicant's supervising physician; and
   (d) Any other information requested by the Board.

3. Each application for a registration certificate to prescribe and dispense controlled substances, poisons, dangerous drugs and devices or to prescribe and dispense poisons, dangerous drugs and devices must include:
   (a) The name, address, social security number and telephone number of the applicant;
   (b) A copy of the license issued by the Board of Medical Examiners or certificate issued by the State Board of Osteopathic Medicine that authorizes the applicant to prescribe and dispense controlled substances, poisons, dangerous drugs and devices or to prescribe and dispense poisons, dangerous drugs and devices;
   (c) The name, address and telephone number of the applicant's supervising physician; and
   (d) Any other information requested by the Board.

4. Each physician assistant who applies for a registration certificate pursuant to subsection 3 [~~must~~] ***may be required to***:
   (a) Personally appear before the Board for determination and assignment of the specific authority to be granted to the physician assistant if the physician assistant:
      (1) Responded affirmatively to any of the questions on the application regarding his or her character or competency; or
      (2) Is requested to do so by the Board; and

(b) Pass an examination administered by the Board on the law relating to pharmacy.

5. Each physician assistant to whom a registration certificate is issued must be registered to a supervising physician.

NAC 639.2971 Authorization; contents of and deviation from written protocol. (NRS 454.213**,** 639.070**,** 639.137**)**

1. A physician may establish a written protocol authorizing pharmacists to administer immunizations by an intranasal, intramuscular or subcutaneous injection. Except as otherwise limited by the physician pursuant to subsection 5, any pharmacist who is trained and certified in accordance with NAC 639.2973 may subscribe to the written protocol and administer immunizations in compliance with the protocol. Such a protocol must contain:
   (a) The name of the physician who is authorizing the administration of immunizations by a pharmacist;
   (b) The immunizations that may be administered by a pharmacist;
   (c) Detailed policies and procedures that a pharmacist must follow while administering immunizations, including, without limitation, procedures to follow in the case of adverse reactions or emergencies following administration;
   (d) A procedure for the review of the protocol and its operation by the physician at least once annually, and the making and keeping of a record of the review;
   (e) When appropriate, specific instructions related to the age of the patient;
   (f) Except as otherwise provided in subsections 2 and 3, a restriction that a pharmacist may not delegate his or her authority to administer an immunization;
   ~~[(g) A restriction that a pharmacist may not administer an immunization except at an authorized location, which location may not be the home of the patient unless the patient resides in a licensed facility for long-term care or in a hospital;]~~
   (h) A requirement that the immunizations will be administered according to all applicable federal, state and local laws; and
   (i) The signature of the physician authorizing the administration of the immunizations and the time period for which the written protocol is effective.
2. An intern pharmacist may administer immunizations by an intranasal, intramuscular or subcutaneous injection under the direct and immediate supervision of a pharmacist who has subscribed to a written protocol established by a physician.
3. A pharmaceutical technician may administer immunizations by an intranasal, intramuscular or subcutaneous injection under the direct and immediate supervision of a pharmacist who has subscribed to a written protocol established by a physician if the pharmacist has determined, in his or her professional judgment, that the patient should be immunized. A record of each immunization administered by the pharmaceutical technician must be maintained in the manner prescribed by NAC 639.2977.
4. If a physician orders a deviation from the written protocol for the benefit of a specific patient, the physician shall note the deviations from the written protocol in the record of the patient.
5. A physician may include restrictions to a written protocol established by the physician pursuant to subsection 1 by limiting the protocol to any of the following:
   (a) A specific pharmacist or pharmacists;

(b) A specific location or locations;

(c) The administration of a specific immunization or immunizations; or

(d) Other limitations as the physician determines necessary.

NAC 639.406 Hearing to approve or deny application from pharmacist. (NRS 639.070)

1. Upon submission of an application pursuant to NAC 639.403, the Board [~~will~~] ***may*** schedule a hearing before the Board. At the hearing, the Board will consider the application and any other relevant information to determine whether the practice and services proposed in the application will be provided in a manner that is safe and in the best interests of the health, safety and welfare of the public. The Board may consider, without limitation, the following factors in determining whether to approve, deny or modify such an application:
   (a) The information contained in the application;
   (b) The education, experience and expertise of the applicant;
   (c) The disciplinary history of the applicant, if any; and
   (d) Whether the applicant has sufficient malpractice or other liability insurance.
2. At the hearing, the Board may request that the applicant modify his or her application.
3. If the Board approves an application, the Board will provide the applicant with documentation indicating the approval and setting forth the terms and conditions under which the applicant may provide the services approved by the Board.
4. If the Board denies an application, the Board will provide the applicant with a written notice of the denial indicating the reasons for the denial and identifying any deficiencies in the application.

