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NEVADA STATE BOARD OF PHARMACY

nonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

TION 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 Pending
☐ 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: Optum Compounding Services, LLC

Physical Address: 24416 N. 19th Ave, Ste. 200

City: Phoenix State: AZ Zip Code: 85085

Telephone: (877) 358-9030 Fax: (623) 869-7151

Toll Free Number: (877) 358-9030 (Required per NAC 639.708)

E-mail: orxpharmlic@optum.com Website: www.avella.com/sourceb (anticipated to change)

Supervising Pharmacist: Christopher Dinoffria Nevada License #: Pending

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

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3012890460

Please provide the name of the facility as registered with the FDA and the registration number:
Optum Compounding Services, LLC & 3012890460

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A - facility will not use a DBA

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Christopher Dinoffria Nevada License Number: Pending

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.

Karen Peterson

Original Signature of Person Authorized to Submit Application, no copies or stamps

Karen Peterson

Print Name of Authorized Person

7/20/2020

Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: AZ (State of Organization for the LLC)

Parent Company if any: Optum Pharmacy 801, Inc. (sole member of the LLC)

Address: 24416 N. 19th Ave, Ste. 200

City: Phoenix State: AZ Zip: 85085

Telephone: (623) 742-1700 Fax: (623) 742-1705

Contact Person: Christopher Dinoffria

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) No individual owners
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A - LLC

3) What was the price paid per share? N/A - LLC

4) What date did the corporation actually receive the cash assets? No cash assets received; intracompany acquisition of 503B asset on 07/29/2020

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

Optum Compounding Services, LLC

Officer and Ownership Information

Officers:

Name	Title
Jeffrey Grosklags	Manager
Michael Zeglinski	Manager, CEO & President
Peter Gill	Treasurer
Karen Peterson	Secretary
Heather Lang	Assistant Secretary
David Oberg	Assistant Secretary

The facility is wholly owned by:
Optum Compounding Services, LLC
FEIN: 20-3253658
24416 N. 19th Ave., Ste. 200
Phoenix, AZ 85085

The sole member of Optum Compounding Services, LLC is:
Optum Pharmacy 801, Inc.
FEIN: 13-4318552
24416 N. 19th Ave., Ste. 100
Phoenix, AZ 85085

20071015036317

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:

OPTUM COMPOUNDING SERVICES, LLC

ACC file number: 23101764

was incorporated under the laws of the State of Arizona on 06/30/2020, 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: **07/10/2020**

Matthew Neubert, Executive Director

Disciplinary Action History

Optum Pharmacy 801, Inc. (fka Avella of Deer Valley, Inc.)

Colorado Board of Pharmacy, 2010. Colorado Board of Pharmacy issued a Stipulation and Final Agency Order inclusive of a $5500 fine to Avella of Deer Valley, Inc. for failing to submit required data or zero reports, regarding controlled substances, to the Colorado Electronic Prescription Drug Monitoring Program.

Colorado Board of Pharmacy, 2011. Colorado Board of Pharmacy issued a Stipulation and Final Agency Order inclusive of a $11,000 fine to Avella of Deer Valley, Inc. for failing to submit required data or zero reports, regarding controlled substances, to the Colorado Electronic Prescription Drug Monitoring Program.

Colorado Board of Pharmacy, 2014. Colorado Board of Pharmacy issued a Stipulation and Final Agency Order inclusive of a $1,000 fine to Avella of Deer Valley, Inc. for failing to submit required data or zero reports, regarding controlled substances, to the Colorado Electronic Prescription Drug Monitoring Program for the December 1 through December 10, 2013 reporting period.

Hawaii Board of Pharmacy, 2015. Hawaii Board of Pharmacy and Avella of Deer Valley, Inc. entered into a Settlement Agreement for Avella's failing to report Colorado Board of Pharmacy disciplinary actions in a timely manner. Settlement agreement included $2,500 payment for administrative costs.

Colorado Board of Pharmacy, 2015. Colorado State Board of Pharmacy issued a Stipulation and Final Agency Order in Case No. 2014-3990 to Avella Deer Valley for distributing prescription drug product to a veterinarian intended for in-office use for an animal-patient, without first obtaining a patient specific prescription.

Please note, although the California Board of Pharmacy does not consider a citation disciplinary action, we are disclosing the citation in an abundance of caution.

California Board of Pharmacy, 2018. California Board of Pharmacy issued a citation to Avella of Deer Valley for shipping non-patient specific sterile drug preparations to facilities in California without obtaining the required documentation from the prescribers to meet the requirements for office administration, and for not obtaining a license with the board as an outsourcing facility prior to shipping non-patient specific sterile drug preparations into this state. The non-patient specific sterile drug products were made in Avella of Deer Valley, Inc.'s FDA licensed 503b facility located in suite 16 of the same premises as Avella of Deer Valley, Inc, (NRP 991) and (NSC 99593), which according to board records is located in suite 12.

Pending Action Summary

The California Board of Pharmacy filed an Accusation against Avella of Deer Valley, Inc. and its shareholder Apothecary Holdings Inc. on August 6, 2019. The Accusation sets forth alleged violations of current Good Manufacturing Practices observed during inspections conducted in July 2017 and June 2018, prior to the time that the current owners acquired and took over the operations of the facility in August 2018. A subsequent inspection conducted in July 2019 did not identify any deficiencies requiring corrective action. Based on that inspection and other efforts undertaken by the new owners, the California Board has agreed to continue the hearing that was scheduled for later this summer, to allow the parties the opportunity to discuss settlement.

Karen Peterson

Karen Peterson

STATE OF ILLINOIS)
) ss.
COUNTY OF)

On this 13th day of July, 2020 before me, Maleta G Beahan, Notary Public, personally appeared Karen Peterson, personally known 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.

WITNESS my hand and official seal.

Official Seal
Maleta G Beahan
Notary Public State of Illinois
My Commission Expires 03/06/2022

Maleta G. Beahan

Notary Public

Optum Compounding Services, LLC
f/k/a Avella of Tucson II, Inc.
f/k/a Apothecary Shop of Tucson II, Inc.

STOCK LEDGER

Certificate #	Issued To	No. of Shares	Date of Certificate	Transferred To	No. of Shares	Date of Transaction/ Cancellation	Location of Original	Notes
The Corporation is authorized to issue 1,000,000 Common Shares, no par value								
1	John D. Musil	100,000	8/3/2005	Apothecary Holdings, Inc.	100,000	12/31/2008	Cancelled	
2	Apothecary Holdings, Inc.	100,000	12/31/2008	Apothecary Holdings, Inc.	100,000	6/30/2020	Cancelled	
								8/16/2018 Acquired as part of Avella acquisition when OptumRx Holdings, LLC acquired Apothecary Holdings, Inc. and all of its subsidiaries. No stock certificates or stock ledger provided at time of closing.

MEMBERSHIP LEDGER

Membership Unit	Issued To	Membership %	Date of Certificate	Transferred To	Membership %	Date of Transaction/ Cancellation	Location of Original	Notes
6/30/2020 Avella of Tucson II, Inc. converted to a corporation and was renamed Optum Compounding Pharmacy, LLC.								
Uncertificated	Apothecary Holdings, Inc.	100	6/30/2020		100	6/30/2020	Uncertificated	6/30/2020 Assumption and Contribution Agreement whereby Apothecary Holdings, Inc. contributed, assigned, conveyed and delivered 100% of its right, title and interest in Optum Compounding Pharmacy, LLC to Avella of Deer Valley, Inc.
Uncertificated	Avella of Deer Valley, Inc.	100	6/30/2020					

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: 05/29/2020
Receipt Number: 202083551
Receipt Amount $: 1000.00

Manufacturer - 503B Outsourcer

PERMIT NO
M001629

EXPIRES
10/31/2021

Issued to

Optum Compounding Services, LLC
Optum Compounding Services, LLC
24416 N. 19TH AVE STE. 200
PHOENIX, AZ 85085

Optum Compounding Services, LLC
24416 N. 19TH AVE STE. 200
PHOENIX, AZ 85085

Sam Gaddis
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 : Optum Compounding Services, LLC
LICENSE NUMBER : M001629
EXPIRES : 10/31/2021

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: 1616 W. Adams, Suite 120, 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 :	Optum Compounding Services, LLC
Address :	24416 N. 19th Ave Ste. 200 Phoenix AZ 85085
License No :	M001629
Permit Type :	Manufacturer
Sub Type :	503B Outsourcer
Date Issued :	06/30/2020
Expiration Date :	10/31/2021
Status :	OPEN
Discipline :	No

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 07/18/2020

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 8/7/2020

- 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]
Advanced Pharmaceutical Technology, Inc., Elmsford, NY	Marco Persichillo 914-358-5260	2/26/2019	11/18/2019	Not yet inspected	N/A	N/A	Yes
AnazaoHealth Corporation, Las Vegas, NV	Jaclyn Wong 800-995-4363 Ext=3120	9/23/2014	10/22/2019	9/19/2019	Yes (https://www.fda.gov/media/132898/download)	Open[7]	Yes
Apollo Care, Columbia, MO	Jarred Dudding 573-441-8900	9/14/2017	12/11/2019	3/13/2018	Yes (/media/112143/download)	Warning Letter - 3/20/2019	Yes
AptiPharma, LLC, Loveland, CO	Jennifer Travis 970-685-1078	2/7/2020	2/7/2020	Not yet inspected	N/A	N/A	No
ASP CARES, San Antonio, TX	Jacqueline Esqueda 210-417-4567	2/14/2017	12/3/2019	8/23/2018	Yes (/media/120742/download)	Open	Yes
Athenex Pharma Solutions, LLC, Clarence, NY	Michael Scribner 888-629-8593	4/10/2017	10/25/2019	8/28/2019	Yes (https://www.fda.gov/media/132333/download)	Open[7]	Yes
Atlas Pharmaceuticals, Phoenix, AZ	Nickolaus Banda 480-208-1855	11/8/2016	11/22/2019	9/26/2017	Yes (/media/108456/download)	Warning Letter - 9/11/2018 (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/atlas-pharmaceuticals-llc-564139-09102018)	Yes
Optum Compounding Services, LLC, formerly registered as Avella of Deer Valley, Inc., Phoenix, AZ	Christopher Dinoffria 877-794-0404	6/21/2016	12/11/2019	4/20/2018	Yes (/media/112827/download)	Open	Yes
BayCare Integrated Service Center, LLC dba BayCare Central Pharmacy, Temple Terrace, FL	Kenneth Jozefczyk 813-901-6339	6/4/2019	12/7/2019	12/10/2019	Yes	Yes	No
BPI Labs LLC, Largo, FL	Chandra Kasireddy 727-471-0850	3/4/2019	12/3/2019	Not yet inspected	N/A	N/A	Yes
Brookfield Medical/Surgical Supply, Inc., Brookfield, CT	James Cangelosi 203-775-0862	1/12/2015	1/16/2020	12/21/2018	Yes (https://www.fda.gov/media/120806/download)	Open	Yes
BSO LLC, Lakewood, CO	David W. Hill 303-589-8677	11/24/2015	10/17/2019	9/20/2019	Yes (https://www.fda.gov/media/132339/download)	Open[7]	Yes
Central Admixture Pharmacy Services, Inc., Allentown, PA	Wm. John Brandon 205-945-1955 Ext=106	2/28/2014	10/18/2019	8/22/2018	Yes (https://www.fda.gov/media/120740/download)	FMD-145 Issued 6/17/2020	Yes
Central Admixture Pharmacy Services, Phoenix, AZ	Wm. John Brandon 205-945-1955 Ext=106	3/29/2018	10/18/2019	4/26/2019	No	FMD-145 Issued 6/3/2020 (https://www.fda.gov/media/139371/download)	Yes
Central Admixture Pharmacy Services, Inc., San Diego, CA	Wm. John Brandon 205-945-1955 Ext=106	6/4/2014	10/18/2019	9/11/2018	Yes (/about-fda/central-admixture-pharmacy-services-inc-san-diego-ca-483-issued-09112018)	FMD-145 Issued 5/27/2020 (https://www.fda.gov/media/139369/download)	No

Accredited Drug Distributors

DRUG DISTRIBUTOR ACCREDITATION

Apply

Criteria

Accredited Drug Distributors

Find an Accredited Drug Distributor

Facility Name

State

Search Reset

Current list of 1 Verified-Accredited Wholesale Distributors®

VAWD accreditation is valid for 5 years.

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

Name	Address	Accreditation Date
Medical of Deer Valley, Inc	24414 W. 19th Ave. Phoenix, AZ 85085	12/13/2015

CHOW proceeding

CHN processing

The National Association of Boards of Pharmacy®

hereby awards

Verified-Accredited Wholesale Distributors®

Accreditation

to

Avella of Deer Valley, Inc 38

located at

24416 N 19th Ave, Phoenix, AZ 85085

This facility has met all the Verified-Accredited Wholesale Distributors (VAWD) criteria set in place by the National Association of Boards of Pharmacy. The current status of this facility's accreditation may also be verified by visiting the VAWD section of the NABP website, located at www.nabp.pharmacy.

Carmen A. Catizone, Executive Director/Secretary

December 13, 2019 - December 12, 2022

Period of Accreditation

National Association of Boards of Pharmacy | 1600 Feehanville Drive, Mount Prospect, IL 60056 | www.nabp.pharmacy

1819

Christopher J. Dinoffria, Pharm.D.
N. 51st St.
Scottsdale, AZ 85254
(480) 6 – cell

EDUCATION

Midwestern University College of Pharmacy — 2005-2008
Doctor of Pharmacy

University of Arizona — 1996-97, 1998-2001
Bachelor of Science – Chemistry
Minor – Math & Physics

LICENSURE

Pharmacist License

Arizona Board of Pharmacy	2008
Mississippi Board of Pharmacy	2012
Alabama Board of Pharmacy	2014
Arkansas Board of Pharmacy	2014
Kentucky Board of Pharmacy	2014
Louisiana Board of Pharmacy	2014
Maryland Board of Pharmacy	2014
Nebraska Board of Pharmacy	2014
Oregon Board of Pharmacy	2014
Oklahoma Board of Pharmacy	2014
Tennessee Board of Pharmacy	2014
Virginia Board of Pharmacy	2014
West Virginia Board of Pharmacy	2014
Michigan Board of Pharmacy	2015
Massachusetts Board of Pharmacy	2015
New York Board of Pharmacy	2016
Texas State Board of Pharmacy	2016
Kansas Board of Pharmacy	2018

Pharmacist Non-Resident Registration

Idaho Board of Pharmacy	2014
Iowa Board of Pharmacy	2018

EXPERIENCE

Director, Compliance — 2018-Present
Optum Compounding Services (formerly Avella of Deer Valley, Inc. #38)
24416 N. 19th Ave.
Phoenix, AZ 85085
(623) 238-7073

Responsible for compliance to state and federal regulations governing the operation of a duly-licensed outsourcing facility under Section 503B of the Food, Drug, & Cosmetic Act. Serves as Pharmacist-in-Charge/Designated Representative for all licensure held by the facility. Provides directional guidance on state and federal statutes as they relate to outsourcing facility operations, as well as oversight pertaining to product safety, including surveillance, process, recalls, and reporting. Responsible for all government liaison activities relating to outsourcing facility operations, including interactions with state regulators, FDA, CDC, DEA, OSHA, EPA, and DHHS.

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0 N. 51st St.
Scottsdale, AZ 85254
(480) · cell
·om

Director, Compliance 2015-2018
Avella
24416 N. 19th Ave.
Phoenix, AZ 85085
(623) 238-7073

Responsible for executing Avella's Corporate Compliance Program under the direction of the Chief Compliance Officer and Chief Executive Officer. Subject-matter expert for all Avella locations, ensuring they operate appropriately within the bounds of applicable regulatory requirements. Point of contact and subject-matter expert for all regulatory, corporate standard and/or professional practice questions. Provides regulatory input for Quality Assurance department. Collaborates with all site Pharmacists-in-Charge to ensure regulatory compliance and adherence to corporate standards of practice, including multi-state licensure, regulatory body inspection, safe and proper handling and distribution of medications to end-users and disaster-recovery contingencies

Pharmacist-in-Charge – Avella of Deer Valley 2011-2015

Pharmacist of record for the National Mail order facility while managing growth from annual revenue to $240 million from $80 million. Responsible for all regulatory and compliance matters involved in conducting business nationally, including clinical expertise as well as logistics requirements necessary for safe and proper handling and nationwide fulfilment of specialty medications. Maintains permits and licensure requirements for all 50 states. Oversees largest compounding facilities within Avella, with capabilities to supply sterile and non-sterile compounded medications nationally. Manages pharmacist activities and workflow to ensure standards of practice and proper dispensing procedures as dictated by multi-state regulations including Responds to regulatory agency inspection inquiries when applicable.

Clinical Pharmacist – Avella of Deer Valley 2008-2011

Clinical Pharmacist for specialty pharmacy's national mail order facility. Helped develop distribution policies and medication therapy management system to coordinate drug utilization and implementation to ensure proper adherence and persistency of medications for national specialties including transplant, HIV, oncology, fertility, ophthalmology, sports medicine and extemporaneous sterile and non-sterile compounding. Closely involved in REMS programs monitoring limited-distribution medications. Acting subject-matter reference for pediatric therapeutics. Involved with strategic drug information gathering/implementation both internally for colleagues and externally for specialty practices.

ACTIVITIES

VAWD Accreditation (503B Outsourcing Facility) 2019

Led accreditation application process in order to obtain VAWD accreditation for 503B Outsourcing Facility through NABP

Registered Outsourcing Facility 2013-Present

Provided regulatory oversight of construction, installation, and maintenance of three cGMP-compliant facilities for compounding of sterile products in compliance with Drug Quality and Security Act of 2013; led efforts for facilities

Christopher J. Dinoffria, Pharm.D.
N. 51st St.
Scottsdale, AZ 85254
(480) - cell

in order to obtain national licensure for nation-wide distribution

Adjunct Assistant Professor 2014-2015
Midwestern University: College of Pharmacy - Glendale
PPRA 1433 – Introduction to Specialty Pharmacy
Designed to develop confidence and competence to efficiently and effectively provide pharmaceutical care in a specialty pharmacy environment. Focus includes lecture series on 4 unique disease states commonly found in specialty pharmacy, and the role specialty pharmacists play in providing comprehensive clinical care within those disease states.

URAC Accreditation (Specialty & Mail-Service) 2012-2013
Assisted in drafting, editing and implementing policies and procedures for the facility in compliance with accreditation by the Utilization Review Accreditation Commission (URAC) as both Specialty Pharmacy and Mail-Service Pharmacy to ensure the company is conducting business in a manner consistent with national standards.

PCAB Accreditation (Sterile & Non-Sterile Compounding) 2009
Assisted in drafting, editing and implementing compounding methods, policies and procedures for facility in accordance with the Pharmacy Compounding Accreditation Board (PCAB) designed to recognize compounding pharmacies that meet or exceed the high quality standards established by the United States Pharmacopeia (USP) for both sterile and non-sterile compounding.

SKILLS

Pharmacy Regulatory Specialist 2015
CE certificate program, administered by Pharmaceutical Education Consultants, focusing on regulatory standards governing the practice of pharmacy.

Limited Drug Distribution 2008-Present
Oversight of facility operations in dispensing drugs with restricted distribution networks or REMS programs limiting end-user access for safety, post-marketing, clinical, financial and/or adherence concerns, as well as safe and proper storage, handling and fulfilment of medication to end-users throughout the country

Cold Chain Technologies Training 2014
Pre-qualified packaging solution employed by Avella's national distribution centers designed to ensure safe and proper handling and fulfilment of medications

RevAssist Certified Counselor 2010

Pharmaceutical Compounding 2001-present
Trained in extemporaneous compounding of pharmaceutical formulations in order to provide medication options to patients that are unable to be solved with commercially available products. Fluent in formulations including oral, topical, transmucosal, transdermal and sterile dosage forms for many therapeutic needs such as Pediatrics, Hormone Replacement, Pain Management, Ophthalmology, and Veterinary Medicine.

Christopher J. Dinoffria, Pharm.D.
N. 51st St.
Scottsdale, AZ 85254
(480) [illegible]

RESEARCH EXPERIENCE	Research Assistant, University of Arizona Assisted in laboratory research of natural products designed to extract and isolate compounds for pharmaceutical testing	2000-2001
PROFESSIONAL ORGANIZATIONS	Phi Delta Chi Fraternity	2007
AWARDS	Pharmacist of the Year – Mail Order The Apothecary Shop	2011
	Rookie Preceptor of the Year Midwestern University: College of Pharmacy – Glendale	2011
SPECIAL PROJECTS	Medication Utilization Review Evaluated administration and efficacy of injectable Ibuprofen Lysine to induce closure of the Patent Ductus Arteriosus in premature infants.	December 2007

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. 107255232

Application/License No. WH02302 (CHOW processing)

Optum Compounding Services, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 24416 N. 19th Ave, Suite 200, Phoenix, AZ 85085 (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, Bond/5PB, 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 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 20, 2020 (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 17th day of August, 20 20.

APPLICANT/PRINCIPAL
Optum Compounding Services, LLC

Authorized Representative

SURETY COMPANY
Travelers Casualty and Surety Company of America

Surety Company's Representative

Sandra M. Winsted, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness K. Hannigan

Witness

Witness Jessica B. Dempsey

Countersigned by:

Nevada ~~Resident Agent~~ Non-Resident Agent
Susan Ann Welsh

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 M. Winsted** of **Chicago** **Illinois** , 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
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 17 day of August 2020.

Kevin E. Hughes
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.

Quarles & Brady LLP

411 East Wisconsin Avenue
Suite 2400
Milwaukee, Wisconsin 53202-4426
414.277.5000
Fax 414.271.3552
www.quarles.com

Attorneys at Law in
Chicago
Indianapolis
Madison
Milwaukee
Naples
Phoenix
Scottsdale
Tampa
Tucson
Washington, D.C.

Writer's Direct Dial: 414.277.5303
E-Mail: Elizabeth.Gebarski@quarles.com

August 21, 2020

VIA UPS OVERNIGHT

Mr. Mark Sedar
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

RE: Change of Ownership, Name, and Officers and Address Update
Avella of Deer Valley, Inc. #38 – Phoenix, AZ
Wholesaler License No.: WH02302
Outsourcer License No.: Application Pending

Dear Mr. Sedar:

This will follow-up on our June 29, 2020 notice letter. Please be advised that there was a sale of assets of Avella of Deer Valley, Inc. #38 related to the FDA Registered 503B Outsourcing Facility in an intracompany change of ownership to Optum Compounding Services, LLC. The new owner of the 503B Outsourcing Facility, Optum Compounding Services, LLC, is now wholly owned by the prior owner, Avella of Deer Valley, Inc. (NKA Optum Pharmacy 801, Inc.). The enclosed organizational chart shows the facility's ownership structure before and after the intracompany change.

As a result of this intracompany change, there was a change in the facility's name, federal tax identification number, and officers. The facility discontinued use of any and all DBAs. It is not using any DBA going forward. The facility did not move, but updated its address to include a suite number. The effective date was July 29, 2020.

Per our July 15, 2020 discussion, this change application is due within 30 days of the change; but, because the license will expire in October, we are submitting the application prior to August 25, 2020. In addition, as we discussed on August 20, 2020, we are enclosing an updated new Outsourcing Facility (503B) license application to reflect the new ownership. **We request that you please put the Wholesaler application on the October Agenda and that the Outsourcing Facility (503B) application currently on the October Agenda be replaced with the enclosed.**

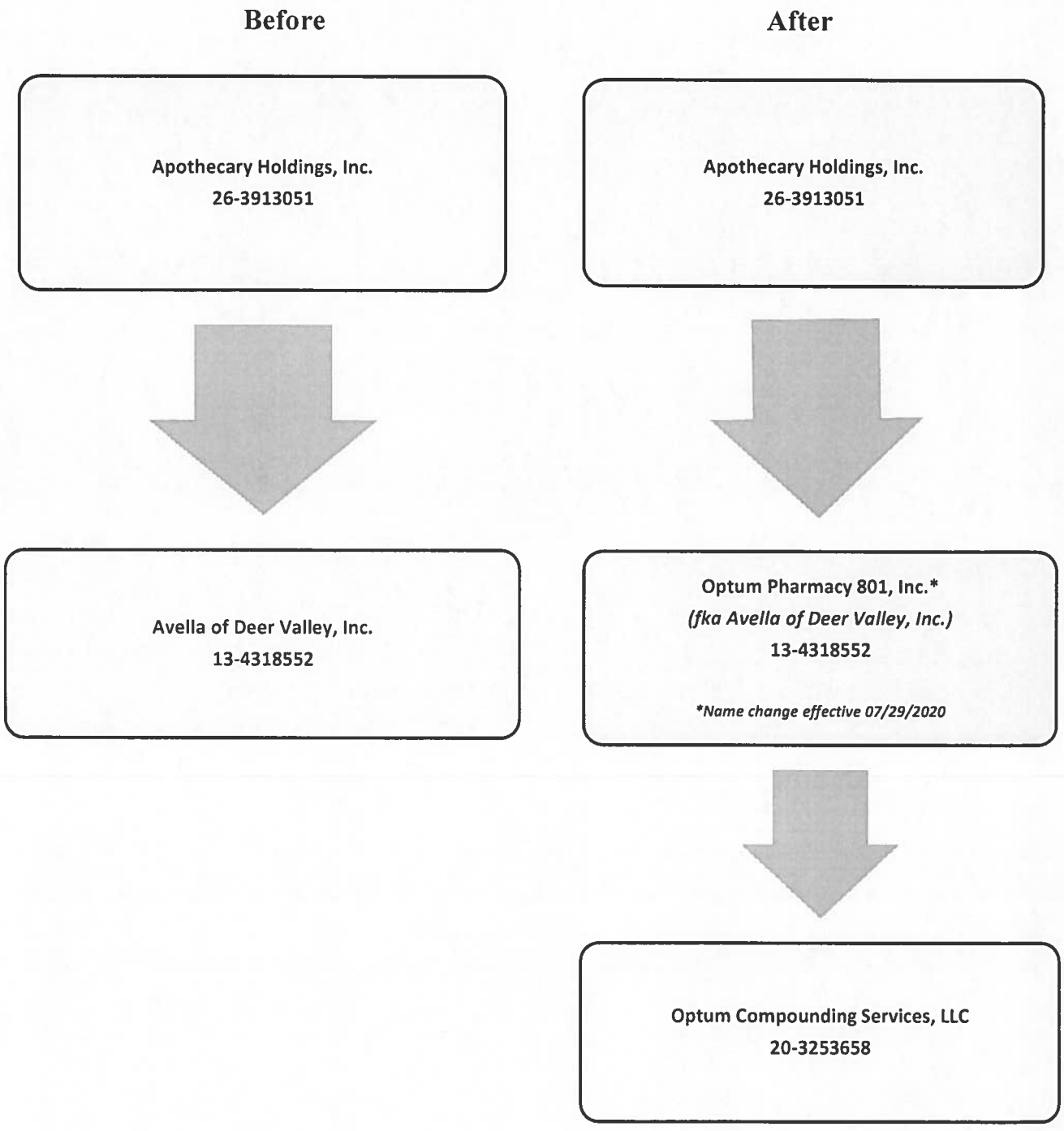
The application, supporting documents, and fees are enclosed. The pharmacist in charge's Nevada license application is pending. Because the facility is FDA registered and VAWD certified, we have not enclosed fingerprints or a list of employees. Should you have any questions or require additional information, please contact me at 414-277-5303 or Elizabeth.Gebarski@quarles.com. Thank you for your consideration.

Very truly yours,

Elizabeth R. Gebarski

Enclosures

Intracompany Transfer



OPTUM®

Via Email to kmangosing@pharmacy.nv.gov

September 30, 2020

Nevada State Board of Pharmacy
985 Demonte Ranch Pkwy, Suite 206
Reno, NV 89521
775-850-1440

Re: Optum Compounding Services, LLC f/k/a Avella of Deer Valley, Inc. #38
24416 N. 19th Ave., Suite 200, Phoenix, AZ 85085
Outsourcing Facility Application

To Whom It May Concern:

With this letter, I am providing authorization for Christopher Dinoffria, Supervising pharmacist, to appear and speak before the Nevada Board of Pharmacy on behalf of Optum Compounding Services, LLC f/k/a Avella of Deer Valley, Inc. #38.

Thank you,

Karen E. Peterson
Secretary

15B

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: Imprimis NJOF, LLC

Physical Address: 1705 Route 46, Suite 6B

City: Ledgewood State: NJ Zip Code: 07852

Telephone: (844) 446-6979 Fax: (855) 405-4669

Toll Free Number: (844) 446-6979 (Required per NAC 639.708)

E-mail: imprimisnjof@imprimisrx.com Website: www.imprimisrx.com

Supervising Pharmacist: Kathleen A. Fucillo Nevada License #: 20055 exp 10/31/21

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: 5-27-2020 Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3013024146

Please provide the name of the facility as registered with the FDA and the registration number:
Imprimis NJOF, LLC - Reg. # 080431967

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: Kathleen A. Fucillo Nevada License Number: 20055

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.

Heidi Morales on behalf of Sanjay Samudre
Original Signature of Person Authorized to Submit Application, no copies or stamps

Sanjay Samudre, VP - Mfg. & Technical Services
Print Name of Authorized Person

5/15/2020
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 4**

OWNERSHIP IS A PUBLICY TRADED COMPANY

State of Incorporation: Delaware

Parent Company if any: Harrow Health, Inc. / fka Imprimis Pharmaceuticals, Inc.

Corporation Name: Imprimis NJOF, LLC (applicant)

Address: 12264 El Camino Real, Suite 350 (mailing address)

City: San Diego State: CA Zip: 92130

Telephone: (844) 446-6979 Fax: (862) 244-4340

Contact Person: John Saharek (President)

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 01/11/2006 (Delaware)

Registration number issued: CIK#0001360214

Stock Exchange: NASDAQ

Include with the application for a 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. **(see attached)**

List of officers and directors. **(see attached)**

BEFORE THE NORTH DAKOTA
STATE BOARD OF PHARMACY

IN THE MATTER OF IMPRIMIS NJOF,	)
	)
RESPONDENT.	)
	)

Admin No. 2018-10-20

STIPULATION AND SETTLEMENT AGREEMENT AND PROPOSED RECOMMENDATION OF SANCTIONS

COMES NOW, MARK J. HARDY, R. Ph., PharmD, Executive Director of the North Dakota State Board of Pharmacy, hereinafter called "the Board" and Chairman and member of the investigating committee of the North Dakota State Board of Pharmacy, and IMPRIMIS NJOF, sometimes hereafter referred to as "Respondent", located at 1705 Route 46, Suite 6B, Ledgewood, NJ 07852, and hereby stipulate and agree to enter into the Stipulation and Settlement Agreement and Recommendation of Sanctions, as follows:

RECITALS

A. Respondent, IMPRIMIS NJOF, is an out of state out-sourcing facility located at 1705 Route 46, Suite 6B, Ledgewood, NJ 07852.

B. Respondent, IMPRIMIS NJOF, does not hold an out-sourcing facility permit to distribute wholesale prescription drugs, medical gases, or medical equipment in this state.

C. That a Complaint and Statement of Charges was served upon the Respondent based upon allegations that Respondent made unauthorized shipments of non-patient specific prescription medications to eye clinics located in the State of

proceedings based upon the Complaint and Statement of Charges can be resolved on a stipulated basis without the need for a hearing under the North Dakota Administrative Agency's Practices Act, Chapter 28-32 of the North Dakota Century Code.

NOW, THEREFORE, it is hereby Stipulated and Agreed to by and between the parties as follows:

A. Respondent agrees to be subject to the jurisdiction of the Board.

B. Respondent expressly waives formal hearing for all facts and legal conclusions referenced herein and any and all procedures before the Board relative to said facts and conclusions to which it might otherwise be entitled by law.

C. That as Executive Director of the board and Chairman of the investigating committee, Mark J. Hardy, R.Ph. PharmD, received information regarding the possible unauthorized distribution non-patient specific prescription medication to opthamologists located in the State of North Dakota. Respondent, IMPRIMIS NJOF, is not licensed as a outsourcing facility under chapter 43-15.3 NDCC in the State of North Dakota and correspondence from Pramod Sharma, Ph.D, Vice-President, Quality, with IMPRIMIS NJOF, admitted that IMPRIMIS NJOF, does not hold a outsourcing facility permit but shipped drug orders to clinics in North Dakota at least 232 times within the past two years.

D. In the event the Board, in its discretion, does not approve this Stipulation and Proposed Recommendation of Sanctions, it shall be deemed withdrawn and of no evidentiary value and shall not be introduced or relied upon by either party, nor disclosed to any third party and the Board shall not be considered prejudiced against the Respondent in any way.

occurring after the date of the Stipulation, Settlement Agreement and Proposed Recommendation of Sanctions which is not related to the facts, circumstances and requirements therein.

The parties agree that this agreement is the recommendation Mark J. Hardy, R.Ph., PharmD, will present to the Board and that the Board may reject this recommendation after the presentation to the Board. In the event the Board in its discretion does not approve this Stipulation, Settlement Agreement and Proposed Recommendation of Sanctions, it shall be deemed withdrawn and of no evidentiary value and shall not be introduced or relied on by either party nor disclosed to any third party and the Board shall not be considered prejudiced toward Respondent in any way.

This Stipulation, Settlement Agreement and Proposed Recommendation of Sanctions was read in its entirety by Respondent prior to its execution. Respondent understands all of the provisions and has had the opportunity to review the Stipulation, Settlement Agreement and Proposed Recommendation of Sanctions with its attorney and Respondent affirms it was entered into freely and voluntarily by it. The Stipulation, Settlement Agreement and Proposed Recommendation of Sanctions contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies from this Stipulation.

Dated this 13th day of March, 2019.

IMPRIMIS NJOF

~~IMPRIMUS~~ NJOF

Mark Baum, CEO

STATE OF NEW JERSEY)
(ss
COUNTY OF)

On this _____ day of March, 2019, before me, a notary public in and for said county and state, personally appeared MARK BAUM, CEO, known to me to be the person described in and who executed the foregoing Stipulation and Proposed Recommendation of Discipline and acknowledged to me that she executed the same.

Notary Public

(SEAL)

My commission expires:

See attached

Dated this 21st day of March, 2019.

NORTH DAKOTA STATE BOARD
OF PHARMACY

By _____

Mark J. Hardy, R.Ph., PharmD
Executive Director, Chairman and
Member of Investigating Committee
1906 East Broadway Avenue
PO Box 1354
Bismarck, ND 58502-1354
701-328-9535

Dated this 21st day of March, 2019.

_____

David A. Lindell
Special Assistant Attorney General
Counsel for North Dakota State Board of Pharmacy
PO Box 427
Washburn, ND 58577
701-462-8566

STATE OF NORTH DAKOTA)
(ss
COUNTY OF BURLEIGH)

On this 21st day of March, 2019, before me, a notary public in and for said county and state, personally appeared MARK J. HARDY, R. Ph., PharmD, Executive Director of the North Dakota State Board of Pharmacy, known to me to be the person described in and who executed the foregoing Stipulation and Proposed Recommendation of Discipline and acknowledged to me that he executed the same.

_____
Notary Public

(SEAL)

KATHY R. ZAHN
Notary Public
State of North Dakota
My Commission Expires April 12, 2023

My commission expires:

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0739016

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:

1705 ROUTE 46, SUITE 6B LEDGEWOOD, NJ 07852-

Reg. No.
5005097

IMPRIMIS NJOF, LLC
1705 ROUTE 46, SUITE 6B
LEDGEWOOD, NJ 07852-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2021

Establishment Copy

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 4/30/2020

Registration Number: 5005097 **Registered as:** Manufacturer and Wholesale

Parent Company Name: IMPRIMIS NJOF, LLC

Trade Name:

Original Issue Date: 01/11/2017 **Expiration Date:** 01/31/2021

Current Issue Date: 01/16/2020

Disciplines: No

Heidi Morales

Subject: FW: FY2020 Outsourcing Facility Invoice - Imprimis NJOF, LLC

-----Original Message-----
From: DoNotReply_CDER@fda.hhs.gov <DoNotReply_CDER@fda.hhs.gov>
Sent: Thursday, November 14, 2019 2:08 PM
To: Brad Bingham <bbingham@imprimisrx.com>
Cc: CDERCollections@fda.hhs.gov; Compounding@fda.hhs.gov; EDRLS@fda.hhs.gov
Subject: FY2020 Outsourcing Facility Invoice - Imprimis NJOF, LLC

Good Afternoon,

We have received the establishment registration fee for Imprimis NJOF, LLC, in the amount of $18,288. Effective January 01, 2020, your facility located at 1705 Route 46, Suite 6B Ledgewood, NJ 07852 is now registered as a human drug outsourcing facility through December 31, 2020.

For more information on the Compounding Quality Act, visit FDA's Compounding Website:
https://nam03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.fda.gov%2FDrugs%2FGuidanceComplianceRegulatoryInformation%2FPharmacyCompounding%2Fdefault.htm&data=02%7C01%7Cmorales%40imprimisrx.com%7C6452cead221642fc762d08d769523439%7C3ee10f8a0392483a87fda18c1f4b557b%7C0%7C0%7C637093674090873378&sdata=3USBo9wFe%2BtM1oiX1sYFtwrjmyzwYuZPFXSmCcrq4RE%3D&reserved=0

CQA User Fee Staff

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HARROW 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 TWELFTH DAY OF MAY, A.D. 2020.

Jeffrey W. Bullock, Secretary of State

4092296 8300

SR# 20203762303

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

Authentication: 202920290

Date: 05-12-20

IMPRIMIS NJOF, LLC

Imprimis NJOF, LLC Directors & Officers	Harrow Health, Inc. Directors & Officers
John Saharek- President Jole Deal- Secretary Sanjay Samudre – VP (Manufacturing & Technical Services)	Mark L. Baum- CEO and Board member Andrew R. Boll- CFO Robert J. Kammer- Chairman of the Board Teresa F. Sparks- Board member Richard Lindstrom- Board member Anthony Principi- Board member

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

HARROW HEALTH, INC.

Form: 10-K

Date Filed: 2020-03-13

Corporate Issuer CIK: 1360214

15C

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: KRS GLOBAL BIOTECHNOLOGY, INC.

Physical Address: 791 PARK OF COMMERCE BLVD.

City: BOCA RATON State: FL Zip Code: 33487

Telephone: 888-502-2050 Fax: 866-480-3322

Toll Free Number: 888-502-2050 (Required per NAC 639.708)

E-mail: PHARMACY@KRSBIO.COM Website: KRSBIO.COM

Supervising Pharmacist: SCOTT STANISLAW Nevada License #: 19917

OK 10/31/21

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: 5.12.2020 Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3006412304

Please provide the name of the facility as registered with the FDA and the registration number:
KRS GLOBAL BIOTECHNOLOGY, INC. 3006412304

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
NONE

Please provide the name and Nevada license number of the supervising pharmacist:
Name: SCOTT STANISLAW Nevada License Number: 19917

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

ELSA KERPI, PRESIDENT
Print Name of Authorized Person

05/06/2020
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: FLORIDA

Parent Company if any: NONE

Address: _____

City: _____ State: _____ Zip: _____

Telephone: 561-430-2360 Fax: 561-430-2360

Contact Person: SCOTT STANISLAW, R.Ph.

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) CLEVELAND DIABETES CARE, INC. 10752 DEERWOOD PARK BLVD SOUTH JACKSONVILLE, FL 32256 (100%)
Name Address

b) —
Name Address

c) —
Name Address

d) —
Name Address

2) Provide the number of shares issued by the corporation. 100

3) What was the price paid per share? $28.00

4) What date did the corporation actually receive the cash assets? 11/08/2019

5) Provide a copy of the corporation's stock register evidencing the above information ATTACHED

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. ATTACHED

List of officers and directors

ATTACHED

KRS GLOBAL BIOTECHNOLOGY
AN FDA HUMAN OUTSOURCING FACILITY

791 Park of Commerce Blvd.
Suite 600
Boca Raton, FL 33487
888.242.7996
www.gbtbio.com

May 7, 2020

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

Re: Out-of-State Outsourcing Facility Application

To Whom it May Concern,

With respect to the licensing questions 2, 3 and 5, please find our response below. These matters have been previously reported under our Pharmacy Permit PH02535.

Colorado - 2009-2010: There were two issues which were clerical in nature. They were related to bi-monthly zero reporting of controlled substances. The matters were settled and closed.

Missouri - 2009-2010: We shipped office use medication which was not permitted. We were placed on probation which was successfully completed on December 31, 2014.

DEA - 2010-11: We voluntarily surrendered our DEA Registrations. In 2014, we re-applied and received a Pharmacy and Manufacturer Registration, as our business had changed servicing hospitals.

Nebraska – December 2013: We had a non-resident pharmacy application denied based upon the two disciplines mentioned above. We were, years prior, previously licensed in the state.

Alabama -August 2, 2016: KRS was disciplined based on a 2015 Warning Letter from the FDA. The observations in the letter were addressed and the corrections completed several years ago. There has been no further communication from the FDA on this matter. We have disputed the validity of this Alabama action and the matter is under appeal.

California: In August 2017, the California Board of Pharmacy inspected our facility for the Pharmacy Renewal and Outsourcing Permit. Several observations were noted, and the renewals were denied. Since we had ceased doing business in California at that time, we agreed to voluntarily surrender the permits effective April 3, 2019. Please note during the 2017 Inspection, Florida simultaneously conducted a full inspection. There was no discipline taken and all observations were corrected years ago. In addition, the FDA conducted a five-day inspection three months after the California inspection. None of the California Inspection observations were noted by the FDA

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Colorado: On April 3, 2018, Colorado temporarily suspended our permit. There were two findings: 1) we dispensed drugs ordered by individuals not licensed to prescribe and 2) we distributed compounds to an animal hospital. Neither of these findings were true. Once we submitted supporting documents, the suspension was vacated.

Oklahoma: On October 25, 2018, Oklahoma denied our renewal for an Outsourcing Permit. They stated this is due to the "Board's inability to monitor non-resident facility corrective actions".

Arkansas: On May 22, 2019, Arkansas denied our application for a Wholesale Distributor Permit. The denial was based on matters mentioned above.

Virginia: On January 22, 2020, Virginia suspended our Pharmacy permit based on the California matter above.

Colorado: On February 6, 2020, Colorado suspended our Pharmacy permit based on the California matter above.

These matters did not involve controlled substances or drugs of concern. We have never had any action taken in our home state of Florida from these matters or any other matter. If you need any additional information, please let me know.

Sincerely,

Scott Stanislaw, R.Ph.
561-430-2360
pharmacy@krsbio.com

KRS GLOBAL BIOTECHNOLOGY
AN FDA HUMAN OUTSOURCING FACILITY

791 Park of Commerce Blvd.
Suite 600
Boca Raton, FL 33487
888.242.7996
www.gbtbio.com

Corporate Officers & Directors

Charles P. Richardson, M.D., M.B.A.
Chief Executive Officer
Director

Elsa Kerpi
President
Chief Operating Officer
Secretary
Registered Agent

James Roberts, M.D.
Chairman of the Board
Treasurer
Director

Kevin Hall, M.D.
Director

Haemoon Oh, Ph.D.
Director

Viviana Rodriguez
Director of Finance

KRS Global Biotechnology, Inc. (FEIN 65-1099340) is owned 100% by Cleveland Diabetes Care, Inc. (FEIN 20-8735962).

KRS Officer's Address

791 Park of Commerce Blvd.
Boca Raton, FL 33487

Cleveland Diabetes Care, Inc.

10752 Deerwood Park Blvd. South
Jacksonville, FL 32256

State of Florida
Department of State

I certify from the records of this office that KRS GLOBAL BIOTECHNOLOGY, INC. is a corporation organized under the laws of the State of Florida, filed on April 12, 2001.

The document number of this corporation is P01000038423.

I further certify that said corporation has paid all fees due this office through December 31, 2019, that its most recent annual report/uniform business report was filed on March 26, 2019, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twentieth day of February, 2020

GREAT SEAL OF THE STATE OF FLORIDA
IN GOD WE TRUST

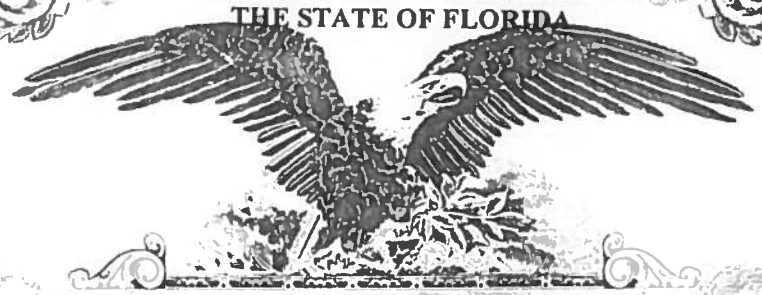
Secretary of State

Tracking Number: 5333393304CU

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

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

ORGANIZED UNDER THE LAWS OF
THE STATE OF FLORIDA



No. 4

100

See Reverse for
Certain Definitions

KRS GLOBAL BIOTECHNOLOGY, INC.
Common Stock, $1.00 par value

This is to certify that CLEVELAND DIABETES CARE, INC. is the owner of

ONE HUNDRED (100)

fully paid and non-assessable shares of the above Corporation transferable only on the books of the Corporation by the holder thereof in person or by a duly authorized Attorney upon surrender of this Certificate properly endorsed.

Witness, the seal of the Corporation and the signatures of its duly authorized officers.

Dated November 8, 2019

Charles Richardson

Charles Richardson, CEO

Elsa Kerpi

Elsa Kerpi, ~~CFO~~ COO

1856

DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
11/06/2018	PH 23506	103784

The **PHARMACY**
named below has met all requirements of
the laws and rules of the state of Florida.
Expiration Date: **FEBRUARY 28, 2021**

KRS GLOBAL BIOTECHNOLOGY, INC
791 PARK OF COMMERCE BLVD
BOCA RATON, FL 33487

QUALIFICATION(S):
-SPECIAL P/E

Rick Scott
GOVERNOR

Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW

Department of Health

License Number: PH23506

Data As Of 5/5/2020

Profession	Pharmacy
License	PH23506
License Status	CLEAR/
Qualifications	Special P/E
License Expiration Date	2/28/2021
License Original Issue Date	07/24/2008
Address of Record	791 PARK OF COMMERCE BLVD BOCA RATON, FL 33487
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.