NAC 639.415 Hearing to approve or deny application from licensed pharmacy. (NRS 639.070)

1. Upon submission of an application pursuant to NAC 639.412, the Board [~~will~~] ***may*** schedule a hearing before the Board. At the hearing, the Board will consider the application and any other relevant information to determine whether the practice and services proposed in the application will be provided in a manner that is safe and in the best interests of the health, safety and welfare of the public. The Board may consider, without limitation, the following factors in determining whether to approve, deny or modify such an application:
   (a) The information contained in the application;
   (b) The disciplinary history of the applicant, if any; and
   (c) Whether the applicant has sufficient malpractice or other liability insurance.
2. At the hearing, the Board may request that the applicant modify the application.
3. If the Board approves an application, the Board will provide the pharmacy whose application is approved with documentation indicating the approval and setting forth the terms and conditions under which the pharmacists employed by or under contract with the pharmacy may offer the services approved by the Board.
4. If the Board denies an application, the Board will provide the applicant with a written notice of the denial indicating the reasons for the denial and identifying any deficiencies in the application.

NAC 639.757 Preparation and sale of compounded drugs by pharmacy or pharmacist: License as manufacturer not required under certain circumstances; unsafe or ineffective drug; restrictions on sale. (NRS 639.070**)**

1. A pharmacy or pharmacist is not required to obtain a license as a manufacturer to compound drugs if:
   ~~(a)~~ The compounded drugs are prepared in a quantity that is:
      (1) Necessary to fill a prescription or chart order; or
      (2) Reasonably necessary to fill future prescriptions or chart orders based upon the previous history of practitioners and patients who regularly use the pharmacy;
   ~~(b)~~ The compounded drugs are not sold or otherwise provided by the pharmacy or pharmacist to any person other than the ultimate user of the drugs, the agent of the ultimate user of the drugs or a practitioner who will be administering the drugs to a patient;
   ~~(c)~~ The compounded drugs are dispensed pursuant to a prescription or chart order;
   ~~(d)~~ Except as otherwise provided in paragraph (e) and subsection 2, the active ingredients used to compound the drugs:
      (1) Have a monograph in and meet or exceed the standards of the *United States Pharmacopoeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670;
      (2) Have been components of drugs approved by the Food and Drug Administration; or
      (3) Are authorized to be used in pharmacy compounding pursuant to 21 U.S.C. § 353a(b)(1) or the regulations adopted pursuant thereto;
   ~~(e)~~ Except as otherwise provided in subsection 2, for an active ingredient used to compound the drugs that does not have a monograph in the *United States Pharmacopoeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, the active ingredient is:
      (1) Prepared by a manufacturer or distributed by a distributor registered with the Food and Drug Administration;
      (2) Accompanied by a certificate of analysis provided by the manufacturer or distributor of the ingredient; and
      (3) Prepared to a grade that, at a minimum, satisfies the requirements set forth in:
         (I) The *Food Chemicals Codex*, as adopted by reference in paragraph (d) of subsection 1 of NAC 639.670; or
         (II) *Reagent Chemicals: Specifications and Procedures*, as adopted by reference in paragraph (e) of subsection 1 of NAC 639.670, if the active ingredient is a certified analytical reagent, is for use in high pressure liquid chromatography, is for use in spectrophotometric applications or is a primary standard grade for use in standard solutions for analytical purposes.
2. In compounding a drug product, a pharmacy or pharmacist may use an active ingredient that does not satisfy the requirements of paragraphs (d) and (e) of subsection 1 if the pharmacy or pharmacist establishes the purity and safety of the ingredient by reasonable means, satisfactory to the Board, which include, without limitation, analysis of the lot in

which the ingredient was packaged, the reputation of the manufacturer of the ingredient and the reliability of the source of the ingredient. A pharmacy shall make and maintain a record of the means that the pharmacy relied upon in determining that an ingredient was pure and safe pursuant to this subsection.