U.S. Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Compounding Quality Act Billing

FY 2020 Compounding Quality Act Invoice	Invoice Date: 18-DEC-2019	Invoice Number: CQA207000610
	Due Date: 02-JAN-2020	Invoice Amount: $18,288.00

KRS Global Biotechnology, Inc.
Attention: Charles Richardson, MD
791 Park of Commerce Blvd., Suite 600
Boca Raton, FL 33487
US

Type of Fee	Fiscal Year to which this payment applies	Total
Annual Establishment Fee	2020	$18,288.00
	Total Fee:	**$18,288.00**

Payment Information

Online payments:

The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card.

Make an online payment at https://userfees.fda.gov/pay.

Alternative Payment Options

Checks:

Mail payment and copy of your invoice to:
Food and Drug Administration
P.O. Box 979033
St. Louis, MO 63195-6733

For overnight courier use only:
U.S. Bank
ATTN: Government Lockbox 979033
1005 Convention Plaza
St. Louis, MO 63101

If a phone number is also required for courier delivery, use 314-418-4013.

Wire Transfers:

U.S. Department of the Treasury
TREAS NYC
33 Liberty Street
New York, NY 10045

FDA Deposit Account Number: 75060099
Routing/Transit Number: 021030004
SWIFT Number: FRNYUS33

Reference - Invoice # CQA207000610

Payments should include the invoice number with the payment. *All fees assessed by your financial institution for wire transfers should be added to your payment to ensure that the full invoice amount is received.*

Payment must be received by the U.S. Food and Drug Administration by the due date. Any check or bank draft should be drawn on or payable through U.S. financial institutions located in the United States. Payments made by wire transfer must include the invoice number with the payment. **Bank fees assessed for wire transfers or currency exchange are the responsibility of the firm and should not be deducted from the payment amount.**

If full payment is not received by 02-JAN-2020, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

This invoice will not be considered paid until full payment has been cleared and the amount is received by the U.S. Food and Drug Administration.

For further information concerning this invoice, please contact the Office of Management Division of User Fee Management and Budget Formulation at CDERCollections@fda.hhs.gov or by phone (301) 796-7900.

STATE OF FLORIDA DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE – ISU

503b Outsourcing Inspection Form

CORPORATE NAME KRS GLOBAL BIOTECHNOLOGY, INC.	INSPECTION NUMBER 167345	TYPE OF PERMIT OUTSOURCING FACILITY	DATE OF INSPECTION 7/30-8/2, 8/5,8/6, 8/14/2019
DOING BUSINESS AS	FILE NUMBER 15916	LICENSE # PH23506	
STREET ADDRESS 791 PARK OF COMMERCE BLVD		TELEPHONE #	EXT #
CITY BOCA RATON	COUNTY PALM BEACH	STATE/ZIP FL/33487	

QUALITY 21CFR part 211 subpart B: Responsibilities of Quality Unit

Remark

Out of Specifications (OOS) investigations that include environmental excursions, sterility failures, and production equipment issues are deficient. Many investigations are closed without root cause analysis and assessing impact on batches that may or may not have been released.

Observation

- Investigation, impact of additional batches, preventative and corrective actions into environmental monitoring excursions in critical sterile compounding areas is not done.

  - Surface sampling collected on 3/19/2019 in hood #313 located in cleanroom 4 resulted in mold growth. Batches produced in this hood include, and that were distributed include, L-Carnitine 170mg/ml (Lot 03192019@2) and Methylcobalamin 1mg/ml (Lot 03192019@8).

  - Dynamic weekly surface sampling conducted in ISO 7 cleanroom 5 on 3/20/2019 resulted in TNTC (Too Numerous to Count) CFU's on syringe bin. Lot 03202019@12 (METHIONINE/INOSITOL/CHOLINE/CYANO-B12 25/50/50/1MG/ML, 30ML VIAL) and 03202019@3 (NICOTINAMIDE ADENINE DINUCLEOTIDE 500 MG/VIAL (PF) LYOPHILIZED, COMPOUNDED) were compounded in this room and distributed without determining root cause of growth.

  - Quality failed to determine cause of EM OOS from 7/16/2018 through 5/22/2019 (OOS reports 1908, 1911, 1919, 1920, 1937, 1938, 1942, 1945, 1949, 1955, 1960, 1963, 1965, 1966, 1968, 1969, 1972, 1979, 1985, 1986, 1989, 1990, 1995, 2003, 2005, 2006, 2007, 2008, 2014, 2015, 2019, 2032, 2033, 2057, 2059, 2075). There was no assessment on possible batches that may have been affected and no documentation of preventative and corrective actions.

Observation

- Sterility failures were not investigated.

  - The following batches were released from OOS 1910 L-Asparaginase 10,1000 IU lyophilized (lot 0702218@1 Norepineprhine 8mg/ 250ml IV (lot 03122019@10).
  - There was no root cause determined for sterility failures found during sterility testing from 7/2/2018 through 5/13/2019 (OOS 1910, 1917, 1933, 1936, 1950, 1957, 1961, 1996, 1998, 1999, 2012, 2014, 2022, 2023, 2024, 2025, 2035, 2037, 2044, 2052, 2056, 2077).

Observation

- BI failure in de-pyrogenation oven that ensures glassware used in production (beakers / cylinders) and final product (vials 5ml, 10ml, 30ml, 50ml) is free from endotoxin.

  - OOS 1980, 2011, 2036, and 2049 indicates BI failure was due to technician error without identifying organism. Vials from two lots (11052018@4 and 11052018@20) were released.

Observation

- Quality Unit failed to monitor, review and remediate alerts for CIMScan monitoring of cleanrooms and PEC's for particle counts, temperature and cleanroom differential pressures.

  - On 8/13/2018, 8/22/2018, 8/24/2018, 8/28/2018, 9/19/2018 and 10/17/2018 non-viable particle counts were out of range in ISO 5 cleanroom 4. Excursions were not investigated and eight batches made on these days were released for distribution.

Observation

- Cleanroom and device certification reports are not reviewed and signed by Quality.

  - Internal cleanroom certification reports dated 6/4/2019 indicate primary and secondary engineering controls (PEC's and SEC's) were not reviewed by Quality.
  - Internal certification report dated 6/4/2019 indicates HEPA filters in hoods #301 and #610 were within conformance, however on 7/1/2019 third-party vendor failed both PEC's due to HEPA filter leaks. There was no investigation on impact of lots that were produced in the affected PEC's.

Observation

- Evoqua water system validation for WFI was not reviewed and approved by Quality and lacks substantiated data to support that the unit is within conformance as intended by manufacturer.

  - Non-sterile WFI from system is used in production of sterile product and for dilution of sterile cleaning agents used to clean PEC's and compounding production equipment.

- Quality failed to investigate cause of TNTC (Too Numerous to Count) micro contamination from water sampling. Reports show elevated micro-contamination collected from Port 3 of Evoqua water system on 4/25/2019. The WFI was used in seven sterile batches that were released for distribution.

Observations

- Quality failed to perform investigation that resulted in Out-of-Tolerance for Total Organic Carbon (TOC) meter during calibration on 7/26/2016 and 5/28/2018.

FACILITIES 21CFR part 211 subpart C: Design and Construction Features

Remark

The control of air pressure, dust, humidity and temperature is inadequate for the manufacturing, processing, and storage of drug products and containers.

Observation

- Records indicate recording of continuous particle counts inside ISO 5 and ISO 7 compounding rooms exceeded particle limits.
- Particle counts in ISO 5 cleanroom 4 were not continuously monitored from 7/1/2018 through 7/25/2019.
- ISO 7 cleanrooms 6 and 7 were not monitored from 7/1/2018 through 7/25/2019.
- ISO 7 cleanroom 8 was not monitored from 7/1/2018 through 8/1/2019.
- Non-viable particle counts are not monitored during production in any ISO 5 PEC or production equipment.
- Cleanroom certification report (7/12/2019) indicates non-viable particle counts were collected during "at-rest" conditions without production equipment on or components (vials, syringes, IV bags) inside PEC's.
- Policy P-OPS-009.11.7 requires triple clean when there are particle count excursions, but this is not documented.

Observation

- Air pressure differentials are not continuously monitored and do not demonstrate that a cascading pressure differential is maintained throughout the compounding area during production of sterile compounding.

  - Differential pressure logs dated 6/1/2019 through 7/31/2019 indicate cleanrooms 1, 2, 4, 5, 6, 7, and 8 were not in a state of control in that a cascading pressure differential was maintained throughout the compounding rooms.

Observation

- Smoke studies do not demonstrate sweeping action of HEPA filtered air over drug product.

- HEPA filters in PEC's, automated production equipment (Dara cleanroom 1; Colanar cleanroom 3; Cozzoli cleanroom 4) and ISO 5 path (from Cozzoli to lyophylizer) do not provide sufficient velocity to sweep particles over and away from product.
- HEPA filtered air does not show laminar air over partially stoppered vials from the Cozzoli to the lyophylizer (ISO 5 cleanroom 4). Partially stoppered vials are placed on a work table under a non-HEPA filtered ceiling tile prior to transporting.

- Design and placement of Colanar fill line blocks vertical HEPA filtered air. During filling, arm rotates over vials inside a vertical laminar flow hood.
- ISO 5 cleanrooms 3 and 4 that contain fill equipment lack laminar airflow.
- Smoke studies show they were conducted without components (IV bags, syringes, vials) and repeater pumps inside PEC's.

Remark

The layout and organization of the facility is not designed in a way to prevent contamination.

Observation

- HEPA filter located in BSC hood #568 is dirty/rusted.

Observation

- Inadequate pressure and design of ISO 8 prep room 3 where in-process de-pyrogentated glassware (beakers, cylinders) and end-product containers (5ml, 10ml, 30ml, 50ml vials) are stored.

  - Return vents in prep room 3 are in the ceiling which prevents top to down diluted HEPA filtered air.

Remark

Primary engineering controls are not re-certified whenever the unit is relocated.

Observation

- The following PEC's were not-recertified after moving: hood 903 was transferred from cleanroom 5 to cleanroom 7 on 7/12/2019; hood 568 was transferred from cleanroom 5 to cleanroom 2 on 7/12/ 2019; hood 303 was transferred from cleanroom 2 to cleanroom 3 on 8/3/2018.

ENVIROMENTAL MONITORING 21CFR part211

Remark

Adverse changes in the environment are investigated and promptly remediated.

Observation

- Firm uses CIMScan system to monitor pressure, temperature and particles of cleanrooms.

- Records indicate there are numerous temperature, particle counts and pressure excursions that were not addressed.
- Alerts from CIMScan system were not monitored prior to June 2019.
- Alerts that were identified on monitoring system were not addressed and there was no corrective action.

Observation

- OOS 1990 Environmental monitoring logs indicate mold contamination in ISO 5 hoods, cleanrooms and ISO 7 airlock. No root cause or corrective actions documented in investigation.

  - EM conducted on 11/29/2018; All lots produced on this day were rejected.
  - Air settling plates: Mold - hoods 310, 305, 312, 313.
  - Surface sampling: Mold - hoods 313, 306, 301, 302, 302, 303, 308, 310, 315.
  - Surface sampling: Mold - cleanrooms 1, 2, 3, 4, 5, 6, 7, 8 and ISO 7 airlock.

Remark

Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment.

Observation

- Environmental re-testing of CFU excursions are not collected in affected areas.

  - OOS 2075 (5/22/2019) indicates dynamic surface sampling of syringe bins in cleanrooms 1 and 7 exceeded limits for ISO 7 environment. A level 3 remediation cleaning was performed (5/29/2019) and static surface sampling logs indicate syringe bins were not re-sampled.

Equipment 21CFR part 211 subpart D: Equipment design, construction, cleaning and maintenance, Filters

Remark

Cleaning and disinfecting of aseptic equipment is not done in a way to prevent possible contamination of sterile product.

Observation

- Firm does not have cleaning effective studies for critical compounding equipment.
- Surfaces inside LAFW's, BSC's and production equipment (Dara, Colanar, Cozolli, Cozzoli crimper, Baxter repeater pumps) are cleaned with cleaning agents (LPH and Vesphene) that are diluted with non-sterile WFI or deionized water that are contained in non-sterile spray bottles.

Observation

- CIMScan non-viable count excursions are not remediated with level three cleanings per your SOP P-Prod-009 Sterile Compounding Area Cleaning and Disinfecting.
- Evoqua water system that produces DI used to dilute cleaning agents used to clean ISO 5 hoods and production equipment is not validated.

LABORATORY 21 CFR part 211 subpart I: Laboratory Controls

Remark

Sterile formulations lack supportive evidence to support assigned Beyond Use Dates.

Observation

- Container closure studies have not been done for all CSP formulations to determine if there are impurities or degradants are contained in final product as a result of aging.
- Final drug containers for formulations are vials, syringes and IV bags.
- Stability studies of the following formulations are currently in process:
  - Glycopyrrolate (PF) 0.2mg/ml (90-day BUD)
  - Ketamine HCL (PF) 10 mg/ml (90-day BUD)
  - Moxifloxacin (PF) 1mg/ml ophthalmic syringe (90-day BUD)
  - Neostigmine Methyl sulfate (PF) 1mg/ml (90-day BUD)
  - Rocuronium Bromide (PF) 10mg/ml (45-day BUD)

21CFR210.1(b) "The failure to comply with any regulation set forth in this part and in parts 211 through 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)2(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action".

Additional Remarks

Prior to this inspection, firm has responded to deficiencies via email based on June 20, 2019 inspection conducted by DOH.

Some observations documented from June 2019 inspection are in process for compliance.

This cGMP inspection was co-conducted with FDA Investigator Jennifer Huntington. Adam Malhoit QA Manager and Despina Menon VP Quality and Regulatory Affairs were present during inspection.

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.

Riccardo D. Roscetti, Owner and President

PRINT NAME OF RECIPIENT

ID _____

Institutional Representative

Date

Investigator/Sr. Pharmacist Signature

15D

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: NEPHRON STERILE COMPOUNDING CENTER, LLC

Physical Address: 4500 12th Street Ext.

City: West Columbia State: SC Zip Code: 29172

Telephone: 800-443-4313 Fax: 803-926-9853

Toll Free Number: 800-443-4313 (Required per NAC 639.708)

E-mail: LICENSE@NEPHRONPHARM.COM Website: https://www.nephronpharm.com/

Supervising Pharmacist: Stuart Tolman Nevada License #: 10916 ✓

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: 3-26-2020 Amount: 500.00

RECEIVED 3-9-2020

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3011158388

Please provide the name of the facility as registered with the FDA and the registration number:
NEPHRON STERILE COMPOUNDING CENTER, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
NEPHRON 503B OUTSOURCING FACILITY

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Stuart Tolman Nevada License Number: 10916

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.

X _____

Original Signature of Person Authorized to Submit Application, no copies or stamps

Lou w. Kennedy

Print Name of Authorized Person

03/04/2020

Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: SOUTH CAROLINA

Parent Company if any: NEPHRON SC, INC

Address: 4500 12th Street Ext.

City: West Columbia State: SC Zip: 29172

Telephone: 800-443-4313 Fax: 803-926-9853

Contact Person: LOU W. KENNEDY

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Lou W. Kennedy (Name) 4500 12th Street Ext. Columbia, SC 29172 (Address)

b) William P. Kennedy (Name) 4500 12th Street Ext. Columbia, SC 29172 (Address)

c) Ashley Kennedy Whitner (Name) 4500 12th Street Ext. Columbia, SC 29172 (Address)

d) Courtney Kennedy Mcgowan (Name) 4500 12th Street Ext. Columbia, SC 29172 (Address)

2) Provide the number of shares issued by the corporation. 10,000

3) What was the price paid per share? No par value

4) What date did the corporation actually receive the cash assets? 11/04/2011

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

Business Entities Online

File, Search, and Retrieve Documents Electronically

NEPHRON STERILE COMPOUNDING CENTER LLC

Corporate Information

Entity Type: Limited Liability Company

Status: Good Standing

Domestic/Foreign: Domestic

Incorporated State: South Carolina

Important Dates

Effective Date: 03/12/2014

Expiration Date: N/A

Term End Date: N/A

Dissolved Date: N/A

Registered Agent

Agent: CT CORPORATION SYSTEM

Address: 2 OFFICE PARK COURT, SUITE 103
COLUMBIA, South Carolina 29223

Official Documents On File

Filing Type	Filing Date
Amendment	04/24/2014
Organization	03/12/2014

Former Names

Name	Filing Date
NEPHRON COMPOUNDING CENTER LLC	03/14/2014

Business Entities Online

File, Search, and Retrieve Documents Electronically

NEPHRON STERILE COMPOUNDING CENTER LLC

Corporate Information

Entity Type: Limited Liability Company

Status: Good Standing

Domestic/Foreign: Domestic

Incorporated State: South Carolina

Important Dates

Effective Date: 03/12/2014

Expiration Date: N/A

Term End Date: N/A

Dissolved Date: N/A

Registered Agent

Agent: CT CORPORATION SYSTEM

Address: 2 OFFICE PARK COURT, SUITE 103
COLUMBIA, South Carolina 29223

Official Documents On File

Filing Type	Filing Date
Amendment	04/24/2014
Organization	03/12/2014

Former Names

Name	Filing Date
NEPHRON COMPOUNDING CENTER LLC	03/14/2014

PRC1035984

PERMIT NO. 16464
DATE ISSUED 05/20/2019

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

Outsourcing Facility Permit

2019-2020

Expires 06/30/2020

NEPHRON STERILE COMPOUNDING CENTER, LLC
Permit Holder: WILLIAM P. KENNEDY
4500 12th ST EXT
WEST COLUMBIA SC 29172

(Spencer A. Morris, Chairman

Eric Strauss, Vice Chairman

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)

- Information Concerning Outsourcing Facility Registration
- Outsourcing Facility Product Reporting Information

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility	Date of Most Recent Registration as an Outsourcing Facility	End Date of Last FDA Inspection Related to Compounding	Was a Form FDA 483 Issued?	Other Action, if Any, Based on Last Inspection*	Intends to Compounds Sterile Drugs From Bulk Drug Substances*

Nevada State Board of Pharmacy

Online reporting of disciplinary action is currently being updated. For current information on disciplinary actions taken against licensees please contact Board Staff at shunting@pharmacy.nv.gov (mailto:shunting@pharmacy.nv.gov) or (775) 850-1440.

VERIFY LICENSE

Last Name	First Name	License#	City	State	Country	Discipline	Action
Tolman	Stuart	10916	TROUTMAN	NC	United States	None	

License Number : 10916
Name : Tolman, Stuart
License Type : Pharmacist
License Status : Active
License Date : 03/04/1992
Discipline :
Expiration Date : 10/31/2021

State of Incorporation: South Carolina
Corporate Address:
4500 12th Street Extension
Columbia, SC 29172
Parent Company: Nephron Inc.
FEIN: 37-175-2439

Nephron Sterile Compounding Center LLC Corporate Officers

Name	Title	Business Contact Information	Date of Birth
William Kennedy	Director (49%)	4500 12th St. Ext. West Columbia, SC 29172	
Lou Kennedy	President, CEO, Owner (17%)	4500 12th St. Ext. West Columbia, SC 29172	
Ashley Kennedy Whitner	Vice President Owner (17%)	4500 12th St. Ext. West Columbia, SC 29172	
Courtney Kennedy McGowan	Vice President Owner (17%)	4500 12th St. Ext. West Columbia, SC 29172	
Daniel Stoner	Secretary/ Treasurer	4500 12th St. Ext. West Columbia, SC 29172	

NEPHRON SC, INC.

A South Carolina Corporation

STOCK TRANSFER LEDGER

Cert. No.	Date	No. of Shares	Issued To	Transfer			
				Date	To Cert. No.	To Whom Transferred	Shares
Authorized Issuance: ***10,000 shares of Common Stock, of which 1,000 shares are Class A Voting Common Stock @ No Par Value and 9,000 shares are Class B Non-Voting Common Stock @ No Par Value***							
CLASS A VOTING COMMON STOCK							
1A	11/4/2011	340	Courtney Berry Kennedy McGowan and Ashley Elizabeth Kennedy, Co-Trustees of the Kennedy Family Irrevocable Trust U/A dated August 16, 2002 (IDIT)				
2A	11/4/2011	170	Lou Wood Kennedy, Trustee of the Lou Wood Kennedy Trust U/A dated September 10, 2007 (QTIP)				
3A	11/4/2011	490	William P. Kennedy, Trustee of the William Kennedy Revocable Trust dated August 16, 2002				
CLASS B NON-VOTING COMMON STOCK							
1B	11/4/2011	3,060	Courtney Berry Kennedy McGowan and Ashley Elizabeth Kennedy, Co-Trustees of the Kennedy Family Irrevocable Trust U/A dated August 16, 2002 (IDIT)				
2B	11/4/2011	1,530	Lou Wood Kennedy, Trustee of the Lou Wood Kennedy Trust U/A dated September 10, 2007 (QTIP)				
3B	11/4/2011	4,410	William P. Kennedy, Trustee of the William Kennedy Revocable Trust dated August 16, 2002				

NEPHRON SC, INC.

A South Carolina Corporation

RECORD OF SHAREHOLDERS

Name of Shareholder	Certificate No.	Date of Issuance	No. of Shares Issued (this certificate)	Total Cumulative Shares Issued	Ownership Percentage
CLASS A VOTING COMMON STOCK					
Courtney Berry Kennedy McGowan and Ashley Elizabeth Kennedy, Co-Trustees of the Kennedy Family Irrevocable Trust U/A dated August 16, 2002 (IDIT) Special Trustee: Christopher E. Erblich	1A	11/4/2011	340	340	34%
Lou Wood Kennedy, Trustee of the Lou Wood Kennedy Trust U/A dated September 10, 2007 (QTIP) Special Trustee: Christopher E. Erblich	2A	11/4/2011	170	170	17%
William P. Kennedy, Trustee of the William Kennedy Revocable Trust dated August 16, 2002 Special Trustee: Christopher E. Erblich	3A	11/4/2011	490	490	49%
TOTAL CLASS A VOTING:				1,000	100%
CLASS B NON-VOTING COMMON STOCK					
Courtney Berry Kennedy McGowan and Ashley Elizabeth Kennedy, Co-Trustees of the Kennedy Family Irrevocable Trust U/A dated August 16, 2002 (IDIT) Special Trustee: Christopher E. Erblich	1B	11/4/2011	3,060	3,060	34%
Lou Wood Kennedy, Trustee of the Lou Wood Kennedy Trust U/A dated September 10, 2007 (QTIP) Special Trustee: Christopher E. Erblich	2B	11/4/2011	1,530	1,530	17%
William P. Kennedy, Trustee of the William Kennedy Revocable Trust dated August 16, 2002 Special Trustee: Christopher E. Erblich	3B	11/4/2011	4,410	4,410	49%
TOTAL CLASS B NON-VOTING:				9,000	100%

RECAPITULATION OF VOTING AND NON-VOTING OWNERSHIP						
Shareholder	**Voting**		**Non-Voting**		**Combined Voting & Non-Voting**	
	Shares	**% of Total Shares (10,000)**	**Shares**	**% of Total Shares (10,000)**	**Shares**	**% of Total Shares (10,000)**
Courtney Berry Kennedy McGowan and Ashley Elizabeth Kennedy, Co-Trustees of the Kennedy Family Irrevocable Trust U/A dated August 16, 2002 (IDIT)	340	3.4%	3,060	30.6%	3,400	34%
Lou Wood Kennedy, Trustee of the Lou Wood Kennedy Trust U/A dated September 10, 2007 (QTIP)	170	1.7%	1,530	15.3%	1,700	17%
William P. Kennedy, Trustee of the William Kennedy Revocable Trust dated August 16, 2002	490	4.9%	4,410	44.1%	4,900	49%
TOTALS:	**1,000**	**10%**	**9,000**	**90%**	**10,000**	**100%**

15E

5-11-2020

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: OPS International Inc. dba Olympia Pharmacy

Physical Address: 6700 Conroy Rd, Ste 155

City: Orlando State: FL Zip Code: 32835.