3. Except as otherwise provided in this subsection, a pharmacy or pharmacist shall not compound a drug that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective. A pharmacy or pharmacist may compound a drug for veterinary use that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective for use in humans if the drug remains available for veterinary use.

4. A pharmacy shall not sell or otherwise provide a compounded drug to a retail pharmacy or a practitioner., [~~except that a pharmacy may sell or otherwise provide a compounded drug to:~~

~~(a) A practitioner who will be administering the drug to a patient; or~~

~~(b) A practitioner or another pharmacy if the compounded drug is:~~

~~(1) A highly concentrated drug product that is not commercially available; or~~

~~(2) Needed to fill a particular prescription or chart order in the possession of the receiving pharmacy at the time the receiving pharmacy orders the compounded drug from the compounding pharmacy.~~

~~5. The quantity of a compounded drug that is sold or otherwise provided to a practitioner or pharmacy pursuant to subsection 4 must not exceed the amount necessary for the practitioner or pharmacy to serve the present needs of the patients of the practitioner or pharmacy.~~]

NAC 639.850 Certificate of registration: Application; appearance before Board. (NRS 639.070**,** 639.2351**)**

1. The application of an advanced practice registered nurse for a certificate of registration to prescribe controlled substances, poisons, dangerous drugs and devices must include:
   (a) The name, address, social security number and telephone number of the applicant;
   (b) A copy of the certificate issued by the State Board of Nursing which authorizes the applicant to prescribe controlled substances, poisons, dangerous drugs and devices;
   (c) The name, address and telephone number of the applicant's collaborating physician, if the applicant is required to have a collaborating physician pursuant to NRS 632.237; and
   (d) Any other information requested by the Board.
2. Each advanced practice registered nurse who applies for a certificate of registration may be required by the Board to appear [~~personally~~] before the Board [~~for a determination and an assignment of the specific authority to be granted to the advanced practice registered nurse~~].

NAC 639.870 Certificate of registration: Application; fee; period of validity; appearance before Board; collaborating physician; late renewal. (NRS 639.070**,** 639.1375**)**

1. The application of an advanced practice registered nurse for a certificate of registration to dispense controlled substances, poisons, dangerous drugs and devices must include:
   (a) The name, address, social security number and telephone number of the applicant;

(b) A copy of the certificate issued by the State Board of Nursing which authorizes the applicant to dispense controlled substances, poisons, dangerous drugs and devices;
(c) The name, address and telephone number of the applicant's collaborating physician, if any;
(d) Written verification from the State Board of Nursing that the applicant has passed an examination on Nevada law relating to pharmacy; and
(e) Any other information requested by the Board.

2. Each application for the issuance or the biennial renewal of a certificate of registration must be accompanied by a nonrefundable fee of $300. The biennial certificate of registration covers the period beginning on November 1 of each even-numbered year.
3. Each advanced practice registered nurse who applies for a certificate of registration and his or her collaborating physician, if any, [~~must~~] ***may be required to*** appear [~~personally~~] before the Board for a determination and an assignment of the specific authority to be granted to the advanced practice registered nurse if the advanced practice registered nurse:
(a) Will be operating in a practice not previously licensed by the Board;
(b) Responded affirmatively to any of the questions on the application regarding his or her character or competency; or
(c) Is requested to do so by the Board.
4. Each advanced practice registered nurse to whom a certificate of registration is issued must be registered to a collaborating physician unless:
(a) The advanced practice registered nurse is not required to have a collaborating physician pursuant to subsection 3 of NRS 632.237; or
(b) The advanced practice registered nurse will not prescribe any controlled substance listed in schedule II.
5. An advanced practice registered nurse who fails to renew his or her certificate of registration within the time prescribed by statute or regulation must pay, in addition to the fee for renewal required by subsection 2, a fee equal to 50 percent of the fee for the renewal of the certificate.