Telephone: 407-673-2222 Fax: 407-673-1234

Toll Free Number: 1-833-684-0495 (Required per NAC 639.708)

E-mail: confidence@OlympiaPharmacy.com Website: www.OlympiaPharmacy.com

Supervising Pharmacist: Brittney Baker Nevada License #: 20400 OK 10/31/2

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: 5.12.2020 Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3009724085

Please provide the name of the facility as registered with the FDA and the registration number:
OPS International Inc. dba Olympia Pharmacy; 017674368

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
Olympia Pharmacy

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Britney Baker Nevada License Number: 20400

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: NIA

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

Marco Loleit

Print Name of Authorized Person

5-4-2020

Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: FL

Parent Company if any: N/A

Address: 6700 Conroy Rd, Ste 155

City: Orlando State: FL Zip: 32835

Telephone: 407-673-2222 Fax: 407-673-1234

Contact Person: Confidence Ekeanyanwu

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

① 100% owner of business

a) ① Marco Loleit - E. Jackson Street, Orlando, FL 3280
Name Address

b) _____
Name Address

c) N/A
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? _____

4) What date did the corporation actually receive the cash assets? _____

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 7**

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Marco Loleit (100% of business owned)

Business Name: OPS International Incorporated

Current Business Address: 6700 Corroy Rd, Ste 155

City: Orlando State: FL Zip Code: 32835.

Telephone: 407-673-2222 Fax: 407-673-1234

List any physician shareholders and percentage of ownership.

Name: NA %:

Name: N %:

Name: X %:

Name: %:

OLYMPIA
COMPOUNDING PHARMACY
FDA REGISTERED 503B OUTSOURCING FACILITY

6700 Conroy Rd, Ste 155
Orlando, FL 32835
Phone (407) 673 2222

To Whom It May Concern:

I, Marco Loleit, is the sole 100% owner of OPS International Inc. DBA Olympia Pharmacy. Olympia Compounding Pharmacy is an FDA registered outsourcing facility; a full service pharmacy for the compounding (admixture) of sterile and non-sterile specialty medications for consumers.

The Pharmacy is open for operation AND call to its toll-free number at (888) 323-7788 **Monday through Friday, 9am to 6pm, Saturdays, 9am-1pm, closed on the Sundays.** Patients during these hours of operation have access to a Pharmacist who in turn has access to patient records in the McKesson pharmacy system.

Please do contact me at marco@olympiapharmacy.com for any further questions in this regard and for any future commitments.

Thank You,

Marco Loleit.

OLYMPIA
COMPOUNDING PHARMACY
FDA REGISTERED 503B OUTSOURCING FACILITY

5 May 2020

To Whom It May Concern:

We wanted to inform since we are certain it is difficult to track these details, occurrences since our April 13th concluded FDA inspection. The inspection resulted in the attached FDA 483 notice, we initiated a response with corrective actions, the first and last of those responses are also attached.

Thereafter, we got a notice from the agency for a regulatory meeting in Dallas, Texas. The meeting was to discuss our corrective actions thus far and reconcile details with the agency since it had been a lot of paperwork back and forth. The outcome of the regulatory meeting held September 12th, 2019 was a Voluntary Action Indicated status. We continue to update the agency on quality improvements with the last of our updates to the agency in March of this year attached for your review as well.

Please feel free to contact me for any further clarification.

Thank You,

05May20

OLYMPIA
COMPOUNDING PHARMACY
FDA REGISTERED 503B OUTSOURCING FACILITY

Confidence Ekeanyanwu
Quality & Regulatory Manager
Olympia Compounding Pharmacy
FDA Registered 503B Outsourcing Facility
6700 Conroy Rd # 155 Orlando, FL 32835
Mobile: (407) 664-6608
Phone: (407) 673-2222
Fax: (407) 673-1234

"Knowledge is power. Information is liberating. Education is the premise of progress, in every society, in every family."
-Kofi Annan.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	DATE(S) OF INSPECTION 4/6/2018-4/13/2018* FEI NUMBER 3009724085
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Marco Loleit, CEO & Owner	
FIRM NAME OPS International Incorporated D/B/A Olympia Pharmacy	STREET ADDRESS 6700 Conroy Rd Ste 155
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

A. Your procedure, Complaint Handling, P-219, Version 2, 28 July 16, fail to provide minimum requirements for an adequate investigation to be conducted in order to determine a root cause, customer complaint assessment requirements to assess for ADR reportability, and the documentation of such actions.

B. Your quality unit failed to have conducted and documented an ADR assessment as part of the following received customer complaints where your firm was made aware of potential side effects for your firm's compounded sterile drug products.

1. CC-2017-005, received 3/31/2017, RX # 4015834 for compounded sterile drug, 10 Testost CYP 200MG/ML *10 ML* Inj., Lot # A3218.

2. CC-2017-004, received 3/29/2017, RX # 4013414 for compounded sterile drug, 20 Testost CYP 200MG/ML *10 ML* Inj, Lot # 11725.

3. CC-2017-001, received 2/17/2017, RX # 6143784 for compounded sterile drug, 600 Polidocanol 0.35% MDV (30 ML).

4. CC-2017-013, received 8/31/2017, RX # 6185196 for compounded drug, 60 Estriol .1 MG/CLOBET .5% PETROL, Lot # H0016.

C. Your quality unit failed to adequately document and conduct an investigation into the following customer complaints to determine the root cause, and assign appropriate corrective action(s) the customer reported issues:

1. CC-2018-05, received 3/28/2018, documents your firm shipping s Rx # 6248938, T-50 (PAP 8.8/PHE 0.29/AP 2.9) to the incorrect patient address. Your quality unit failed to adequately investigate to determine the root cause and document corrective actions to

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator X Cameron E Moore Investigator Signed By: Cameron E. Moore -S Date Signed: 04-13-2018 19:13:08	DATE ISSUED 4/13/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	4/6/2018-4/13/2018* FEI NUMBER 3009724085

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marco Loleit, CEO & Owner

FIRM NAME	STREET ADDRESS
OPS International Incorporated D/B/A Olympia Pharmacy	6700 Conroy Rd Ste 155
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orlando, FL 32835-3515	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

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

A. On 4/9/2018, your technician was observed in Buffer Room 2 (ISO 5 Classified) as having her neck exposed sporadically between the worn sterile hood and gown while aseptic manipulating a bag to bag sterile filtration transfer of drug product, PGE-2, Lot # D3009.

B. On 4/9/2018, during EM sampling at shift end, your pharmacy technician was observed within your Non-Hazardous ISO 7, Prep Room 1 without being adequately gowned while collecting EM samples. Your technician failed to follow your firm's gowning clean room procedure, Hand Hygiene and Garbing, P-404, Version 3, by not wearing a sterile gown.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Camerson E Moore, Investigator X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed 04-13-2018 19:13 CS	4/13/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	DATE(S) OF INSPECTION 4/6/2018-4/13/2018* FEI NUMBER 3009724085
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Marco Loleit, CEO & Owner	
FIRM NAME OPS International Incorporated D/B/A Olympia Pharmacy	STREET ADDRESS 6700 Conroy Rd Ste 155
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

prevent the recurrence.

2. CC-2018-06, received 3/30/2018, documents your firm's failure to apply an auxiliary label on the finished drug product, RX # 6250411, TRIMIX (PA 15/PH .5/PG 5) Injection, which documents the sterile finished compounded drug storage conditions.

3. CC-2018-03, received 3/27/2018, documents your firm's shipping the incorrect finished compounded drug to a customer. Your firm incorrectly shipped HCG 10000, Lot # B18A12, BUD 2/19 instead of the correct sterile compounded sterile drug product HCG 5000, Lot # C18005, BUD 3/19.

4. CC-2017-011, received 8/28/17, documents your firm failure to document and have objective evidence in support of such corrective action. Complainant reported receiving Rx # 4019639 identified on the patient specific label incorrectly as 30 Testost 0.1% (I MG/ML) Cream. The compounded drug should have been labeled as 30 Testosterone 1% (10MG/ML) CRM on the patient specific label.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

D. Your procedure, Cleaning-Sterilizing and Disinfecting of the Compounding Facility, P-304, Version 4 require the use of STERIS Spor-Klenz-Ready to Use (Sterliant/Sporicidal) with a contact time of 10 minutes, and PeridoxRTU Ready to Use (Disinfectant) with a contact time of 10 minutes for weekly and monthly clean room cleaning but fail to require the documentation of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Cameron E Moore, Investigator	DATE ISSUED 4/13/2018

X Cameron E Moore Investigator Signed By: Cameron E. Moore -S Date Signed: 04-13-2018 19:13:08

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	DATE(S) OF INSPECTION 4/6/2018-4/13/2018* FEI NUMBER 3009724085
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Marco Loleit, CEO & Owner	
FIRM NAME OPS International Incorporated D/B/A Olympia Pharmacy	STREET ADDRESS 6700 Conroy Rd Ste 155
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

contact times as a form of verification for activity. Your documented contact time for STERIS Spor-Klenz-Ready to Use (Sterliant/Sporicidal) of 10 minutes failed to meet the manufacturers requirement of 30 minutes.

E. Your firm fails to have scientific data and or performed any studies in support STERIS Alcare Plus Hand Sanitizer effectiveness as a disinfectant on sterile gloves used within your ISO 8, ISO 7, and ISO 5 classified clean room. The sanitizer is labeled as a hand disinfectant. STERIS Alcare Plus Hand Sanitizer labeling contains no information reporting it as being sterile and appropriate for use on gloves. STERIS Alcare Plus Hand Sanitizer has been used as a disinfectant on sterile gloves since 2015.

OBSERVATION 4

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically, no lyophilized sterile drug product reconstitution specification has been established to be used as part of the released criteria prior finished sterile drug product distribution. For example, your firm failed to establish a reconstitution specification for the release of the following drug products:

- HCG
- Sermorelin
- Sermorelin GHRP

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator	DATE ISSUED 4/13/2018

X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 04-13-2018 19:13:08

Detailed Response to Form FDA-483 Dated 13APR18

OLYMPIA
COMPOUNDING PHARMACY
FDA REGISTERED 503B OUTSOURCING FACILITY

03MAY18

OLYMPIA
COMPOUNDING PHARMACY
FDA REGISTERED 503B OUTSOURCING FACILITY

6700 Conroy Road, Suite 155
Orlando, FL 32835
407-673-2222

Thursday, May 3, 2018

Ms. Monica Maxwell
Program Division Director
United States Food and Drug Administration
4040 North Central Expressway, Suite 300
Dallas, TX 75204

Good Day Ms. Maxwell,

We are writing in response to the FDA Form-483 observations issued on April 13, 2018 regarding the inspection of OPS International Incorporated DBA Olympia Pharmacy, located at 6700 Conroy Road, Suite 155, Orlando, FL 32835. Olympia takes FDA's observations very seriously and as such, we are continuing to make improvements to ensure compliance with all applicable laws and regulations. The goal is to protect patients with respect to sterility assurance and product quality which includes compliance with Title 21 CFR Parts 210 and 211.

Below is a detailed response to each observation issued, along with supporting documentation references and commitments. **Table 1** outlines the list of future commitments to the agency with respect to the observation items, while **Table 2** outlines the attachments corresponding to the detailed responses given.

We intend to provide at least one more response to the agency in 90-days specifying the status of the listed commitment action items toward the facility's quality improvement program and continue with reports every six-months thereafter until all commitments have been completed.

We appreciate the opportunity to continue working together with the FDA are fully committed to implementing the DQSA requirements in a way that preserves access to compounded drugs for patients who have a medical need for them, while protecting patients from poor quality or otherwise unsafe compounded drugs that could cause them serious harm.

For any questions or additional clarifications, please feel free to contact us at any time.

Sincerely,

03MAY2018

Marco Loleit
Chief Executive Officer
Olympia Compounding Pharmacy
Mobile: 407-267-6468
Email: marco@olympiapharmacy.com

03May2018

Confidence Ekeanyanwu
Quality Manager
Olympia Compounding Pharmacy
Mobile: 781-686-0640
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NOTE:

- Form FDA-483 text is represented with Bold, Italic text.
- **Table 1** at the end of the document contains the Commitments to FDA outlined throughout this response letter and their due dates.
- **Table 2** contains the Attachment List.

OBSERVATION 1

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

A. On 4/9/2018, your technician was observed in Buffer Room 2 (ISO 5 Classified) as having her neck exposed sporadically between the worn sterile hood and gown while aseptic manipulating a bag to bag sterile filtration transfer of drug product, PGE-2, Lot# D3009.

OLYMPIA'S RESPONSE (1A):

In response to this observation, the Technician was immediately pulled from the cleanroom during the inspection. Deviation D-2018-05 was initiated to investigate this event. The completed and approved deviation can be found in **Attachment 1**. It was determined that the reason for the neck exposure was the Technician's hair in a bun, which caused the hood to bulge out in the back. The root cause of the event was due to the way the hair was tied creating a bulge within the garb hood. Gowning material used, and the general gowning process were found to be adequate and no changes are required. There is no impact to the product that was being filtered as all other environmental monitoring and personnel monitoring passed for the day, and PGE-2 lot # D3009 was ultimately discarded in response to Observation 6. As part of the deviation, the event was discussed with the Technician by the Quality Manager. No additional corrective actions were deemed necessary as this was determined to be a single incident due to the Technician's hair bun.

B. On 4/9/2018, during EM sampling at shift end, your pharmacy technician was observed within your Non-Hazardous ISO 7, Prep Room 1 without being adequately gowned while collecting EM samples. Your technician failed to follow your firm's gowning clean room procedure, Hand Hygiene and Garbing, P-404, Version 3, by not wearing a sterile gown.

OLYMPIA'S RESPONSE (1B):

We have undertaken a comprehensive and on-going corrective action identifying several changes to the control systems in place governing the aseptic technique and garbing protocol. Deviation D-2018-06 and CAPA 2018-02 were initiated to investigate and correct this event during the inspection. The deviation and CAPA documents were shown in draft form to the Inspector in immediate action for the observation to investigate the event. Completion of the investigation for D-2018-06 and execution of CAPA 2018-02 can be found as **Commitment 1** in **Table 1.**

OBSERVATION 2

The responsible procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. ***Your procedure, Complaint Handling, P-219, Version 2, 28 July 16, fail to provide minimum requirements for an adequate investigation to be conducted in order to determine a root cause, customer complaint assessment requirements to assess for ADR reportability, and the documentation of such actions.***

OLYMPIA'S RESPONSE (2A):

During the inspection the inspector was briefed on changes that were in the process of being implemented for the complaint system, specifically surrounding adverse events. This was a known deficiency within the complaint process, and Olympia was taking steps to correct it prior to the inspection. A draft copy of policy P-219, Drug Safety and Surveillance Program, which included new requirements for adverse event evaluation, investigation requirements, root causes analysis, FDA reporting, and documentation of these activities, was reviewed with the inspector. The revised procedure has since been approved and made effective on 27APR18 and can be found in **Attachment 2**.

B. ***Your quality unit failed to have conducted and documented an ADR assessment as part of the following received customer complaints where your firm was made aware of potential side effects for your firm's compounded sterile drug products.***
   1. ***CC-2017-005, received 3/31/2017, RX# 4015834 for compounded sterile drug, 10 Testost CYP 200MG/ML *10 ML* Inj., Lot# A3218.***
   2. ***CC-2017-004, received 3/29/2017, RX# 4013414 for compounded sterile drug, 20 Testost CYP 200MG/ML * 10 ML* Inj, Lot# 11725.***
   3. ***CC-2017-001, received 2/17/2017, RX# 6143784 for compounded sterile drug, 600 Polidocanol 0.35% MDV (30 ML).***
   4. ***CC-2017-013, received 8/31/2017, RX# 6185196 for compounded drug, 60 Estriol 0.l MG/CLOBET 0.5% PETROL, Lot# H0016.***

OLYMPIA'S RESPONSE (2B):

After the revised P-219 was made effective as part of the response to Observation 2A, the complaints listed above will be re-evaluated under the new complaint and adverse event process. This includes an adverse event evaluation, investigation, root cause analysis, and CAPA requirements to be determined and documented in F-219. Completion of this re-evaluation of the above complaints can be found as **Commitment 2** in **Table 1.** As part of the initial investigations for these complaints, it was determined that no adverse event reporting to FDA was required for these events. The summary evaluation conducted as a start to registering the observed complaints

in the revised complaint system can be found as **Attachment 3**.

C. ***Your quality unit failed to adequately document and conduct an investigation into the following customer complaints to determine the root cause, and assign appropriate corrective action(s) the customer reported issues:***

1. ***CC-2018-05, received 3/28/2018, documents your firm shipping s Rx# 6248938, T-50 (PAP 8.8/PHE 0.29/AP 2.9) to the incorrect patient address. Your quality unit failed to adequately investigate to determine the root cause and document corrective actions to prevent the recurrence.***
2. ***CC-2018-06, received 3/30/2018, documents your firm's failure to apply an auxiliary label on the finished drug product, RX# 6250411, TRIMIX (PA 15/PH .5/PG 5) Injection, which documents the sterile finished compounded drug storage conditions.***
3. ***CC-2018-03, received 3/27/2018, documents your finn's shipping the incorrect finished compounded drug to a customer. Your firm incorrectly shipped HCG 10000, Lot# Bl8Al2, BUD 2/19 instead of the correct sterile compounded sterile drug product HCG 5000, Lot# Cl 8005, BUD 3/19.***
4. ***CC-2017-011, received 8/28/17, documents your firm failure to document and have objective evidence in support of such corrective action. Complainant reported receiving Rx# 4019639 identified on the patient specific label incorrectly as 30 Testost 0.1 % (I MG/ML) Cream. The compounded drug should have been labeled as 30 Testosterone 1 % (IOMG/ML) CRM on the patient specific label.***

OLYMPIA'S RESPONSE (2C):

See Olympia's Response for Observation 2B.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A. ***Your procedure, Cleaning-Sterilizing and Disinfecting of the Compounding Facility, P-304, Version 4 require the use of STERJS Spor-Klenz-Ready to Use (Sterilant/Sporicidal) with a contact time of 10 minutes, and PeridoxRTU Ready to Use (Disinfectant) with a contact time of 10 minutes for weekly and monthly clean room cleaning but fail to require the documentation of contact times as a form of verification for activity. Your documented contact time for S'TERIS Spor-Klenz-Ready to Use (Sterilant/Sporicidal) of 10 minutes failed to meet the manufacturers requirement of 30 minutes.***

OLYMPIA'S RESPONSE (3A):

We have revised P-304, Cleaning-Sterilizing and Disinfecting of the Compounding Facility, to include hard coded locations on the cleaning forms to record contact time start time and end times in response to this observation. The revision also included clarification of the contact times for Steris Spor-Klenz-Ready to Use and PeridoxRTU. The manufacturer's specification for contact time for Steris Spor-Klenz-Ready to Use for use as a sterilant is 10 minutes, and for use as a sporicidal agent is 30 minutes. We have included both options in the procedure as Steris Spor-Klen-Ready to Use will be part of the rotation of cleaning agents for both sterilant and sporicidal use. The revised P-304 can be found in **Attachment 4**.

B. ***Your firm fails to have scientific data and or performed any studies in support S'TERIS Alcare Plus Hand Sanitizer effectiveness as a disinfectant on sterile gloves used within your ISO 8, ISO 7, and ISO 5 classified clean room. 'The sanitizer is labeled as a hand disinfectant. S'TERIS Alcare Plus Hand Sanitizer labeling contains no information reporting it as being sterile and appropriate for use on gloves. S'TERIS Alcare Plus Hand Sanitizer has been used as a disinfectant on sterile gloves since 2015.***

OLYMPIA'S RESPONSE (3B):

CAPA 2018-03 was initiated and completed during the inspection in response to this observation, which can be found as **Attachment 5**. The CAPA states that the Alcare Plus Hand Sanitizer was removed from the cleanrooms. The revised P-304, Cleaning-Sterilizing and Disinfecting of the Compounding Facility found in **Attachment 4** includes the change to remove the Alcare Plus Hand Sanitizer from use. Sterile 70% IPA shall be used in the cleanrooms for disinfecting the hands during compounding.

OBSERVATION 4

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release. Specifically, no lyophilized sterile drug product reconstitution specification has been established to be used as part of the released criteria prior finished sterile drug product distribution. For example, your firm failed to establish a reconstitution specification for the release of the following drug products:

- ***HCG***
- ***Sermorelin***
- ***Sermorelin GHRP***

OLYMPIA'S RESPONSE (4):

We have created **Commitment 3** in **Table 1** for performing a study for determining the time for dissolution from solid to liquid state for lyophilized products. This study is in addition to the already completed reconstituted product hold time study supporting a 45-day BUD under 2-8°C refrigerated storage condition. After this study is performed, P-217, Sterile Drug Product

Specifications at Olympia Pharmacy, will be revised to include dissolution time testing as part of the release criteria for lyophilized products, and the dissolution time will be added to the Instructions for Use for these drugs that is provided with each prescription dispensed. In addition to the results for a potency, endotoxin, and sterility report for the finished compound, the dissolution time for the specific batch shall also be reported.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically, on 4/9/2018, your pharmacy technician was observed touching door between Ante Room I (ISO 8 Classified) and Prep Room I (ISO 7 Classified) during the entry and exiting of the two rooms at the time of batch compounding mixing the drug product, PGE-2, Lot# D3009 without re-sanitizing sterile gloved hands with 70/30 % IP A while transferring components in preparation for compound batch mixing.

OLYMPIA'S RESPONSE (5):

The Technician noted in this observation has been re-trained on appropriate aseptic technique. There is no impact to the product that was being filtered as all other environmental monitoring and personnel monitoring passed for the day, and PGE-2 lot # D3009 was ultimately discarded in response to Observation 6. The training documentation can be found in **Attachment 6**.

OBSERVATION 6

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your procedure, Policy on the Environmental and Personnel Monitoring Program, P-21I, Version 7 reports the daily recording of differential pressure shall be performed for all room. Your differential pressures are recorded once per day and visually observe throughout the course of the day. On 4/9/2018, your firm was observed compounding the sterile drug product, PGE-2, Lot# D3009 which you began compounding at 2 :20 pm and finished undergoing your auto fill process at 5: 13 pm. Your recorded differential pressure for the non-hazardous clean room occurred at 7:00 am. No recorded differential pressure readings are available for the time in which the sterile drug PGE-2 was mixed, compounded, and filled to show no excursions in differential pressure occurred.