NAC 639.283 Prescriptions: Orders on charts of hospitalized patients. (NRS 639.070**,** 639.1373**)** A physician assistant shall not write a prescription in the form of an order on the chart of a patient in a hospital unless the physician assistant is authorized by the hospital's rules and has filed a copy of his or her form for prescriptions with the pharmacy of the hospital. [~~The form must be approved by the Board.~~]

NAC 639.7145 Transfer of information between pharmacies: Requirements for transfer by facsimile machine. (NRS 639.070**,** 639.0745**)**

1. Information relating to a prescription may be transferred from a pharmacy to another pharmacy by a facsimile machine pursuant to NAC 639.713 if:
(a) The transmission from the transferring pharmacy:
(1) Includes the information required by subsection 2 of NRS 639.2353, which may be provided in the form of an accurate printout of the pharmacy's computerized record of the prescription; and
(2) Except as otherwise provided in subsection 2, includes:

(I) A copy of the original prescription maintained in the records of the transferring pharmacy on which the pharmacist at the transferring pharmacy has signed the copy and written his or her license number; or

(II) The signature and handwritten license number of the pharmacist at the transferring pharmacy and a notation that specifically indicates that the pharmacist intends to transfer the prescription.

(b) The transmission is prepared and transmitted by a pharmaceutical technician or pharmacist at the transferring pharmacy.

2. A pharmacy may transfer prescriptions by facsimile machine to another pharmacy without complying with the provisions of subparagraph (2) of paragraph (a) of subsection 1 only ***if*** ~~[upon application to and authorization by the Board. The Board may grant that authority to a pharmacy if the Board is satisfied that]~~:

(a) The pharmacy's computer system will accurately represent the identity of the pharmacist responsible for the transfer; and

(b) The identity of the pharmacist responsible for the transfer cannot be falsified, modified, added or otherwise provided without the knowledge and assent of that pharmacist.

3. A pharmacy which maintains its records of prescriptions in a computer system shall invalidate in its system a prescription transferred by a facsimile machine to another pharmacy.

19B

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop - October 12, 2023

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.146; NRS 453.221; NRS 639.070

A REGULATION relating to controlled substances adding synthetic cannabinoids to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.

NAC 453.510 is hereby amended to read as follows:

1. Schedule I consists of the drugs and other substances listed in this section by whatever official, common, usual, chemical or trade name designated

2. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including, without limitation, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Acetylmethadol;

Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other names: acryloylfentanyl);

Allylprodine;

Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-acetylmethadol, levomethadyl acetate or “LAAM”);

Alphameprodine;

Alphamethadol;

Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Benzethidine;

Betacetylmethdol;

Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxythiofentanyl (trade or other names: N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

Betameprodine;

Betamethadol;

Betaprodine;

Butyryl fentanyl (trade or other names: N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Clonitazene;

Cyclopentylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

Cyclopropylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambuten;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine);

Fentanyl carbamate (Ethyl-(1-phenethylpiperidin-4-yl)(phenyl)carbamate);

Fluoro furanyl fentanyl;

Fluoroacryl fentanyl;

Fluorobutyryl fentanyl;

Fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);

~~[4-Fluoroisobutyryl]~~ ***Fluoroisobutyryl*** fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide) ***;*** ~~[(some trade or other names: para-fluoroisobutyryl fentanyl);]~~

Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

Furethidine;

Hydroxypethidine;

Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);

Isotonitazene;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

~~[3-Methylfentanyl (N-3-methyl-1-(2-phenylethyl)-4-piperidyl-N-phenylpropanamide);~~

~~3-Methylthiofentanyl (N-(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl-N-phenylpropanamide);]~~

Methoxyacetyl fentanyl; ~~[(2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide);]~~

Methyl acetyl fentanyl;

Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl));

Methylfentanyl;

Methylthiofentanyl;

Morpheridine;

MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

Noracymethadol;

Norlevorphanol;

Normethadone;

N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro

ortho-fluorofentanyl; 2'-fluro 2'-fluorofentanyl);

Norpipanone;

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;

Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

~~[Para-fluorofentanyl (N-(4-fluorophenyl)-N-1-(2-phenethyl)-4-piperidinylpropanamide);]~~

Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Phenyl fentanyl (some trade or other names: benzoyl fentanyl);

Phenylpropanoyl fentanyl;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl);

Tilidine;

Trimeperidine; or

Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide).