OLYMPIA'S RESPONSE (6):

We have requested and received a quote from Primex for the installation of a continuous monitoring system for differential pressure for the cleanroom facilities. This quote can be found in **Attachment 7.** We are currently evaluating the quote as well as awaiting additional quotes to determine the appropriate system to be installed for our cleanrooms. Installation of a system for

continuous monitoring of differential pressures can be found as **Commitment 4** in **Table 1.** Additionally, P-211, Policy on the Environmental and Personnel Monitoring Program, and P-212, Environmental Monitoring, will be revised after installation of the continuous monitoring system to reflect the change. The revision of these documents can be found as **Commitment 5** in **Table 1.** In the interim until the installation is completed, the compounding formulation sheets have been revised to include a section to record the differential pressure for prior to and at the completion of production activity specific to each compounded product. A sample of this is shown as **Attachment 8** for a Lidocaine 1% Compounding formulation worksheet.

OBSERVATION 7

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 a review of your 2017 smoke study for your Colanar Automated Modular Vial Filling System located in your non-hazardous sterile clean room, Buffer Room 3, failed to adequately assess the most complicate filling configuration to ensure equipment appropriately designed and unidirectional air flow in the prevention of contamination that would alter the safety, identify, strength, quality, or purity of the sterile finished drug product. The firm's smoke study only assessed the filling for 12 of 64 10 mL clear vials in a tray.

OLYMPIA'S RESPONSE (7):

In response to this observation, we initiated a work order to perform an additional smoke study for Buffer Room 3 to include dynamic operation of the Colanar Automated Modular Vial Filling System. This smoke study was completed by Micro Filtration on 26APR18. A copy of the work order and the new smoke study video can be found as **Attachment 9.**

OBSERVATION 8

Product Reporting:

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B (b)(2)(A). The following are examples of products that were compounded and not identified on your December 2017 product report:

- ***a. Alprostadil (PGE) 250 mcg/mL***
- ***b. 300 mcg/mL and 350 mcg/mL injection***
- ***c. anastrozole 0.5 mg and 0.75 mg capsule***
- ***d. ascorbic acid 250 mg/mL and 500 mg/mL MDV***
- ***e. avanafil 200 mg and 300 mg troche***
- ***f. bacteriostatic water***
- ***g. estradiol cypionate/testosterone cypionate 2 mg/50 mg/mL***
- ***h. estradiol cypionate 2 mg/mL and 5 mg/mL injection***

i. *L-carnitine 500 mg/mL MDV*
j. *Lysine 62.5 mg/arginine 50 mg cream*
k. *papaverine 30 mg/mL injection MDV*
l. *phenylephrine 1 mg/mL injection*
m. *sildenafil citrate 110 mg and 150 mg troch*
n. *tadalafil 20 mg, 25 mg, 40 mg, and 75 mg troche*
o. *terbutaline 3 mg capsule*
p. *vardenafil 40 mg and 75 mg troche*
q. *Vitocin (oxytocin) spray 401U/spray*
r. *zinc chloride 10 mg/mL MDV.*

This is not an all-inclusive list.

OLYMPIA'S RESPONSE (8):

With the initial use of the SPL reporting system for reporting away from the excel sheet method, several technical difficulties were encountered as far as finding the drug actives and the form of entry. We communicated with Mr. Troy Cu, a CDER Technical Information Specialist, to address these issues. We entered what was able to be entered into the system at the time, but due to the technical issues, we were unable to add all drugs. The omissions were not intentional, but due to a technical issue from the transition to the new SPL reporting system. As part of the response to this observation, we attempted to edit the 2017 report to include the missing drugs but encountered the same technical issue. We have another request for help from Mr. Troy Cu. Therefore, we have created a commitment to revise the 2017 report, as well as perform a comparison of the report to the drugs compounded to what was submitted ensure all drugs are included. This activity can be found as **Commitment 6** in **Table 1**.

OBSERVATION 9

Product Labeling:

The labels of some of your outsourcing facility's drug products do not include information required by section 503B(a)(l 0)(A). Specifically,

A. *The exact date the drug was compounded. Examples of product labels that do not contain this information include:*
   - *NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 30 mcg/ml)*
B. *The expiration date. Examples of product labels that do not contain this information include:*
   - *NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 30 mcg/ml)*
C. *Lot or batch number. Examples of product labels that do not contain this information include:*
   - *NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 30 mcg/ml)*
D. *A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Examples of product labels that do not contain this information include:*

- ***NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 30 mcg/ml)***
- ***QM4 (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 300 mcg/ml; atropine 0.2 mg/ml)***

OLYMPIA'S RESPONSE (9):

We have reviewed the labels provided to the inspector and would like to clarify parts A-C of this observation, as all three of these requirements were included on the label provided. There may have been some confusion during review due to the labels being presented within the batch record and which label is on the units themselves. Both labels presented on the batch record can be used as the final unit label. The NB-343 labels provided to the Inspector can be found in **Attachment 10**. The date of compounding (printed as "CPD 03 14 18" or "CPD 14 MAR 18" on the labels), the expiration date (printed as "BUD 03/19" on the labels), and the lot number (printed as "Lot C18014 on the labels) can be found on the black strip portion of the label. We recognize that the single inactive ingredient "Sterile Water" is only included on one of the two labels for both NB-343 and QM-4. We have revised the labels to include "Sterile Water." A copy of the label proof for NB-343 and QM-4 can be found in **Attachment 11**. The use of these labels was made effective on 30APR18.

OBSERVATION 10

The containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10) (B).

Specifically,

A. ***The phone number, 1-800- FDA-1088, to facilitate adverse event reporting. Examples of product labels that do not contain this information include:***
   - ***NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; Alprostadil 30 mcg/ml) Polidocanol 2% injection***
   - ***Sodium bicarbonate 8.4% injection***
   - ***Testosterone cypionate 200 mg/ml injection***
   - ***HCG 10,000IU (lyophilized powder)***

OLYMPIA'S RESPONSE (10):

We have created an auxiliary label that will be affixed on the outer product container for the product unit that includes FDA's phone number for the adverse reporting line. As this auxiliary label was already part of the labeling process and procedure, no additional revisions are required. Please note that the current labels include the adverse reporting website. A sample of this revised label can be found in **Attachment 12**.

Table 1: Future Commitments to FDA

No.	Description of Action Required	Due on or Before	Status	Related FDA Observation	Attachment No.
1	Completion of D-2018-06 and execution of CAPA 2018-02.	08JUL18	In-Progress	1B	N/A
2	Complete re-evaluation of complaints for observation under the revised Drug Safety and Surveillance system.	31MAY18	In-Progress	2B & 2C	N/A
3	Perform study for time for dissolution from solid to liquid state for lyophilized drugs. Revise P-217 and IFUs once times are determined.	31JUL18	In-Progress	4	N/A
4	Installation of Continuous Differential Pressure monitoring system.	31JUL18	Quote	6	7
5	Revised P-211 and P-212 to include the Differential Pressure continuous monitoring system.	31JUL18	Not Started	6	N/A
6	Revise 2017 drug report and perform a comparison of the updated drug report to drugs compounded to ensure all drugs from reporting period are included.	31MAY18	In-progress	8	N/A

Table 2: Attachments

No.	Document No. Reference	Attachment Description	Related Observation Number	Approval Date
1	D-2018-05	Deviation Record for gowning neck exposure	1A	16APR18
2	P-219, Version 3	Drug Surveillance and Safety Program	2A	27APR18
3	N/A	Complaint Summary	2B	N/A
4	P-304, Version 5	Cleaning-Sterilizing and Disinfecting of the Compounding Facility	3A, 3B	30APR18
5	CAPA-2018-03	CAPA Record for removal of Alcare Plus Hand Sanitizer	3B	30APR18
6	N/A	Aseptic Training and Qualifier for Technician	5	N/A
7	N/A	Quotation from Primex for Differential Pressure System	6	N/A
8	N/A	Sample Compounding Formula Worksheet for Differential Pressure Data	6	N/A
9	N/A	Copy of Work Order and Revised Smoke Study	7	N/A
10	N/A	Labels provided from inspection - NB343 & QM-4	9	14MAR18
11	N/A	Label Proof for NB-343 and QM-4	9	30APR18
12	N/A	Revised auxiliary label	10	30APR18

OLYMPIA
COMPOUNDING PHARMACY
FDA REGISTERED 503B OUTSOURCING FACILITY

6700 Conroy Road, Suite 155
Orlando, FL 32835
407-673-2222

Wednesday, August 22, 2018

LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II
FDA/Office of Regulatory Affairs
John.diehl@fda.hhs.gov
4040 North Central Expressway, Suite 300
Dallas, TX 75204

Good Day Mr. Diehl,

We are writing to update the agency on the status of the commitments we made in our initial response to the FDA Form-483 observations issued on April 13, 2018 regarding the inspection of OPS International Incorporated DBA Olympia Pharmacy, located at 6700 Conroy Road, Suite 155, Orlando, FL 32835. As described in our detailed response below, Commitments 1, 2, 4, 5, and 6 are complete. Commitment 3 is currently in progress.

It is imperative to mention that Olympia is committed to continuously improve our systems and processes. We strive to make improvements and uphold integrity in all aspects of service that we provide for quality and safety in patient care.

For any questions or additional clarifications, please feel free to contact us at any time. We appreciate the opportunity to continue working together with the FDA and are fully committed to implementing the DQSA requirements in a way that preserves access to compounded drugs for patients in need.

Sincerely,

Confidence Ekeanyanwu
Quality Manager
Olympia Compounding Pharmacy
Mobile: 781-686-0640
Email: confidence@olympiapharmacy.com

NOTE:

- **Table 1** contains the Commitments to FDA outlined in the initial response letter and their due dates.
- **Table 2** contains the Attachment List for this response.

Table 1: Commitments to FDA

No.	Description of Action Required	Due on or Before	Status	Related FDA Observation	Related Attachment No.
1	Completion of D-2018-06 and execution of CAPA 2018-02.	08JUL18	**Complete**	1B	1 & 2
2	Complete re-evaluation of complaints for observation under the revised Drug Safety and Surveillance system.	31MAY18	**Complete**	2B & 2C	3 & 4
3	Perform study for time for dissolution from solid to liquid state for lyophilized drugs. Revise P-217 and IFUs once times are determined.	~~31JUL18~~ 31OCT18	**In-Progress**	4	5
4	Installation of Continuous Differential Pressure monitoring system.	31JUL18	**Complete**	6	6
5	Revised P-225 and P-212 to include the Differential Pressure continuous monitoring system.	31JUL18	**Complete**	6	7
6	Revise 2017 drug report and perform a comparison of the updated drug report to drugs compounded to ensure all drugs from reporting period are included.	31MAY18	**Complete**	8	8

COMMITMENT 1:

The approved deviation for D-2018-06 is can be found in **Attachment 1.** The associated approved CAPA. CAPA-2018-02, can be found in **Attachment 2.** This commitment is complete.

COMMITMENT 2:

The complaints specified by the agency in the issued FDA Form-483 has been evaluated for adverse drug event reporting and there were no qualifiers. The initial response to this observation listed corrective actions that were executed with emphasis on the retraining and training of Pharmacy personnel for Drug Safety and Surveillance. The Pharmacists have been adequately trained on MEDDRA Coding. A Watchlist and trend reporting program are in place to assess the frequency of allergic reactions and ADR reports. The revised policy and procedure for complaint handling, P-219, version 3, can be found in **Attachment 3.** The pharmacy personnel training record can be found in Attachment 4 of this response. This commitment is complete.

COMMITMENT 3:

Attachment 5 to this response is the Reconstitution Study Quotation from Analytical Research Laboratories (ARL) for the study to determine the total amount of time required for dissolution for various lyophilized preparations. A study protocol shall be written by ARL to be approved by ARL and the Olympia. It is imperative to note that the study shall be for just the HCG combination products that the pharmacy offers, excluding Sermorelin and GHRP mentioned in the Form-483 observation. This is due to Olympia's Compliance letter to the agency issued, Wednesday, July 18th, 2018 to cease use of bulk drug substances in compounding (including Sermorelin, GHRP-2, and GHRP-6). This commitment is in progress still due for protocol execution, report, release testing criteria revision, and the instructions for use revision. The due date has been updated in **Table 1** to reflect the status of this commitment.

COMMITMENT 4:

In the initial response, the quote from Primex was attached for the proposed work. The differential pressure monitoring system was installed on 06AUG18. The completed work order for the installation and installation documentation from Primex can be found in **Attachment 6**. This commitment is complete.

COMMITMENT 5:

As part of the installation of the differential pressure monitoring system for Commitment 4, P-225 and P-212 for environmental monitoring required revision. These revisions are approved and effective as of 20AUG18. The document change request forms for these revisions can be found in **Attachment 7**. This commitment is complete.

COMMITMENT 6:

Revised Drug Product Reporting record for December 2017 pursuant to FDA Form-483 Observation #8 is noted as **Attachment 8** to this response. This commitment is complete.

Table 2: Attachments

No.	Document No. Reference	Attachment Description	Related Observation Number	Approval Date
1	D-2018-06	Deviation Record for Gowning	1B	09MAY18
2	CAPA-2018-02	CAPA Record D-2018-06-Gowning	1B	09MAY18
3	P-219, Version 3	Drug Safety and Surveillance	2B & 2C	27APR18
4	N/A	Training for P-219.3	2B & 2C	27APR18
5	N/A	Dissolution Study Quote	4	N/A
6	WO-18-015	Installation Documentation and Certificates for the Primex System for Differential Pressure continuous Monitoring	6	08AUG18
7	F-215.a	Document Control for P-225 and P-212	6	06AUG18
8	N/A	Revised Drug Reporting for December 2017	8	N/A

U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

October 31, 2018

VIA Electronic Mail

Marco Loleit, CEO and Owner
OPS International Inc. dba Olympia Pharmacy
6700 Conroy Road, Suite 155
Orlando, Florida 32835
marco@olympiapharmacy.com

Reference: CMS WA 213460 and FEI 3009724085

Mr. Loleit:

We completed our review of the Establishment Inspection Report (EIR) for the inspection conducted by an FDA investigator at your facility in Orlando, Florida, from April 6, 2018, to April 13, 2018. A Form FDA 483 was issued to your firm at the conclusion of the inspection.

We have also reviewed your firm's responses dated May 3, 2018, July 18, 2018, August 22, 2018, and September 27, 2018, including the supportive documentation attached. However, additional information is required to fully evaluate whether you have adequately addressed the inspectional observations. Within five working days of receipt of this letter, submit the following so that we may complete our evaluation of your facility inspection and Form FDA 483 response.

1. Your response to Observation 3A included a copy of your revised procedure, P-304, *Cleaning-Sterilizing and Disinfecting of the Compounding Facility*, which was updated "to include hard coded locations on the cleaning forms to record contact time start time and end times". Provide copies of completed logs for the previous three months to demonstrate that appropriate contact times are being adhered to for sporicidal agents. Please clarify whether Spor-Klenz is reapplied to keep the surface wet and ensure a full 30-minute contact time as specified in your procedure.

2. Provide any updates to your response to Observation 4 since your September 27, 2018, response, including revision of release testing criteria and documentation of the additional testing on drug product batches, if completed. Additionally, the ARL "Reconstitution Study for HCG Formulations Final Report" provided via email on 09/27/2018 appears to be missing page 7; provide a complete copy of this report.

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
www.fda.gov

3. Provide copies of your firm's revised procedures, P-225, *Continuous Monitoring Systems*, and P-212, *Environmental Monitoring for the Positive Pressure and Negative Pressure Cleanrooms at Olympia*, referenced in your response to Observation 6.

4. Describe your storage conditions for depyrogenated vials. Note that if you store vials in an unclassified area for an extended period of time, they may become contaminated.

5. A smoke study labeled "Micro Filtrations, Inc.", "Olympia Compounding Pharmacy USP 797 Smoke Video", "Buffer Room Vial Transfer" was provided during the inspection. This video does not support that vials are protected by unidirectional air flow during transfer to the lyophilizer. Provide any additional videos or documentation to support the protection of these vials during transfer from the laminar flow hood to the lyophilizer. If your firm no longer lyophilizes drug products in this room, please state such, and any plans to resume.

6. The document titled "Batch Record for Process 1 Aseptic Process Simulation", provided during the inspection, includes the production of four intermediates which are stored "at the appropriate temperature for no less than 3 days". Provide the following information regarding this process:

    a. Provide a list of products produced by your firm which use intermediates, as well as a recent executed batch record for each product.
    b. Clarify whether intermediates are sterilized prior to storage.
    c. Provide information on the integrity of the container closures used to store the intermediates and describe under what conditions (temperature and location) intermediates are stored.

If the requested information cannot be submitted within five working days, state the reason for the delay and the time frame within which you will submit the information. Your written response should be electronically submitted to Dayna I. Martinez at dayna.martinez@fda.hhs.gov and ORAPHARM2_RESPONSES@fda.hhs.gov.

If you have any questions about this letter, please contact Ms. Martinez, Compliance Officer, via (787) 729-8608 or dayna.martinez@fda.hhs.gov.

Sincerely,

John W. Diehl -S

Digitally signed by John W. Diehl -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S, 0.9.2342.19200300.100.1.1=2000099727
Date: 2018.10.31 11:11:31 -05'00'

LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

OLYMPIA
COMPOUNDING PHARMACY
FDA REGISTERED 503B OUTSOURCING FACILITY

6700 Conroy Road, Suite 155
Orlando, FL 32835
407-673-2222

November 8, 2018

LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II
FDA/Office of Regulatory Affairs
John.diehl@fda.hhs.gov
4040 North Central Expressway, Suite 300
Dallas, TX 75204

Reference: CMS WA 213460 and FEI 3009724085

Good Day Mr. Diehl,

We are writing in response to the additional information requested to fully evaluate whether we have adequately addressed the inspectional observations from FDA-Form 483 dated 13APR18. Below is a detailed response to each of the inquiry made by the agency. **Table 1** represents the attachment list of documents and supplemental information for this response.

Olympia is committed to continuously improve our systems and processes for the services that we provide with respect to safety in patient care. For any questions or additional clarifications, please feel free to contact us at any time.

Sincerely,

08NOV18

Confidence Ekeanyanwu
Quality Manager
Olympia Compounding Pharmacy
Mobile: 781-686-0640
Email: confidence@olympiapharmacy.com

1. ***Your response to Observation 3A included a copy of your revised procedure, P- 304, Cleaning-Sterilizing and Disinfecting of the Compounding Facility, which was updated "to include hard coded locations on the cleaning forms to record contact time start time and end times". Provide copies of completed logs for the previous three months to demonstrate that appropriate contact times are being adhered to for sporicidal agents. Please clarify whether Spor-Klenz is reapplied to keep the surface wet and ensure a full 30-minute contact time as specified in your procedure.***

    a. **Attachment 1** of this response represents Olympia's cleaning logs for the past three months in reflection of the revised procedure, P-304, Cleaning-Sterilizing and Disinfecting of the Compounding Facility.
    b. Spor-Klenz utilized as a sporicidal agent in our facility is applied in enough volume to completely immerse the hard, non-porous surfaces for a full wet 30-minutes contact time **(Olympia SOP-P-304.6, Section 7.1.1.1.1).** No reapplication of the cold sterilant is performed to keep the surface wet for the time duration specified.

2. ***Provide any updates to your response to Observation 4 since your September 27, 2018, response, including revision of release testing criteria and documentation of the additional testing on drug product batches, if completed. Additionally, the ARL "Reconstitution Study for HCG Formulations Final Report" provided via email on 09/27/2018 appears to be missing page 7; provide a complete copy of this report.***

    a. The purpose of the study was to outline the procedure for the reconstitution of various lyophilized formulations at Olympia. The study was executed as cGMP work comprised on three (3) separate vials of each formulation reconstituted with bacteriostatic water for injection at a specified volume.
    b. Reconstitution instructions for dispensing of these compounds have been revised accordingly. The revised instructions are represented as **attachment 2** of this response.
    c. The complete and revised ARL reconstitution study final report is reattached as **attachment 3.**

3. ***Provide copies of your firm's revised procedures, P-225, Continuous Monitoring Systems, and P-212, Environmental Monitoring for the Positive Pressure and Negative Pressure Cleanrooms at Olympia, referenced in your response to Observation 6.***

    a. **Attachment 4** represents P-225, continuous Monitoring Systems, and **attachment 5**, P-212, Environmental Monitoring for the Positive Pressure and Negative Pressure Cleanrooms at Olympia.

4. ***Describe your storage conditions for depyrogenated vials. Note that if you store vials in an unclassified area for an extended period of time, they may become contaminated.***

    a. Depyrogenated vials are stored in a controlled cleanroom space at the Pharmacy; the controlled room space is at a minimum, ISO 8 certified. The depyrogenated vials are prepared for sterilization wrapped thricely for a procedure of removing each layer of foil according to each cleanroom air exposure. **Attachment 6** for this response is Olympia's operating procedure for the Sterilization of Components and Utensils used for compounding.

5. ***A smoke study labeled "Micro Filtrations, Inc.", "Olympia Compounding Pharmacy USP 797 Smoke Video", "Buffer Room Vial Transfer" was provided during the inspection. This video does not support that vials are protected by unidirectional air flow during transfer to the lyophilizer. Provide any additional videos or documentation to support the protection of these vials during transfer from the laminar flow hood to the lyophilizer. If your firm no longer lyophilizes drug products in this room, please state such, and any plans to resume.***

    a. **Attachment 7** is an additional smoke study video to support the protection of vial transfer from the laminar flow hood to the lyophilizer by unidirectional air in the ISO 5 cleanroom. Micro Filtrations, the cleanroom certification vendor to further clarify the tests performed in the cleanrooms, has also provided a letter of notice to this effect. This letter is **attachment 8** for this response.
    b. Secondly, the compounding technicians are trained on conduct in controlled areas and aseptic technique for handling and manipulation of drug products to purport sterile drug compounds. Education is specific to critical sites, Contact surfaces, First Air, Direct Compounding Area, and movement in the cleanroom. Refer to **attachment 9** for this response.

6. **The document titled "Batch Record for Process 1 Aseptic Process Simulation", provided during the inspection, includes the production of four intermediates which are stored "at the appropriate temperature for no less than 3 days". Provide the following information regarding this process:**

    a. ***Provide a list of products produced by your firm which use intermediates, as well as a recent executed batch record for each product.***
        i. **Attachment 10** is listing of products compounded at Olympia by Process 1 Aseptic Process Simulation. **Attachment 11** represents a batch record organized in the numerical listing of attachment 10.
        ii. **Attachment 12** of this response is a Labeling Memo for clarification.

b. Clarify whether intermediates are sterilized prior to storage.

i. Intermediates are not sterilized prior to storage. They are utilized in production within three (3) days for the finished drug product. An intermediate is one step in the preparation of a finished sterilized drug product. The intermediates are combined in the appropriate volumes for a bulk solution, filtered for sterilization, and filled into vials. This is the overall process of producing sterile injectables at Olympia by Process 1 Aseptic Process Simulation. This is further represented by the batch records in attachment 11.

c. Provide information on the integrity of the container closures used to store the intermediates and describe under what conditions (temperature and location) intermediates are stored.

i. For the hold time of these Intermediates prior to their combination into a bulk solution, the intermediates are either held in a 1000-ML, 3000-ML, or 5000-ML sterile flexible bag. These are gamma irradiated sterilized bags with verified certificate of analysis for each batch received.

ii. If an intermediate is prepared in a volume less than 100-ML, it is held in a glass vial. These vials obtained from Wheaton Vials are precleaned/washed and sterilized by method of depyrogenation prior to use.

iii. The certificate of analysis for the bags and vial from the manufacturer is **attachment 12** for this response to validate the integrity of these containers for intermediates.

iv. The intermediates are held in a validated controlled environment according to the intermediate drug's specification, i.e. controlled room temperature or refrigeration.

Table 1: Attachments

No.	Document No. Reference	Attachment Description
1	F-304.b/F-304.d	Cleaning Logs
2	N/A	Revised reconstitution instructions for dispensing of lyophilized drug products.
3	N/A	Reconstitution study final report- ARL Biopharma
4	P-225	Continuous Monitoring Systems
5	P-212	Environmental Monitoring for the Positive Pressure and Negative Pressure Cleanrooms at Olympia
6	P-601	Sterilization of Components and Utensils
7	N/A	Additional smoke video for Vial Transfer to Lyophilizer
8	N/A	Letter of Notice from Micro Filtration
9	P-412	Conduct of Personnel in Controlled Areas and Aseptic Technique Overview
10	N/A	Product Listing for which Intermediates are used for Process 1
11	N/A	Most recent executed batch records for the products listed
12	N/A	Labeling Memo
13	N/A	Sterile bags and Vial certificate of analysis.

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

DATE 03/27/2019

CMS Case # 573273

Regulatory Meeting Request Letter

VIA UPS EXPRESS

Marco Loleit
Owner/CEO
OPS International, Inc. dba Olympia Pharmacy
6700 Conroy Road, Suite 155
Orlando, FL 32835

Dear Mr. Loleit:

We request that you and your management staff attend a regulatory meeting, with the FDA at the Office of Pharmaceutical Quality Operations, Division II, located at 4040 N. Central Expressway, Suite 300 Dallas, Texas 75204. Please contact Dayna Martinez Division Compliance Officer, at 787-729-8608, to schedule a date and time to meet with us.

The purpose of the meeting is to discuss the compliance status of OPS International, Inc. dba Olympia Pharmacy, including your efforts to bring your operations, facilities, and procedures into compliance with requirements of the Federal Food, Drug, and Cosmetic Act. Enclosed as an attachment is a request for information relating to our concerns.

Please respond with the requested information and documentation, via email, by 15 business days from letter issuance date to Dayna Martinez, Division Compliance Officer, at Dayna.Martinez@fda.hhs.gov. In addition, please submit a signed copy of your response to ORA ORAPHARM2_RESPONSES@fda.hhs.gov. Please include in your response your confirmed attendee list with titles, a contact name and number, and any materials that you plan to present to FDA during the meeting. Please confirm receipt of this letter. If you have any questions regarding the contents of this letter you may contact Ms. Martinez by email, or by phone at 787-729-8608.

Sincerely,

Tamala P. Magee -S

Digitally signed by Tamala P. Magee -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13001185 38, cn=Tamala P. Magee -S
Date: 2019.03.27 16:36:39 -05'00'

Tamala Magee
Acting Program Division Director
Office of Pharmaceutical Quality Operations
Division II

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
www.fda.gov

Enclosure:
FDA Comments and/or Request for Information

ATTACHMENT
FDA Questions and Requests for Information

1. **Dissolution Time Testing**
   Your firm's May 3, 2018, response stated, "P-217, Sterile Drug Product Specifications at Olympia Pharmacy, will be revised to include dissolution time testing as part of the release criteria for lyophilized products" … "In addition to the results for a potency, endotoxin, and sterility report for the finished compound, the dissolution time for the specific batch shall also be reported." Provide your revised procedure P-217, as well as documentation to show that dissolution time testing is performed on lyophilized drug product batches as part of batch release and when such testing began.

2. **Depyrogenation of Components**
   SOP P-601, Sterilization of Components and Utensils, provided in your firm's November 8, 2018, response letter, states that depyrogenated vials are wrapped in three layers of foil and stored in a controlled room space (ISO 8 minimum). Provide scientific justification to support that these storage conditions are adequate to protect against contamination and ensure the sterility of depyrogenated vials for the assigned expiry period of one month.

3. **Lyophilization**
   Regarding the non-hazardous cleanroom smoke study video provided in your firm's November 8, 2018, response letter:
   a. What lyophilized products are currently produced at your facility? What are your plans for future production within the non-hazardous cleanroom?
   b. How does your firm decontaminate and/or sterilize the lyophilizer prior to production?
   c. Provide documentation showing the air velocity in the critical area where lyophilized drug products are transferred within the non-hazardous cleanroom, and justification that this velocity is adequate to protect vials during the transfer process.

4. **Sporicidal Disinfection**
   Regarding the use of Spor-Klenz as described in your firm's November 8, 2018, response letter, how does your firm ensure that a surface, being exposed to multiple air changes, remains wet for the entire 30-minute contact time without reapplication?

5. **Production Intermediates**
   Regarding the use of intermediates as described in your firm's November 8, 2018, response letter, the Agency is concerned with the prolonged storage of non-sterile intermediates. While the product will be filter sterilized at a later step, there is the potential for bioburden to proliferate during storage. Endotoxin will not be removed by filter sterilization. While endotoxin testing can be performed as a release test on the finished drug product, this process represents a poor practice.

6. **Product Labeling**
Regarding your corrective actions to your firm's drug product labels as described in your firm's November 8, 2018, response letter, we note that most of the labeling deficiencies appear to be adequately addressed. However, it appears that your corrective action with respect to the list of inactive and active ingredients and the quantity or proportion of each ingredient is not adequate. Section 503B(a)(10)(A)(iii)(X) requires a list of active and inactive ingredients, identified by established name and the ***quantity or proportion of <u>each</u> ingredient***, to be listed on the label. If there is not space for such information on the label, per section 503B(a)(10)(B)(i), the container from which the individual units of the drug are removed for dispensing or for administration shall include such information. We request that you provide revised labels or container labels to address this deficiency.

7. **Dynamic Medical Solutions (DMS)**
We understand that you have partnered with Dynamic Medical Solutions (DMS), a company that seeks to meet the needs of healthcare providers by offering sterile and non-sterile products from your facility. We have the following questions regarding your partnership with DMS:

   a. Describe your business relationship with Dynamic Medical Solutions (DMS)? Do you have a contract with DMS? If so, please provide a copy of the contract.
   b. How does your firm receive orders for these drug products? What is the quantity that is ordered? Please provide any documents related to the ordering process.
   c. Describe the process from prescribing to receipt of the medications (who is doing what, and where is the product throughout the process).
   d. Are products distributed with DMS labels on them? Do products ship with DMS branding affixed to the products? If so, who provides the DMS labels? Please provide labels if available.
   e. Does DMS provide the product specifications to your firm?
   f. What products are manufactured/stored/distributed by your firm when DMS is used as an intermediary?
   g. Does your firm receive any complaints or adverse event reports regarding these drug products? Do you have a procedure for investigating the reports? Do you communicate complaints or adverse events to DMS?

8. **Ineligible Bulk Substances**
On July 18, 2018, your firm submitted a written response to FDA stating, "as a corrective action, effective May 1, 2018, Olympia Pharmacy ceased use of bulk drug substances in compounding (including Sermorelin, GHRP-2, and GHRP-6)." However, during a recent FDA inspection of a 503A facility we observed that Sermorelin, GHRP-2 and GHRP-6 were produced and distributed to the facility from your firm subsequent to your

commitment to cease production with these bulk drug substances that are not eligible under FDA's interim policy on bulk drug substances that may be used in compounding by outsourcing facilities. Additionally, we note that your December 2018 product report (covering the period of June 1, 2018, through November 30, 2018) shows that you have produced thousands of vials of drug product containing these ineligible bulk drug substances during this reporting period. Please provide your rationale as to why your firm committed to cease the production and distribution of drug products using ineligible bulk drug substances but has continued this practice. Do you intend to continue to produce and distribute drug products using bulk drug substances that are not eligible under FDA's interim policy on bulk drug substances that may be used in compounding by outsourcing facilities?

OLYMPIA
COMPOUNDING PHARMACY
FDA REGISTERED 503B OUTSOURCING FACILITY

6700 Conroy Road, Suite 155
Orlando, FL 32835
407-673-2222

Monday, May 6, 2019

LCDR John W. Diehl, M.S.
Director, Compliance Branch
C/O: Dayna Martinez
Division Compliance Officer
Office of Pharmaceutical Quality Operations, Division II
4040 North Central Expressway, Suite 300
Dallas, TX 75204

Reference: CMS Case # 573273

Good Day Mr. Diehl,

We are writing in response to the regulatory meeting request letter issued March 27th, 2019 by the FDA to discuss the compliance status of OPS International, Inc. dba Olympia Pharmacy ("Olympia"), located at 6700 Conroy Road, Suite 155, Orlando, FL 32835. This letter details the specific information requested by FDA prior to the regulatory meeting. **Table 1** represents Olympia's quality improvement commitments to the FDA. **Table 2** represents the list of attached documents and supplemental information for this response. Please note that Olympia received an extension until May 6, 2019, to respond to the regulatory meeting request letter.

The following will be in attendance for the proposed meeting date of **Thursday, August 8th, 2019**:

- Ms. Confidence Ekeanyanwu, Olympia Quality Manager and the designated contact for all correspondences – contact information is listed below
- Ms. Naomi Loomis RPh., Olympia Director of Operations – (407) 673-2222
- Ms. Rachael Pontikes, Partner, Reed Smith LLP, the firm's legal counsel – (312) 207-2857
- A representative from Kymanox, the firm's CGMP Consultant – (919) 246-4896

Olympia is committed to continuously improving our systems and processes in alignment with FDA's expectations. For any questions or additional clarifications, please feel free to contact us at any time.

Sincerely,

Confidence Ekeanyanwu
Digitally signed by Confidence Ekeanyanwu
Date: 2019.05.06 17:13:11 -04'00'

Confidence Ekeanyanwu
Quality Manager
Olympia Compounding Pharmacy
Mobile: 781-686-0640
Email: confidence@olympiapharmacy.com

1. **Dissolution Time Testing**
   Your firm's May 3, 2018, response stated, "P-217, Sterile Drug Product Specifications at Olympia Pharmacy, will be revised to include dissolution time testing as part of the release criteria for lyophilized products" ... " In addition to the results for a potency, endotoxin, and sterility report for the finished compound, the dissolution time for the specific batch shall also be reported." Provide your revised procedure P-217, as well as documentation to show that dissolution time testing is performed on lyophilized drug product batches as part of batch release and when such testing began.

Response:

Olympia concluded reconstitution dissolution time studies on all lyophilized drug products on 20MAR19. The signed final reports can be referenced in **Attachment 1**. Following completion of the studies, Olympia's Standard Operating Procedure (SOP) P-217, Sterile Drug Product Specification at Olympia Pharmacy, was revised to include dissolution time testing as part of release requirements. This revision was made effective on 01APR19 and can also be referenced in **Attachment 1**. Dissolution time testing was included as part of batch release criteria for all lyophilized drug products as of 01APR19, in conjunction with the effective date of the associated P-217 revision. Refer to **Attachment 2** for an example Certificate of Analysis (COA) for reconstitution dissolution time of a recent batch of lyophilized drug product that is now required for batch release. Refer to **Attachment 3** for the newly revised patient advisory for reconstituting lyophilized products compounded by Olympia.

2. **Depyrogenation of Components**
   SOP P-601, Sterilization of Components and Utensils, provided in your firm's November 8, 2018, response letter, states that depyrogenated vials are wrapped in three layers of foil and stored in a controlled room space (ISO 8 minimum). Provide scientific justification to support that these storage conditions are adequate to protect against contamination and ensure the sterility of depyrogenated vials for the assigned expiry period of one month.

Response:

The established process for depyrogenation and storage (assigned expiry period of one month) of glass vials at Olympia involves the use of a dry heat oven that resides immediately outside of the controlled environment in a non-classified area. To mitigate the potential exposure of the vials to particulates for depyrogenation preparation and storage, prior to use in aseptic filling, the vials are transferred into the controlled environment, specifically the ISO 7 cleanroom, to be triple-wrapped in aluminum foil. Each layer of foil contains a chemical indicator affixed on the surface of the pack. The wrapped vials are then transferred out of the controlled classified environment and placed in a validated dry heat oven for depyrogenation, with biological indicators for each shelving space that a pack of vials is placed into. The dry heat oven is re-assessed annually to ensure it remains in an appropriate validated state. After depyrogenation, the vials are transferred back into the controlled environment and stored in the ISO 8 cleanroom until needed for aseptic filling.

When needed for aseptic filling, the triple-wrapped vials follow a controlled process for transfer into the aseptic filling environment. From storage in the ISO 8 cleanroom, the first and outermost layer is removed as the vials transition into the ISO 7 cleanroom. The second layer is then removed as the vials transition into the ISO 5 cleanroom. The third and innermost foil layer is unwrapped within the Laminar Airflow Workbench (LAFW) as the vials transition into the ISO 5 LAFW prior to filling. The wrapped vials are visually checked during removal of each layer of foil and prior to filling to ensure that the packaging and vials have not been compromised during storage or transit. All rooms and LAFWs noted during this transfer process are cleaned, certified by an external party semi-annually, and monitored through the environmental monitoring program per internal procedures. Additionally, to date, airborne particulate levels within the affected cleanrooms have been in a state of control as shown during routine certification and air monitoring testing. Refer to **Attachment 4** for a trend on particulate testing and cleanroom certification for the last year for the storage cleanroom space.

To further validate this process for the assigned expiry period of one month, Olympia is performing a sterility and endotoxin challenge study for depyrogenated glass vials. The study protocol can be referenced in **Attachment 5**. The final report of this study shall be reported to the FDA in a follow-up response, which is represented as **Commitment 1** in this response letter.

Olympia is evaluating a change to using pre-sterilized glass vials in place of the current process described above. While we feel the current process provides an adequate level of microbiological and particulate control based on all available data, we understand there may be benefits to using pre-sterilized vials that are adequately protected and ready-to-use upon receipt. However, a change of this nature requires re-validation of our aseptic process and so the potential benefit may be outweighed by the risks and complexity of implementing the change. Therefore, we will inform FDA of our evaluation once complete, which is represented as **Commitment 2** in this response letter.

3. **Lyophilization**
   Regarding the non-hazardous cleanroom smoke study video provided in your firm' s November 8, 2018, response letter:
   a) *What lyophilized products are currently produced at your facility? What are your plans for future production within the non-hazardous cleanroom?*

Response:

The following lyophilized products are compounded at Olympia's facility currently:

- HCG 2000IU Injection per vial
- HCG 5000IU Injection per vial
- HCG 10,000IU Injection per vial
- HCG 5000IU/Hydroxocobalamin 5mg Injection per vial
- HCG 10,000IU/Hydroxocobalamin 5mg Injection per vial
- Sermorelin Acetate 3mg Injection per vial

- Sermorelin Acetate 9mg Injection per vial
- NAD+ 500mg/vial
- Sincalide 5mcg/vial

Presently, Olympia houses two Virtis Ultra Lyophilizer Units attached to their respective cleanrooms for the separate compounding of hazardous and non-hazardous drugs. The future for production within the non-hazardous cleanroom consists of compounding lyophilized the drug products Sincalide and Methylcobalamin. No other lyophilized products are planned at this time in the non-hazardous cleanroom.

b) *How does your firm decontaminate and/or sterilize the lyophilizer prior to production?*

Response:

The lyophilizers are manually disinfected daily using a disinfecting agent (Iradecon Bleach) followed by a residue removal with sterile water for injection, and finally a secondary disinfection using 70% sterile isopropyl alcohol. A manual sporicidal disinfection is carried out weekly using one of two sporicidal agents (Spor-Klenz and Peridox) on a rotating basis, followed by a secondary disinfection using 70% sterile isopropyl alcohol.

The most recent cleaning and disinfecting log for each of the lyophilizers at Olympia can be referenced in **Attachment 6.**

c) *Provide documentation showing the air velocity in the critical area where lyophilized drug products are transferred within the non-hazardous cleanroom, and justification that this velocity is adequate to protect vials during the transfer process.*

Response:

Olympia has carried out air velocity mapping of the critical area where lyophilized drug products are transferred within the non-hazardous cleanroom. Refer to **Attachment 7** for the report provided by an external party that performed the mapping. The data collected testing the air velocity in this critical area had a range of 41 feet per minute (FPM) and a high of 150 FPM within the sampled area, with an average airflow of 82 FPM. This meets the requirement of a minimum of 40 FPM to provide protection to the partially stoppered vials.

4. **Sporicidal Disinfection**
Regarding the use of Spor-Klenz as described in your firm' s November 8, 2018, response letter, how does your firm ensure that a surface, being exposed to multiple air changes, remains wet for the entire 30-minute contact time without reapplication?

Response:

Olympia has not historically performed a re-application of Spor-Klenz to ensure the surfaces remain wet for the entire 30-minute contact time, as the environmental monitoring data for the facility have not indicated any undesirable trends with respect to spores since the facility has been in operation. Olympia agrees that it is important to follow the manufacturer's recommended wet contact time unless objective evidence can be provided to support alternative approaches. To that end, Olympia has decided to perform a disinfecting process validation study with an external party, represented as **Commitment 3** in this response letter. Revision of P-304 to align with results of this study is represented as **Commitment 4** in this response letter.

Analytical Research Laboratories (ARL) has been contracted for the validation study of all decontamination and cleaning agents used at the facility to confirm the manufacturer's claims regarding the efficacy of the agents at the concentrations of use and to establish minimum wet contact times on simulated facility surfaces. Through this evaluation and based on historical environmental monitoring data, Olympia hopes to validate the current disinfecting process used and potentially achieve shorter wet contact times than what the manufacturer recommends in their labeling. The pass/fail criteria for the study shall be based on log reduction values from the inoculation population. Refer to **Attachment 8** for the study protocols.

5. ***Production Intermediates***
   Regarding the use of intermediates as described in your firm's November 8, 2018, response letter, the Agency is concerned with the prolonged storage of non-sterile intermediates. While the product will be filter sterilized at a later step, there is the potential for bioburden to proliferate during storage. Endotoxin will not be removed by filter sterilization. While endotoxin testing can be performed as a release test on the finished drug product, this process represents a poor practice.

Response:

Olympia would like to clarify that the duration of the hold times during Aseptic Process Simulation (APS) are not the routine hold times used during compounding. The hold times during APS (3 days for intermediate bulks, 24 hours for sterilized final bulk) represented the "worst case" scenario for hold times that might be encountered if an unexpected delay in processing occurred during operations. In routine operations, the hold times are typically <24 hours for intermediate bulks and <6 hours for sterilized final bulks.

Although the APS batches to-date have not resulted in any failures or concerns regarding hold times, Olympia is committed to continued quality improvement in this area. As such, we intend to revise the current aseptic process to include an additional sterile filtration of the intermediate bulk materials prior to the hold time, which will help to further mitigate the risk of microbiological growth in our product formulations. We will also shorten the hold times during APS to 24 hours for the intermediate bulks and 12 hours for the sterilized final bulks, which still allows for operational flexibility but is well beyond our typical hold time duration.

These changes will require a re-validation of the APS process by three consecutive passing trials, which will be executed in place of the July semi-annual re-qualification. This is represented as **Commitment 5** in the response letter.

6. ***Product Labeling***
   Regarding your corrective actions to your firm's drug product labels as described in your firm's November 8, 2018, response letter, we note that most of the labeling deficiencies appear to be adequately addressed. However, it appears that your corrective action with respect to the list of inactive and active ingredients and the quantity or proportion of each ingredient is not adequate. Section 503B(a) (l 0) (A)(iii)(X) requires a list of active and inactive ingredients, identified by established name and the ***quantity or proportion of each ingredient****, to be listed on the label. If there is not space for such information on the label, per section 503B(a)(I0) (B)(i), the container from which the individual units of the drug are removed for dispensing or for administration shall include such information. We request that you provide revised labels or container labels to address this deficiency.*

Response:

Refer to **Attachment 9** for samples of newly revised label proofs for product labeling of the Bimix, Trimix, and QuadMix products produced by Olympia. These proofs are consistent with the firm's November 8th, 2018 response letter for products that utilize production intermediates for finished product compounding.

7. ***Dynamic Medical Solutions (DMS)***
   We understand that you have partnered with Dynamic Medical Solutions (DMS), a company that seeks to meet the needs of healthcare providers by offering sterile and non- sterile products from your facility. We have the following questions regarding your partnership with DMS:
   a) *Describe your business relationship with Dynamic Medical Solutions (DMS)? Do you have a contract with DMS? If so, please provide a copy of the contract.*

Response:

Dynamic Medical Solutions (DMS) is a Value-Added Reseller (VAR), also known as an independent sales representative with Olympia, with no exclusivity to Olympia. As a VAR, DMS builds relationships with physicians who use compounded medications to treat patients. DMS becomes a liaison between Olympia and the physician to facilitate the ordering process only. DMS does not stock or directly distribute any medications that Olympia compounds. DMS sets up the physician/pharmacy relationship using an account set-up form, which collects all necessary and applicable information about the physician's office. Refer to **Attachment 10** for the account set-up forms utilized by DMS, which are provided by Olympia. There is a reseller contract in place between Olympia and DMS for the relationship just described. Refer to **Attachment 11** for the contract.

b) *How does your firm receive orders for these drug products? What is the quantity that is ordered? Please provide any documents related to the ordering process.*

Response:

Olympia receives the orders by fax at 877-622-3232 and by email to a designated email account, orders@olympiapharmacy.com. The email order is sent by the ordering physician to a DMS representative who serves as the liaison between the physician's office and Olympia, ensuring that the order is received, fulfilled and shipped. The quantity ordered is determined by the physician and varies with each order; it is included on the order form at the time an order is placed. Refer to **Attachment 13** for mocked DMS order forms as would be received by Olympia for fulfilment.

c) *Describe the process from prescribing to receipt of the medications (who is doing what, and where is the product throughout the process).*

Response:

The physician sends the completed and signed order form to DMS. DMS verifies availability with Olympia, BUD, and turnaround time. DMS then transmits the order via email or fax to Olympia Pharmacy. Once the order is received by Olympia pharmacy, it is handled in the same manner as any other order. It is received and entered the pharmacy's McKesson software by a licensed pharmacy technician, the licensed pharmacist does a pre-verification/clinical review for appropriateness of order and physician credentials are verified. If there is an issue with the order the physician is contacted directly by the pharmacist for clarification or correction. The order is fulfilled by a licensed pharmacy technician and a final check for accuracy of the medication is done by a licensed pharmacist. After which the completed order is transferred to the shipping department where it is shipped directly to the physician's office.

d) *Are products distributed with DMS labels on them? Do products ship with DMS branding affixed to the products? If so, who provides the DMS labels? Please provide labels if available.*

Response:

No, the compounded products distributed have Olympia labels affixed on the unit vials and prescriptions labels for designated physician's office on the outer container. No DMS branding is affixed to the products. Olympia only labels products according to its policy on labeling. No vendor labels are used.

e) *Does DMS provide the product specifications to your firm?*

Response:

No, Olympia compounds products pursuant to the CGMP requirements and internal policies and procedures for drug product specifications. DMS does not provide any product specifications to Olympia Pharmacy.

f) What products are manufactured/stored/distributed by your firm when DMS is used as an intermediary?