3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyl fentanyl;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except hydrochloride salt);

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine; or

Thebacon.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

ADB-4en-PINACA (some trade or other names: N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3-carboxamide)

Adinazolam (some trade or other names: 8-chloro-1-((dimethylamino)methyl)-6-phenyl-4H-s-triazlo(4,3-a)(1,4)benzodiazepine; adinazolamum; Deracyn);

Alpha-ethyltryptamine (some trade or other names: ET, Trip);

Alpha-methyltryptamine (some trade or other names: AMT);

Bromazolam (some trade or other name: 8-bromo-1-methyl-6-phenyl H[1,2,4]triazolo[4,3a][1,4]benzodiazepine; XLI-268);

1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);

4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);

1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);

4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine (some trade or other names: Etizolam);

Clonazolam (some trade or other names: 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; clonitrazolam);

1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18; BTM-8; RCS-8);

CUMYL-PEGACLONE (some trade or other names: SGT-151; 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one; 2,5-dihydro-2-(1-methyl-1-phenylethyl)-5-pentyl-1H-pyrido[4,3-b]indol-1-one)

Diclazepam (some trade or other names: 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepine-2-one; 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one; 2'-chlorodiazepam; Chlorodiazepam; Ro 5-3448);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA);

2,5-dimethoxy-4-ethylamphet-amine (some trade or other names: DOET);

2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);

2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivative thereof (some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N- o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-NBOMe; 25D-NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);

2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);

3-[(2-Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy- N, N-dimethyltryptamine;4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT);

5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or other names: CP-47,497);

5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other names: cannabicyclohexanol; CP-47,497 C8 homologue);

Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4- ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);

4F-MDMB-BUTICA (some trade or other names: 4F-MDMB-BICA; Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(4-fluorobutyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, methyl)

5F-EDMB-PICA (some trade or other names: 5F-EDMB-2201; Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(5-fluoropentyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, ethyl ester)

Flualprazolam (some trade or other names: 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; 2'-fluoro alprazolam; ortho-fluoro alprazolam);

Flubromazepam (some trade or other names: 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-Bromo-5-(2-fluorophenyl)-1H-benzo[e][1,4]diazepin- 2(3H)-one; 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one);

Flubromazolam (some trade or other names: 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine);

Flunitrazolam (some trade or other names: 6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

(1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);

[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluorpentyl JWH-018 indazole);

[1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);

[1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophyenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);

(1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);

1-(5-fluoropentyl)-N-(tricyclo[3.3.1.13,7]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA;

1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22);

Flutoprazepam (some trade or other names: 7-chloro-1-(cyclopropylmethyl)-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

MDMB-4en-PINACA (some trade or other names: Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1H-indazole-3-carboxamido)butanoate)

Meclonazepam (some trade or other names: (3S)-5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one; Ro 11-3128);

Methoxetamine (some trade or other names: MXE; 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone)

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-methylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine (some trade or other names: MMDA);

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; “DOM”; “STP”);

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-122);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-ADB; 5F-MDMB-PINACA);

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine (MDMA);

Methylenedioxy-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-200);

MMB-FUBICA ester (some trade or other names: Methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate; N-[[1-[(4-fluorophenyl)methyl]-1H-indol-3-yl]carbonyl]-L-valine, methyl ester

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other names: ADB-CHMINACA; MAB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (trade or other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trade or other name: AB-FUBINACA);

N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other name: AB-CHMINACA);

N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);

Nifoxipam (some trade or other names: 5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7- nitro-

2H-1,4-benzodiazepin-2-one; 1,3-Dihydro-5-(2-fluorophenyl)-3-hydroxy-7-nitro- 2H-1,4-benzodiazepin-2-one; 3-hydroxydesmethylflunitrazepam; DP 370);

Nitrazolam (some trade or other names: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Norflurazepam (some trade or other names: 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; nor-Flurazepam; N-Desalkylflurazepam; Desalkylflurazepam; Ro 5-3367);

1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);

1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);

1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);

1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);

(1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: UR-144);

1-pentyl-N-(tricyclo[3.3.1.$1^{3,7}$]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);

1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC);

Phenazepam (some trade or other names: 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-bromo-5-(2-chlorophenyl)-1,2-dihydro-3H-1,4-benzodiazepin- 2-one; BD 98; Fenazepam; Elzepam; Phezipam; Phenorelaxan; Phenzitat);

Pyrazolam (some trade or other names: 8-bromo-1-methyl-6-(2-pyridinyl)-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine; 8-bromo-1-methyl-6-(pyridin-2-yl)-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; Pirazolam);

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);

Gamma hydroxy butyric acid (some trade or other names: GHB);

Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; *Tabernanthe iboga*);

Lysergic acid diethylamide;

Marijuana;

Mescaline;

Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP, 3-MeOPP, 4-MeOPP);

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as *Lophophora williamsii Lemaire*, whether growing or not, the seeds thereof, any extract from any part of

such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzofisochromene-7-carboxylate);

Ethylamine analog of phencyclidine (some trade or other names: N-ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidine (some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine; TFMPP).

 For the purposes of this subsection, “isomer” includes, without limitation, the optical, position or geometric isomer.

5. All parts of the plant presently classified botanically as Datura, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound, manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone or methaqualone having a depressant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

7. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers:

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one, alpha- pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha- pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: alpha-PHP);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1- one, β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alpha- aminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,Ndimethylcathinone; N,N-dimethyl MDCATH; N,N-dimethyl-3,4- methylenedioxycathinone; N,N-dimethylβ-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one; bk-MDDMA);

N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3- benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA);

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade or other names: ephylone);

Fenethylline;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4- FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-2(methylamino)propan-1- one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-methylcathinone, 1-(2-fluorophenyl)- 2-(methylamino)propan-1-one, 2-FMC);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone,

4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N Methylcathinone,cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

4'-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);

4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-Methylenedioxypyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2(pyrrolidin-1-yl)pentan-1-one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482);

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one,

α- methylaminovalerophenone); or

Pentylone (trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolylpentanamine; bk-MBDP; bk-methyl-K).

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule, Tetrahydrocannabinols (natural or synthetic equivalents of substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances, derivatives and their isomers with a similar chemical structure; and

Since nomenclature of these substances is not internationally standardized, compounds of

these structures, regardless of numerical designation of atomic positions covered).

10. Unless specifically listed in another schedule and except as otherwise provided in subsection 11, any material, compound, mixture or preparation which contains any quantity of CBD (natural or synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity).

11. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight,

➥ is not a controlled substance.

20

21

EXECUTIVE SECRETARY REPORT
October 11-12, 2023

- **FINANCIAL REPORT**
- **TEMPORARY LICENSES**
- **CHANGE OF ADDRESS BUSINESS LIST**
- **Citations & Fines issued pursuant to NRS 639.2895**
- **STAFF ACTIVITIES**
  - Meetings with Other Health Care Boards
- **REPORT TO BOARD**
  - Legislative Update
  - 2024 Board Meeting Calendar
- **BOARD RELATED NEWS**
- **ACTIVITIES REPORT**
  - Renewal
  - State of Nevada Opioid Summit

October 2023 Temporary Licenses since the last Board Meeting

Name	License Type
Vivek Purani	Pharmacist
Patrick Sather	Pharmaceutical Technician
Daniel Williams	Pharmacist

Business Name	License Type
Carl Zeiss Meditec, Inc.	Wholesaler

Citations & Fines issued pursuant to NRS 639.2895

(Since the last Board Meeting)

- Cease & Desist/Cite & Fine
  - Unlicensed Practice: 9
- Cite & Fine
  - Misfill: 2
  - Unlicensed Practice: 2

2024 - Nevada Board of Pharmacy Calendar

Board Meeting Dates

January 17-18	Las Vegas, NV
March 6-7	Las Vegas, NV
April 17-18	Reno, NV
May 29-30	Las Vegas, NV
July 17-18	Reno, NV
September 4-5	Las Vegas, NV
October 16-17	Las Vegas, NV
December 4-5	Las Vegas, NV

January

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

February

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29		

March

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

April

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

May

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

June

S	M	T	W	T	F	S
						1
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9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

July

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

August

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

September

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

October

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

November

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

December

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

STATE HOLIDAYS (OBSERVED)

New Years Day	January 1
Martin Luther King's Day	January 15
President's Day	February 19
Memorial Day	May 27
Nevada Day	June 19
Independence Day	July 4
Labor Day	September 2
Nevada Day	October 25
Veteran's Day	November 11
Thanksgiving Day	November 28
Family Day	November 29
Christmas Day	December 25

ANNUAL MEETINGS

APhA Annual	March 22-25 | Orlando, FL
NACDS Annual	April 27-30 | Palm Beach, FL
NABP Annual	May 15-17 | Fort Worth, TX
ASHP Summer	June 8-12 | Portland, OR
NASCSA Annual	Oct 28-31 | Greenville, SC
ASHP Mid Year	Dec 8-12 | New Orleans, LA
NABP District 8	TBD