Response:

Olympia does not compound any products specifically for DMS; rather, our product offering menu is the same for all physicians and patients. Refer to **Attachment 12** for mock order forms used by DMS for compounded products offered by Olympia.

g) Does your firm receive any complaints or adverse event reports regarding these drug products? Do you have a procedure for investigating the reports? Do you communicate complaints or adverse events to DMS?

Response:

No complaints or adverse event reports have been made to Olympia from DMS for any compounded drug product compounded by Olympia. The physician's office also has the FDA and Olympia's direct contact information, provided on the vial labels, should they wish to report an adverse event directly to the FDA or Olympia. Olympia has a procedure for investigating any such reports if we receive them. Refer to **Attachment 13** for the SOP on complaint handling, P-219, Drug Safety and Surveillance. Olympia will communicate complaints and or adverse events to DMS for all applicable circumstances.

8. ***Ineligible Bulk Substances***
On July 18, 2018, your firm submitted a written response to FDA stating, "as a corrective action, effective May 1, 2018, Olympia Pharmacy ceased use of bulk substances in compounding (including Sermorelin, GHRP-2, and GHRP-6)." However, during a recent FDA inspection of a 503A facility we observed that Sermorelin, GHRP-2, and GHRP-6 were produced and distributed to the facility form your firm subsequent to your commitment to cease production with these bulk drug substances that are not eligible under FDA's interim policy on bulk drug substances that may be used in compounding by outsourcing facilities. Additionally, we note that your December 2018 product report (covering the period of June 1, 2018, through November 30, 2018) shows that you have produced thousands of vials of drug product containing these ineligible drug substances during this reporting period. Please provide your rationale as to why your firm committed to cease the production and distribution of drug products using ineligible bulk drug substances but has continued this practice. Do you intend to continue to produce and distribute drugs using bulk drug substances that are not eligible under FDA's interim policy on bulk drug substances that may be used in compounding by outsourcing facilities?

Olympia's Response:

Olympia appreciates and acknowledges the importance of compounding with eligible bulk drug substances and meeting the FDA's current expectations. Toward that end, Olympia would like to take this opportunity to provide further insight into its rationale for its compounding with bulk substances Sermorelin Acetate, GHRP-2, and GHRP-6, as well as provide our proposed strategy for compounding with bulk substances moving forward.

Olympia's Use of Bulk Substances Sermorelin Acetate, GHRP-2, and GHRP-6

Although Olympia represented to the FDA that it would cease compounding Sermorelin Acetate, GHRP-2, and GHRP-6, Olympia continued to compound with these bulk substances to balance the FDA's evolving expectations with Olympia's commitment to continuity of care to its patients. Sermorelin Acetate, GHRP-2, and GHRP-6 are not components of any commercially available drug products, and, therefore, Olympia can only prepare compounded medication containing these drugs if it uses bulk substances. As such, Olympia was concerned that an abrupt and immediate cease in compounding using these bulk substances would cause medical harm to the thousands of patients that rely on these compounded medications. Olympia felt it had a commitment to avoid any interruption in care, and, accordingly, continued to compound with bulk Sermorelin Acetate, GHRP-2, and GHRP-6 to keep these compounded medications available for patient care.

Effective June 1st, 2019 Olympia will cease compounding with bulk GHRP-2 and GHRP-6, as it understands these substances are currently not eligible for the exemptions provided by section 503A or 503B, are not the subject of an applicable USP or NF monograph, and are not components of an FDA approved human drug and do not appear on the 503A or 503B bulks list. As noted above, this makes these compounds unavailable for patient care as they cannot be prepared from any commercially available drug; however, in deference to the FDA, Olympia will cease to prepare these compounds and will inform its physicians and patients that compounding pharmacies can no longer offer this treatment.

Regarding compounding from bulk Sermorelin Acetate, Olympia believes the FDA should exercise enforcement discretion over the compounding with nominated bulk substances until the FDA has completed its review of the nominated bulk substance. Based on Olympia's longstanding involvement in the industry and as a member of the Outsourcing Facilities Association ("OFA"), Olympia understands the FDA's position on compounding bulk drug substances by an outsourcing facility to be as follows: If a bulk drug substance is nominated and does not appear in Category 1, 2, or 3, then FDA will exercise enforcement discretion over the compounding with that particular bulk substance until FDA makes a determination on the categorization of the bulk substance. As such, because Sermorelin Acetate was nominated by OFA for the FDA's consideration, Olympia expects that the FDA will exercise enforcement discretion as to compounding with bulk Sermorelin Acetate until a determination has been made on the categorization of this bulk substance. Refer to **Attachment 14** for the Sermorelin Acetate Nomination. Olympia will immediately cease compounding Sermorelin Acetate if FDA does not place this substance in Category 1 and/or on the final 503B Bulks List.

As indicated above, Sermorelin Acetate is also not a component of any commercially available drug, and therefore, if bulk Sermorelin Acetate cannot be used to compound, these compounded medications will not be available to patients. Sermorelin Acetate, however, was a component of the commercially available drug product called GEREF, which has been discontinued by the

manufacturer, but was not withdrawn from sale for reasons of safety or effectiveness. Refer to **Attachment 15** for the Federal Register Notice Regarding Withdrawal of GEREF. Thus, the only way for patients to currently receive this treatment is through compounding this bulk substance.

Olympia's Proposed Strategy for Compounding from Bulk Substances

To provide a complete and comprehensive response to FDA's request regarding Olympia's use of bulk drug substances in compounding, Olympia would like to take this opportunity to explain its current business model and the plans it has underway for transitioning the patient-specific portion of its practice to a traditional compounding pharmacy.

Currently, Olympia compounds on both a patient-specific and non-patient-specific basis in its outsourcing facility. Given that Olympia is registered as a 503B outsourcing facility, and, as is required by the statute, all the medications we prepare are compounded pursuant to CGMP standards. However, when Olympia conducted an analysis of the needs of its patients and physicians that require the patient-specific medications, it revealed that these needs would be best served by a traditional pharmacy compounding under Section 503A. Toward that end, Olympia is in the process of establishing a 503A compounding pharmacy so that it can transfer its patient-specific compounding to that facility. This facility will be located at 4600 LB McLeod Rd, Orlando, FL (the "McLeod Location"). Olympia has already leased this space and has ordered a modular pre-fabricated cleanroom for the opening of the compounding pharmacy. Refer to Cleanroom Invoice, McLeod Location Architectural Agreement, McLeod Location Floor Design Drawing, and the McLeod Lease Agreement as **Attachment 16**. As soon as the McLeod Location is fully compliant with Florida regulations and Section 503A standards, all patient-specific compounding practices will be separated from Olympia's current 503B outsourcing facility and transferred to the McLeod Location. The anticipated date of completion for this business segregation is early 2020.

In the interim, Olympia is asking for the opportunity to be able to transition its patient-specific practice to the McLeod Location. Specifically, Olympia is requesting that FDA exercise enforcement discretion during this transition period to allow Olympia to prepare patient-specific compounds with bulk substances that meet the requirements of Section 503A; that is, the bulk substances are compounded according to a USP or NF monograph, are components of a commercially available drug product, or appear on Category 1 of FDA's Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act. All these patient-specific compounds will continue to be prepared under CGMP requirements at Olympia's current facility until they are transitioned to the traditional compounding pharmacy at the McLeod Location. Olympia will only use bulk substances that appear on Category 1 or under FDA consideration pursuant to a nomination for any compounds prepared without a patient-specific prescription.

In summary, going forward and to address the FDA's concerns, Olympia has proposed the following strategy:

(1) Olympia will continue to compound Sermorelin Acetate with the understanding that FDA will exercise enforcement discretion over nominated bulk drug substances until a determination is made on the substance's categorization. If Sermorelin Acetate is not placed in 503B Bulks Category 1, Olympia will cease compounding with this bulk substance unless and until it is placed in 503B Bulks Category 1 and/or on the finalized 503B Bulks List;

(2) Olympia will cease compounding GHRP-2 and GHRP-6 by June 1, 2019, unless and until these substances are placed in 503B Bulks Category 1 and/or on the finalized 503B Bulks List (**Commitment 6**); and

(3) Olympia will fully separate its 503A and 503B compounding operations into two separate locations and anticipates completion of this separation by early 2020 (**Commitment 7**).

Olympia looks forward to discussing its proposed strategy and continuing this constructive dialogue with the FDA at the proposed regulatory meeting.

Table 1: Commitments to FDA

No.	Description of Action Required	Due on or Before	Status	Related Inquiry
1	Sterility and Endotoxin Challenge for Depyrogenated Vials	31JUL19	In-Progress	2
2	Evaluation of pre-sterilized vials under change control	30NOV19	In-Progress	2
3	Sterilant and Disinfectant Challenge Study Completion	31JUL19	In-Progress	4
4	Revise P-304, Cleaning- Sterilizing and Disinfecting of the Compounding Facility, to align with study results	31JUL19	Not-Started	4
5	Revision of APS protocols and re-execution of APS with revised hold times	31JUL19	In-progress	5
6	Cease compounding of GHRP-2 and GHRP-6 unless and until these substances are in Category 1 of the 503B Bulks List	01JUN19	N/A	8
7	Separation of 503A and 503B facilities	Early 2020	In-progress	8

Table 2: List of Attachments

No.	Document No. Reference	Attachment Description
1	P-217	Sterile Drug Product Specification at Olympia Pharmacy and Reconstitution Final Reports
2	N/A	Sample Reconstitution Dissolution Release Testing Report
3	N/A	Revised Patient Reconstitution Instructions for Dispensing of Lyophilized Drug Products.
4	N/A	Particulate testing trend report and cleanroom certification for the last year for the ISO 8 cleanroom space for storage of depyrogenated vials.
5	N/A	Sterility and Endotoxin Challenge Study Protocol for Depyrogenated Glass Vials
6	F-304	Most Recent Lyophilizer Cleaning and Disinfecting Log
7	N/A	Micro Filtration Report on Air Velocity Mapping for Lyophilization Vial Transfer
8	N/A	Sterilant and Disinfectant Challenge Study Protocols and Use Dilution Report.
9	N/A	Revised Label Proofs
10	N/A	DMS Account Set-Up Form
11	N/A	DMS Contractual Agreement with Olympia Pharmacy as a VAR
12	N/A	DMS Sample Order forms as received by Olympia Pharmacy
13	P-219	Drug Safety and Surveillance
14	N/A	GEREF Federal Register Notice
15	N/A	Bulks Substance Nomination
16	N/A	Bulks List Compliance Exhibits

From:	Diehl, John
To:	Confidence Ekeanyanwu
Cc:	Martinez, Dayna; ORA PHARM2 Responses
Subject:	RE: OPS International Inc. DBA Olympia Pharmacy- Building UPDATE
Date:	Wednesday, October 23, 2019 10:59:42 AM
Attachments:	image001.png

Good Morning Ms. Ekeanyanwu – thank you for the update and good luck with the new building.

CDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II
FDA/Office of Regulatory Affairs
O: (214) 253-5288
C: (972) 971-7912
John.diehl@fda.hhs.gov

From: Confidence Ekeanyanwu <confidence@olympiapharmacy.com>
Sent: Tuesday, October 22, 2019 3:29 PM
To: Diehl, John <John.Diehl@fda.hhs.gov>
Cc: Martinez, Dayna <Dayna.Martinez@fda.hhs.gov>; ORA PHARM2 Responses <ORAPHARM2_RESPONSES@fda.hhs.gov>
Subject: OPS International Inc. DBA Olympia Pharmacy- Building UPDATE

Good Day Mr. Diehl,

During a Regulatory Meeting held Thursday, September 12th, 2019, OPS dba Olympia Pharmacy informed the agency of the firm's **project**, the 'Separation of 503A and 503B Operations with a separate 503A Facility' intended toward a compliance path on the subject of bulk substances as applicable to the compounding sector. To reiterate our plan, the first phase of the project involved site and facility development and installation of modular cleanrooms. We had submitted our application for a building permit to the City of Orlando but were waiting for approval.

While building permits are rate limiting, today, we are happy to update you and the agency that the building permit for ***4600 LB McLeod Road, Orlando, FL 32811*** has been approved by the City of Orlando. The building permit approval is attached ***(Building Permit-BLD2019)*** for your review and for our file as we continue to update the agency on our progress with compliance commitments made under the VAI status. To further express our commitment to this project, we have made additional payments to Precision Building Construction, LLC. Attached are paid invoices 190049 & 190051 for the LB McLeod build out progress and fire alarm design revisions required by the City of Orlando. This sum of $188,810.73 secures the construction labor critical for the progression of the project.

Olympia is committed to continuously improving its systems and processes in alignment with FDA's expectations to ensure patient and public safety. This email correspondence supplements the regulatory meeting response submitted ***October 3rd, 2019*** to the agency. For any questions or

additional clarification, please feel free to contact me at any time.

Thank You,

OLYMPIA
COMPOUNDING PHARMACY
FDA REGISTERED 503B OUTSOURCING FACILITY

Confidence Ekeanyanwu
Quality Manager
Olympia Compounding Pharmacy
FDA Registered 503B Outsourcing Facility
6700 Conroy Rd # 155 Orlando, FL 32835
(781)686-0640 (407) 673-1234

"Knowledge is power. Information is liberating. Education is the premise of progress, in every society, in every family."
-Kofi Annan.

OLYMPIA
COMPOUNDING PHARMACY
FDA REGISTERED 503B OUTSOURCING FACILITY

6700 Conroy Road, Suite 155
Orlando, FL 32835
407-673-2222

Wednesday, March 11, 2020

LCDR John W. Diehl, M.S.
Director, Compliance Branch
C/O: Dayna Martinez
Division Compliance Officer
Office of Pharmaceutical Quality Operations, Division II
Food and Drug Administration
4040 North Central Expressway, Suite 300
Dallas, TX 75204

Good Day Mr. Diehl,

We are writing to update the agency on the status of our bulk substances commitment with respect to separating our pharmacy operations into separate 503A and 503B facilities. This response will also update the agency on air velocity concerns for current compounding operations in our classified cleanroom space. This is specific to the transfer of drug products to the lyophilizer. For this project at our current facility, a completion response shall be due to the agency on or before **15MAY20**.

These updates are in accordance to the Voluntary Action Indicated (VAI) status discussed and agreed upon at the Regulatory meeting held September 12th, 2019.

For the purpose of this update, **Table 1** shall represent the commitment listing and **Table 2** shall represent the listing of attached supporting documents related to the commitments in **Table 1.**

Olympia is committed to continuously improving its systems and processes in alignment with FDA's expectations to ensure patient and public safety. For any questions or additional clarifications, please feel free to contact me at any time.

Sincerely,

Confidence C. Ekeanyanwu

Confidence C. Ekeanyanwu
Quality Manager
Olympia Compounding Pharmacy
Mobile: 781-686-0640
Email: confidence@olympiapharmacy.com

NOTE:

- The Agency's meeting conclusion comments are represented with *Bold, Italic* text.
- **Table 1** at the end of the document contains the commitments to the agency and their due dates.
- **Table 2** contains the Attachment List.

1. ***In relation to the "Air Velocity Study" included in your May 6, 2019 response, provide justification to support that air velocity and airflow patterns in your non-hazardous cleanroom are adequate to ensure the protection of partially stoppered vials during transfer to the lyophilizer.***

UPDATE:

The previous update informed the agency of the proposed and signed labor contract for a Germfree constructed laminar airflow workstation. The LAF will contain the auto-filling machine for the filling and partial stoppering of vials for lyophilization. As stated, the LAF will maintain a downward, vertical unidirectional barrier of HEPA filtered air during operation to protect the product from contamination and assure product sterility. The LAF will provide an ISO Grade 5 (EU Grade A) environment for all operations that expose components to the environment including Tyvek lid removal, Nest Transport (to and from Olympia's Virtis Ultra 35 XL), Filling, Closing and Capping as well as transfer of materials from Olympia's Virtis Ultra 35 XL.

The project timeline and working engineering drawing for the unit is reflected as **attachment 1** of this response document. The unit is in the fabrication shop now and according to the work schedule provided by Germfree, the unit is set to be completed on 18MAR2020. An initial quality check would be done before preparation for the weld shop, then assembly, testing, and a final quality check. They currently show a ship date of 20APR20. Upon delivery to Olympia, a workstation and cleanroom certification shall be completed, and smoke study done. These documents and videos will be submitted to the agency demonstrating laminar air flow during the transfer of vials to the lyophilizer.

2. ***Provide updates on the new facility as it regards to progression completion.***

UPDATE:

Attachment 2 is a project completion notice from PBC Inc. for the **first phase** of the bulk drug substances' commitment. This phase was the building development and construction stage as the timeline below outlines. The **video clip** showing construction completion and constructed facility with the installed modular cleanrooms for hazardous and non-hazardous drug compounding is **attachment 3** of this response.

The **second phase** of the separation project begins with the qualification/validation plan for the cleanrooms, personnel, and equipment for sterile processing. We have also begun the permitting process which kicked off with the community pharmacy permit application to the Florida Board of Pharmacy. The application and facility are approved after an initial inspection by the board. The permit issuance notice and inspection report are shown as **attachment 4** of this update. The sterile processing application for Florida has since been submitted **(attachment 5)**, awaiting the cleanroom initial qualification and certification for a sterile facility inspection by the Florida DOH for permitting.

The DEA application is pending (application submission shown as **attachment 6**) and the National Practitioner Identifier **(NPI)** and **NCPDP** Provider Identification number, formerly known as the NABP number for the pharmacy has been obtained. This is shown as **attachment 7** of the update response. Non-Resident Pharmacy permit applications are underway, and we hope to obtain licensure in all 49 states on or before DEC20.

Bulk Drug Substances

- Separation of 503A and 503B Operations with a New 503A Facility
- Capital Budget - $3 million USD
- **First Phase** – Site/Facility- **COMPLETE**
    - Building permits from the City of Orlando is complete.
    - Construction labor is secured, and site development is underway.
- **Second Phase** – Qualification/Registration- **Start Date- 04MAR20**.
    - Will need to qualify facility, equipment, and personnel per Validation Master Plan.
    - Obtain licensure in each of the 49 states on a rolling basis.

Table 1: Commitments to FDA

No.	Description of Action Required	Due on or Before	Status
1	Lyophilization compounding process Quality Improvement project	~~31MAR20~~ 15MAY20	In-Progress
2	Separation of 503A and 503B facilities	DEC 20	In-progress

Table 2: List of Attachments

No.	Document No. Reference	Attachment Description
1	N/A	Project timeline and engineering drawing
2	N/A	PBC Inc. construction completion notice.
3	N/A	Constructed facility video clip.
4	N/A	FL permit issue and Inspection report- Community Pharmacy.
5	N/A	Submitted Sterile Processing application.
6	N/A	DEA application submission
7	N/A	NPI and NCPDB notices.

CDER Direct
Electronic Submissions Portal

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Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form required fields.

Header Details

Document Type: * ESTABLISHMENT REGISTRATION

Set ID: * 0b76b8c9-d894-0eb9-e054-00144ff8d46c

Root ID: * 9c326b6f-3caa-40b8-e053-2995a90aed8b

Version Number: * 9

Effective Date: * 01-15-2020

Registrant Details

Registrant Name: * OPS INTERNATIONAL INC. DBA OLYMPIA COMPOUNDING PHARMACY

Registrant DUNS: * 017674368

Registrant Contact Details

Contact Name: * CONFIDENCE EKEANYANWU

Contact Email: * confidence@olympiapharmacy.com

Contact Phone: * 781-686-0640

Phone Extension:

Registrant Contact Address

Country: * United States

Street Address: * 6700 Conroy Windermere Rd Ste 155

City: * ORLANDO

State: * Florida

Postal Code: * 32835

Establishments

row(s) 1 - 1 of 1

ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
☑017674368	3011158365	OLYMPIA COMPOUNDING PHARMACY

Florida HEALTH Department of Health

License Number: PH27414

Data As Of 4/24/2020

Profession	Pharmacy
License	PH27414
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2021
License Original Issue Date	01/24/2014
Address of Record	6700 CONROY ROAD STE 155 ORLANDO, FL 32835 UNITED STATES
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.

Florida HEALTH Department of Health

License Number: PH27363

Data As Of 4/24/2020

Profession	Pharmacy
License	PH27363
License Status	CLEAR/
Qualifications	Community PharmacySchedule II & III
License Expiration Date	2/28/2021
License Original Issue Date	01/09/2014
Address of Record	6700 CONROY ROAD STE 155 ORLANDO, FL 32835
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#8679438

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
12/05/2018	PH 27363	105539

The **PHARMACY**
named below has met all requirements of
the laws and rules of the state of Florida.
Expiration Date: **FEBRUARY 28, 2021**

OPS INTERNATIONAL INCORPORATED
Olympia Pharmacy
6700 CONROY ROAD
STE 155
ORLANDO, FL 32835

QUALIFICATION(S):
COMMUNITY PHARMACY
SCHEDULE II & III
3:1 PHARMACY TECHNICIAN RATIO APPROVED

Rick Scott
GOVERNOR

Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW

AC#8679437

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
12/05/2018	PH 27414	105541

The **PHARMACY**
named below has met all requirements of
the laws and rules of the state of Florida.
Expiration Date: **FEBRUARY 28, 2021**

OPS INTERNATIONAL INCORPORATED
Olympia Pharmacy
6700 CONROY ROAD
STE 155
ORLANDO, FL 32835

QUALIFICATION(S):
SPECIAL STERILE COMPOUNDING
3:1 PHARMACY TECHNICIAN RATIO APPROVED

Rick Scott
GOVERNOR

Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW

State of Florida
Department of State

I certify from the records of this office that OPS INTERNATIONAL INCORPORATED is a corporation organized under the laws of the State of Florida, filed on October 3, 2013, effective October 2, 2013.

The document number of this corporation is P13000081512.

I further certify that said corporation has paid all fees due this office through December 31, 2019, that its most recent annual report/uniform business report was filed on April 6, 2019, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twelfth day of February, 2020

GREAT SEAL OF THE STATE OF FLORIDA
IN GOD WE TRUST

Secretary of State

Tracking Number: 9107518418CU

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

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

15F

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: QuVa Pharma, Inc.

Physical Address: 1075 West Park One Drive Suite 100

City: Sugar Land State: Texas Zip Code: 77478

Telephone: 888 339 0874 Fax: _____

Toll Free Number: 888 339 0874 (Required per NAC 639.708)

E-mail: michelle.kostroun@quvapharma.com Website: www.quvapharma.com

Supervising Pharmacist: Varsha Gaitonde Nevada License #: 20064

OK exp 10/31/21

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: 4-20-2020 Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3012053582

Please provide the name of the facility as registered with the FDA and the registration number:
QuVa Pharma, Inc.

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: Varsha Gaitonde Nevada License Number: 20064

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

Peter Jenkins
Print Name of Authorized Person

4/10/2020
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: QuVa Pharma Holdings, Inc.

Address: 3 Sugar Creek Center Blvd. Ste. 250

City: Sugar Land State: TX Zip: 77478

Telephone: 888-339-0874 Fax: _____

Contact Person: Michelle Kostroun

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) 100% of the shares are owned by QuVa Pharma Holdings
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 1000

3) What was the price paid per share? No Par value

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information N/A

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 - see attached

per conversation will forward Once received mk 04.13.2020

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: QuVa Pharma, Inc.