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 453.510: Schedule I – Isotonitazene	01/13/22	01/14/22	R006-22	02/23/22 02/24/22 – Under review by Dave/Yenh	03/11/22	04/14/22	04/27/22	06/13/22
NAC 453B: Prescription Drug Donation Program	01/13/22	01/14/22	R007-22	03/21/22 – Under review by Dave/Yenh	10/20/22	12/01/22	*12/28/22 Leg Comm*	12/29/22
NAC 453: Registration of a law enforcement officer engaged in training a canine in drug detection, and add methoxetamine.	04/14/22	04/21/22	R050-22	04/27/22 Under review by Dave/Yenh	08/05/22	09/08/22	*9/27/22 Leg Comm*	09/28/22
NAC 639: Requires the holder of any certificate, license or permit issued by the BOP to report certain convictions and administrative actions to the Board.	04/14/22	04/21/22	R051-22	05/05/22	06/09/22	07/14/22	07/20/22 *9/27/22 Leg Comm*	09/28/22
NAC 639: Medical Products Wholesaler	06/02/22	06/09/22	R085-22	07/19/22	08/05/22	09/08/22	09/15/22 *9/27/22 Leg Comm*	09/28/22
NAC 639: Medication Assisted Treatment	06/02/22	06/09/22	R087-22	08/08/22	08/31/22	10/13/22	10/19/22	12/29/22

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
							12/28/22 Leg Comm	
NAC 639.870: APRN Dispensing License/pharmacy applicant appearance	06/02/22	06/02/22 – Dave revising language.	R086-22	06/29/22 07/05/22: under Dave review				
NAC 639: Dispensing Technicians	07/14/22	08/03/22	R178-22	9/29/22 Under review by Dave	10/20/22	12/01/22	*12/28/22 Leg Comm*	12/29/22
NAC 639: Automated Dispensing Device	07/14/22	08/03/22	R179-22	8/24/22: Under review by Dave	10/20/22	12/01/22	*12/28/22 Leg Comm*	12/29/22
NAC 639: Reproductive Health Care Center	07/14/22	08/03/22	R180-22	8/12/22: Under review by Dave LCB returned 9/6/22. 9/13/22: Under review by Dave and Yenh.	10/20/22	12/01/22	*12/28/22 Leg Comm*	12/29/22

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639: Dispensing Practitioners in Reproductive Healthcare Center: single inventory of dangerous drugs.	07/14/22	07/14/22 – Dave revising language. To LCB 08/03/22	R181-22	8/29/22: Under review by Dave	08/31/22	10/13/22	10/19/22 *12/28/22 Leg Comm*	12/29/22
NAC 453.540: Schedule IV – Daridorexant.	07/14/22	07/19/22	R170-22	08/02/22	08/05/22	09/08/22	09/15/22 *9/27/22 Leg Comm*	09/28/22
NAC 639: Narcotic Treatment Program	10/13/22	10/19/22	R196-22	06/30/23 07/11/23: to Dave/ Yenh for review	08/08/23	09/07/23	09/28/23 Leg Comm	
NAC 453.310: DEA Registration	10/13/22	10/19/22	R197-22	05/12/23: to Dave/ Yenh 05/26/23: Under review by Yenh/Peter 05/30/23: Hold till final rule on state specific DEA registration requirement.				

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639.2973 & NAC 639.2974: Basic Life Support Certification	10/13/22	10/19/22	R198-22	05/12/23	06/09/23	07/13/23	07/21/23 08/21/23 Leg Comm	08/22/23
NAC 639.694: DME Administrator for DME Inventory at a Licensed Hospital	09/07/23	09/12/23	R058-23					
NAC 639.520: Security of Pharmacies	09/07/23 Dave to meet with industry							
NAC 639: Administrative Fine in Lieu of Disciplinary Action	09/07/23	09/12/23	R057-23					
NAC 639: Protocol for RPH to Treat OUD (AB156)	09/07/23	09/12/23	R059-23					
Regulations relating Governor Lombardo's Executive Order 003-2023. Changes in these Regulations streamline and clarify licensing requirements while ensuring public safety; and providing other matters properly relating thereto.	10/11/23							

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 453: The proposed amendments relate to controlled substances adding synthetic cannabinoids to the controlled substances listed in Schedule I.	10/11/23							

22

23

24