Address: 5920 South General Bruce Drive

City: Temple State: TX Zip: 76502

I hereby authorize the The Texas Department of Health and Human Services to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant Michelle Cotrown

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
1001828	Current	10.23.2019	11.2.2021

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
[signature]	Chief Pharmacist	TX	4.21.2020	

State of Delaware
Secretary of State
Division of Corporations
Delivered 05:35 PM 05/28/2015
FILED 04:34 PM 05/28/2015
SRV 150811868 - 5755668 FILE

CERTIFICATE OF INCORPORATION

OF

QUVA, INC.

The undersigned, in order to form a corporation under and pursuant to the provisions of the General Corporation Law of the State of Delaware, does hereby certify as follows:

FIRST: The name of the corporation is Quva, Inc. (the "Corporation").

SECOND: The address of the Corporation's registered office in the State of Delaware is 2711 Centerville Road, Suite 400, Wilmington, New Castle County 19808. The name of its registered agent at such address is Corporation Service Company.

THIRD: The purposes for which the Corporation is formed are to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware (the "DGCL") and to possess and exercise all of the powers and privileges granted by such law and any other law of Delaware.

FOURTH: The total number of shares of stock which the Corporation shall have authority to issue is One Thousand (1,000) shares of Common Stock each without par value.

FIFTH: The name and mailing address of the Incorporator are as follows:

Name	Address
Peter Jenkins	135 Central Park West New York, NY 10023

SIXTH: In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors of the Corporation is expressly authorized and empowered to make, alter or repeal the bylaws of the Corporation, subject to the power of the stockholders of the Corporation to alter or repeal any bylaw made by the board of directors.

SEVENTH: The Corporation reserves the right at any time and from time to time to amend, alter, change or repeal any provisions contained in this Certificate of Incorporation, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the right reserved in this Article.

EIGHTH: The election of directors need not be by written ballot, unless the bylaws of the Corporation shall so provide.

NINTH: To the fullest extent permitted by the DGCL as the same exists or may hereafter be amended, a director of this Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that this Article shall not eliminate or limit the liability of a director for (i) any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Incorporation to be executed this 28th day of May, 2015.

Peter Jenkins, Incorporator

State of Delaware
Secretary of State
Division of Corporations
Delivered 05:05 PM 07/13/2015
FILED 05:06 PM 07/13/2015
SRV 151042713 - 5755668 FILE

CERTIFICATE OF AMENDMENT

OF

CERTIFICATE OF INCORPORATION

OF

QUVA, INC.

It is hereby certified that:

1. The name of the corporation (hereinafter called the "Corporation") is QuVa, Inc.

2. The Certificate of Incorporation of the Corporation is hereby amended by striking out Article FIRST thereof and by substituting in lieu of said Article FIRST the following new Article FIRST:

"FIRST: The name of the corporation is QuVa Pharma, Inc. (the "Corporation").

3. The amendment of the Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Amendment to the Certificate of Incorporation of QuVa, Inc. to be executed as of this 10th day of July, 2015.

QUVA, INC.

By: _____

Name: Peter Jenkins

Title: Chief Development Officer, Treasurer and Secretary

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "QUVA PHARMA, 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 THIRTEENTH DAY OF APRIL, A.D. 2020.

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "QUVA PHARMA, INC." WAS INCORPORATED ON THE TWENTY-EIGHTH DAY OF MAY, A.D. 2015.

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

Jeffrey W. Bullock, Secretary of State

5755668 8300

SR# 20202775186

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

Authentication: 202759509

Date: 04-13-20

- 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.state.tx.us/fdlicense.

- If you have any questions or desire additional information concerning the application process or this license, please contact the Food and Drug Licensing Group at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: https://reglicensing.questionpro.com. 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.

OUVA PHARMA INC
1075 W PARK ONE DR STE 100
SUGAR LAND TX 77478

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

QUVA PHARMA INC

1075 W PARK ONE DR STE 100
SUGAR LAND, TX 77478

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:

PRESCRIPTION DRUG MANUFACTURER

License # 1001747
Expires: August 12, 2021

NON-TRANSFERABLE

Commissioner

512042

NABP ACCREDITED
DRUG DISTRIBUTOR

QuVa Pharma, Inc

located at

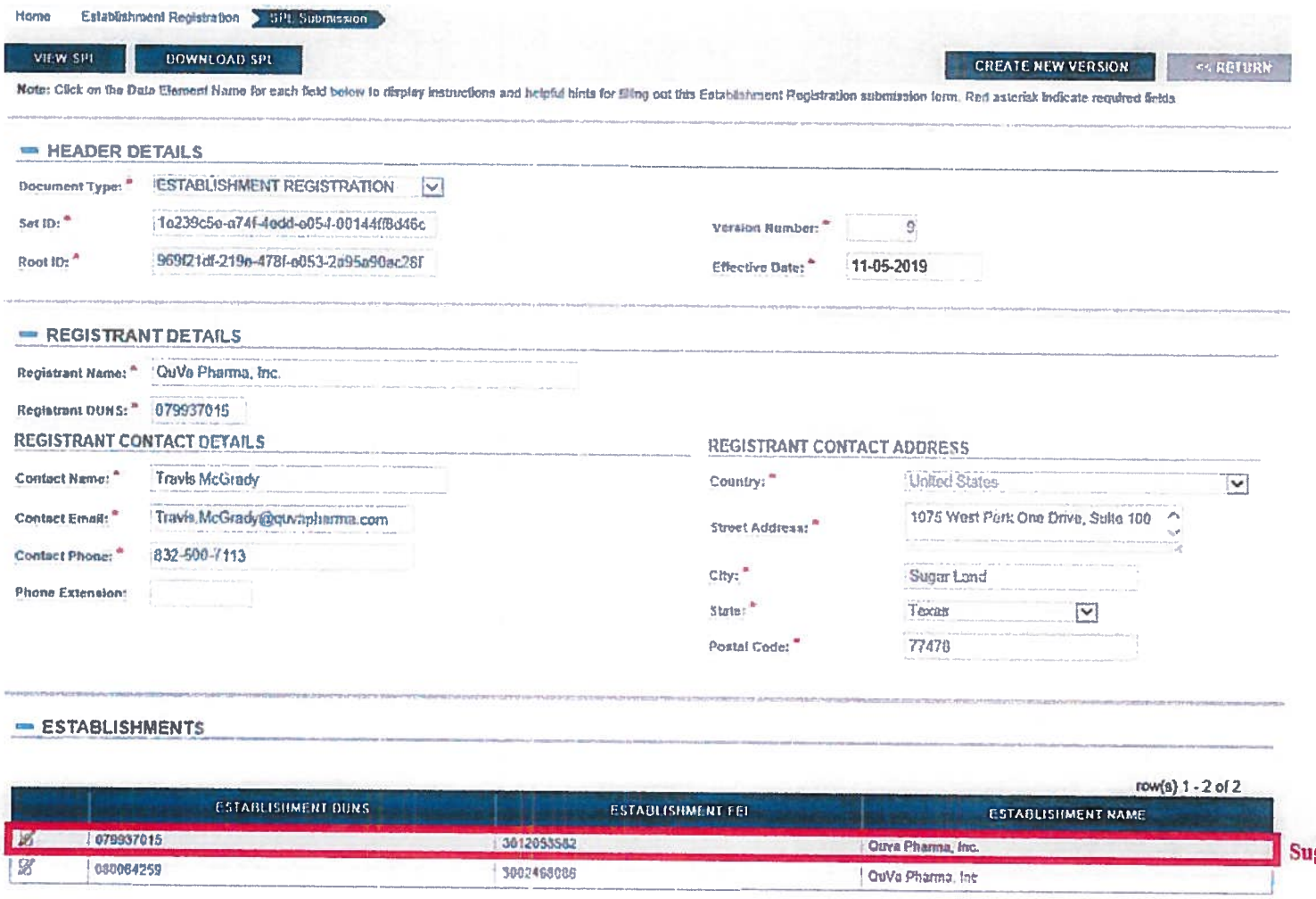
1075 West Park One Dr, Ste 100, Sugar Land, TX 77478

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/.

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

06/08/2018 - 06/07/2021
Period of Accreditation

1956



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HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION

Set ID: * 1a239c5e-a74f-4edd-e054-00144ff8d46c

Version Number: * 9

Root ID: * 969f21df-219e-478f-e053-2a95a90ac28f

Effective Date: * 11-05-2019

REGISTRANT DETAILS

Registrant Name: * QuVa Pharma, Inc.

Registrant DUNS: * 079937015

REGISTRANT CONTACT DETAILS

Contact Name: * Travis McGrady

Contact Email: * Travis.McGrady@quvapharma.com

Contact Phone: * 832-500-7113

Phone Extension:

REGISTRANT CONTACT ADDRESS

Country: * United States

Street Address: * 1075 West Park One Drive, Suite 100

City: * Sugar Land

State: * Texas

Postal Code: * 77478

ESTABLISHMENTS

row(s) 1 - 2 of 2

	ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
	079937015	3012053582	Quva Pharma, Inc.
	080064259	3002468086	QuVa Pharma, Inc

Sugar Land Registration

ESTABLISHMENT DETAILS

Establishment Name: *	Quva Pharma, Inc
Establishment DUNS: *	079937015
Establishment FEI:	3012053582

ESTABLISHMENT ADDRESS

Country: *	United States
Street Address: *	1075 West Park One Drive, Suite 100
City: *	Sugar Land
State: *	Texas
Postal Code: *	77478

ESTABLISHMENT CONTACT DETAILS

Contact Name: *	Travis McGrady
Contact Email: *	Travis.McGrady@QuVaPharma.com
Contact Phone: *	832-500-7113
Phone Extension:	

ESTABLISHMENT CONTACT ADDRESS

Country: *	United States
Street Address: *	1075 West Park One Drive, Suite 100
City: *	Sugar Land
State: *	Texas
Postal Code: *	77478

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment. Click on + button to select multiple business operations, or alternatively importers.

BUSINESS OPERATION(S)

row(s) 1 - 2 of 2

BUSINESS OPERATION	QUALIFIER
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	NOT COMPOUNDING FROM BULK INGREDIENT

Corporate Officers for QuVa Pharma, Inc.

Stuart Hinchen - CEO
Home address:
Dunstan Road Apt
Houston Tx
Business address/Corporate address:
3 Sugar Creek Center
Sugar Land, TX 77478
Business phone no: 832-500-7360

Peter Jenkins - Chief Development Officer/Secretary/Treasurer
Home Address:
Dunstan Road
Houston, Texas
Business address/Corporate address:
3 Sugar Creek Center
Sugar Land, Texas 77478
Business phone no: 832-500-7020

15G

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: QuVa Pharma, Inc.

Physical Address: 5920 South General Bruce Drive

City: Temple State: Texas Zip Code: 76502

Telephone: 888 339 0874 Fax: _____

Toll Free Number: 888 339 0874 (Required per NAC 639.708)

E-mail: michelle.kostroun@quvapharma.com Website: www.quvapharma.com

Supervising Pharmacist: Travis Leeah Nevada License #: 20307

OK exp 10/31/2

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: 4/20/2020 Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3002468086

Please provide the name of the facility as registered with the FDA and the registration number:
QuVa Pharma, Inc.

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: Travis Leeah Nevada License Number: 20307

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

Peter Jenkins
Print Name of Authorized Person

4/10/2020
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: QuVa Pharma Holdings, Inc.

Address: 3 Sugar Creek Center Blvd. Ste. 250

City: Sugar Land State: TX Zip: 77478

Telephone: 888-339-0874 Fax: _____

Contact Person: Michelle Kostroun

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) 100% of the shares are owned by QuVa Pharma Holdings
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 1000

3) What was the price paid per share? No Par value

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information N/A

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. - Ordered will send per our conversation as soon as received. mk 04-13-2020

List of officers and directors - attached

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: QuVa Pharma, Inc.

Address: 5920 South General Bruce Drive

City: Temple State: TX Zip: 76502

I hereby authorize the The Texas Department of Health and Human Services to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant Michelle Kotrous

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
1001828	Current	10.23.2019	11.2.2021

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
[signature]	Chief Pharmacist	TX	9.21.2020	

Home Establishment Registration SPL Submission

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Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form. Red asterisk indicate required fields.

HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION

Set ID: * 1e239c5e-a74f-4edd-e054-00144ff8d46c

Root ID: * 969f21df-219e-478f-e053-2a95a90ac28f

Version Number: * 9

Effective Date: * 11-05-2019

REGISTRANT DETAILS

Registrant Name: * QuVa Pharma, Inc.

Registrant DUNS: * 079937015

REGISTRANT CONTACT DETAILS

Contact Name: * Travis McGrady

Contact Email: * Travis.McGrady@quvapharma.com

Contact Phone: * 832-500-7113

Phone Extension:

REGISTRANT CONTACT ADDRESS

Country: * United States

Street Address: * 1075 West Park One Drive, Suite 100

City: * Sugar Land

State: * Texas

Postal Code: * 77478

ESTABLISHMENTS

row(s) 1 - 2 of 2

	ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
	079937015	3012053582	Quva Pharma, Inc.
	080064259	3002466036	QuVa Pharma, Inc.

Temple registratoin

ESTABLISHMENT DETAILS

Establishment Name: *	QuVa Pharma, Inc.
Establishment DUNS: *	080064259
Establishment FEI:	3002468086

ESTABLISHMENT ADDRESS

Country: *	United States
Street Address: *	5920 S General Bruce Drive, Suite 100
City: *	Temple
State: *	Texas
Postal Code: *	76502

ESTABLISHMENT CONTACT DETAILS

Contact Name: *	Travis Leeah
Contact Email: *	travis.leeah@quvapharma.com
Contact Phone: *	1-254-9334429
Phone Extension:	

ESTABLISHMENT CONTACT ADDRESS

Country: *	United States
Street Address: *	5920 S General Bruce Drive, Suite 100
City: *	Temple
State: *	Texas
Postal Code: *	76502

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment. Click on + button to select multiple business operations, or alternatively importers.

BUSINESS OPERATION(S)

row(s) 1 - 3 of 3

BUSINESS OPERATION	QUALIFIER
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	COMPOUNDING FROM BULK INGREDIENT
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	COMPOUNDING STERILE PRODUCTS

1968

NABP ACCREDITED
DRUG DISTRIBUTOR

QuVa Pharma, Inc

located at

5920 South General Bruce Dr, Temple, TX 76502

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/.

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

06/08/2018 - 06/07/2021
Period of Accreditation

Corporate Officers for QuVa Pharma, Inc.

Stuart Hinchen - CEO
Home address:
Dunstan Road Apt
Houston Tx
Business address/Corporate address:
Sugar Creek Center
Sugar Land, TX 77478
Business phone no: 832-500-7360

Peter Jenkins - Chief Development Officer/Secretary/Treasurer
Home Address:
Dunstan Road Ap
Houston, Texas 77005
Business address/Corporate address:
3 Sugar Creek Center
Sugar Land, Texas 77478
Business phone no: 832-500-7020

DEPARTMENT OF STATE HEALTH SERVICES
P.O. Box 149347
Austin, Texas 78714-9347

No. 07-1307

Date: 01/31/19

Firm Name QuVa Pharma, Inc.

Classification Prescription Drug Manufacturer/503B Outsourcing Facility

Person Contacted Mr. Travis Leeah Title Vice President of Clinical Development

City Temple Address 5920 S General Bruce Dr.

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE. YOUR ATTENTION IS DIRECTED TO THE CONDITIONS OBSERVED AND NOTED BELOW:

1. **Corrective and preventive action (CAPA) activities are not performed as specified by the firm's written operating procedures. Specifically, the firm's CAPA extension request EXT-00131 for CAPA-0004 was submitted two days after the CAPA due date.**

Signature of Firm Representative

State Food and Drug Inspector
Elizabeth Richter

VP Clinical Development, PIC
Title

Sample No. N/A
(If collected)

Form E-14 (revised 09)

QuVa PHARMA

February 11, 2019

To:

Elizabeth Richter

Texas Department of State Health Services

P.O. Box 149347

Austin, TX 78714-9347

Subject: Observation Response - to Texas Department of State Health Services Inspection Report issued January 31, 2019.

Dear Elizabeth Richter,

QuVa Pharma remains committed to our continued work with Texas Department of State Health Services in a cooperative and responsible manner to ensure that effective system enhancements are accomplished to support sustainable cGMP compliance at the Temple manufacturing facility.

Observation 1 in form E-14, No 07-1307 issued January 31, 2019, stated "Corrective and preventive action (CAPA) activities are not performed as specified by the firm's written operating procedures. Specifically, the firm's CAPA extension request EXT-00131 for CAPA-0004 was submitted two days after the CAPA due date.

Demonstrating our level of commitment to cGMP compliance, QuVa Temple has initiated and approved CR-3713, "DCR-TEM-SOP-QS-0004 CAPA Management". This document has been updated to provide clarity of the timely extension request submittals and processing and will be effective February 25, 2019.

If any clarification is required on the information presented in this letter and/or the attached follow-ups, please feel free to contact me as provided below.

Sincerely yours,

Travis Leeah, RPh
Vice President, Clinical Development
Travis.Leah@quvapharma.com
phone: (254) 933-4429

Michael Tuggle
Site Head of Quality
Michael.Tuggle@quvapharm.com
Phone: (603) 261-0672

State of Delaware
Secretary of State
Division of Corporations
Delivered 05:35 PM 05/28/2015
FILED 04:34 PM 05/28/2015
SRV 150811868 - 5755668 FILE

CERTIFICATE OF INCORPORATION

OF

QUVA, INC.

The undersigned, in order to form a corporation under and pursuant to the provisions of the General Corporation Law of the State of Delaware, does hereby certify as follows:

FIRST: The name of the corporation is Quva, Inc. (the "Corporation").

SECOND: The address of the Corporation's registered office in the State of Delaware is 2711 Centerville Road, Suite 400, Wilmington, New Castle County 19808. The name of its registered agent at such address is Corporation Service Company.

THIRD: The purposes for which the Corporation is formed are to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware (the "DGCL") and to possess and exercise all of the powers and privileges granted by such law and any other law of Delaware.

FOURTH: The total number of shares of stock which the Corporation shall have authority to issue is One Thousand (1,000) shares of Common Stock each without par value.

FIFTH: The name and mailing address of the Incorporator are as follows:

Name	Address
Peter Jenkins	135 Central Park West New York, NY 10023

SIXTH: In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors of the Corporation is expressly authorized and empowered to make, alter or repeal the bylaws of the Corporation, subject to the power of the stockholders of the Corporation to alter or repeal any bylaw made by the board of directors.

SEVENTH: The Corporation reserves the right at any time and from time to time to amend, alter, change or repeal any provisions contained in this Certificate of Incorporation, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the right reserved in this Article.

EIGHTH: The election of directors need not be by written ballot, unless the bylaws of the Corporation shall so provide.

NINTH: To the fullest extent permitted by the DGCL as the same exists or may hereafter be amended, a director of this Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that this Article shall not eliminate or limit the liability of a director for (i) any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Incorporation to be executed this 28th day of May, 2015.

Peter Jenkins, Incorporator

State of Delaware
Secretary of State
Division of Corporations
Delivered 05:05 PM 07/13/2015
FILED 05:06 PM 07/13/2015
SRV 151042713 - 5755668 FILE

CERTIFICATE OF AMENDMENT

OF

CERTIFICATE OF INCORPORATION

OF

QUVA, INC.

It is hereby certified that:

1. The name of the corporation (hereinafter called the "Corporation") is QuVa, Inc.

2. The Certificate of Incorporation of the Corporation is hereby amended by striking out Article FIRST thereof and by substituting in lieu of said Article FIRST the following new Article FIRST:

"FIRST: The name of the corporation is QuVa Pharma, Inc. (the "Corporation").

3. The amendment of the Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Amendment to the Certificate of Incorporation of QuVa, Inc. to be executed as of this 10th day of July, 2015.

QUVA, INC.

By: _____
Name: Peter Jenkins
Title: Chief Development Officer, Treasurer and Secretary

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "QUVA PHARMA, 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 THIRTEENTH DAY OF APRIL, A.D. 2020.

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "QUVA PHARMA, INC." WAS INCORPORATED ON THE TWENTY-EIGHTH DAY OF MAY, A.D. 2015.

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

Jeffrey W. Bullock, Secretary of State

5755668 8300

SR# 20202775186

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

Authentication: 202759509

Date: 04-13-20

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	02/26-28/19, 03/01, 4-8, & 14/19
	FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Alicia L. Ashford, Director of Manufacturing Operations

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	5920 S. General Bruce Drive
CITY, STATE AND ZIP CODE Temple, TX 76502	TYPE OF ESTABLISHMENT INSPECTED 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) (WE) OBSERVED:

OBSERVATION 1

Written procedures are lacking which describe in sufficient detail the receipt, identification, approval, and rejection of components.

Specifically, your firm is using non-pharmaceutical grade components in the formulation of sterile drug products. For example,

a) Your firm uses Sodium Hydroxide 10% (w/v) for adjusting the pH of sterile drug products. The Sodium Hydroxide is labeled "NOT FOR DRUG, FOOD, OR HOUSEHOLD USE".
b) Your firm uses Hydrochloric Acid ACS – Reagent Grade for adjusting the pH of sterile drug products.

OBSERVATION 2

There are no established written methods of cleaning or methods of processing to remove pyrogenic properties.

Specifically, your firm has not validated the depyrogenation process for the glass vessels/carboys used in compounding sterile drug products. Your firm has not demonstrated that the washing process you have implemented is adequate for endotoxin removal.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Margaret M. Annes	Margaret M. Annes, CSO Aqualia L. Nelson, CSO	3/14/19

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	02/26-28/19, 03/01, 4-8, & 14/19
	FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Alicia L. Ashford, Director of Manufacturing Operations

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	5920 S. General Bruce Drive
CITY, STATE AND ZIP CODE Temple, TX 76502	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

Your firm had a confirmed endotoxin failure in January 2019 (Finished product lot #10019623 of Heparin PF 0.25 U/mL 48 mL 0.5 NS – Bulk lot # TTX000000003663).

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a) In January 2019, your firm removed the pass thrus in all three (3) ISO 7 Cleanrooms that were between the unclassified hallway and the ISO 7 Cleanroom. As part of the change control, your firm did not perform an assessment to justify how you are bringing the materials into the cleanroom or if any changes were needed to the environmental monitoring program as a result of the change.

b) Your firm is not sampling sites that are frequently touched during production such as the surface of the Baxter Repeater Pump and the door handle from the ISO 7 Cleanroom into the ISO 8 Gowning/Ante Room.

OBSERVATION 4

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, rust and residue could be seen on the metal hinges of the totes used to hold and bring items into and out of the ISO 7 Cleanrooms and/or the ISO 8 Gowning/Ante Rooms, including empty sterile bags used for filling the sterilized product into; packages containing sterile tubing, filters, and environmental monitoring plates; and bags with the unfiltered and filtered drug product. Rust was also noted on the wheels of the trash cart in the ISO 7 Cleanroom 3 and the inside of the lid on the trash can in the ISO 8 Gowning/Ante Room for Cleanroom 3.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Margaret M. Annes	Margaret M. Annes, CSO Aqualia L. Nelson, CSO	3/14/19

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	02/26-28/19, 03/01, 4-8, & 14/19
	FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Alicia L. Ashford, Director of Manufacturing Operations

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	5920 S. General Bruce Drive
CITY, STATE AND ZIP CODE Temple, TX 76502	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 5

Production personnel were not practicing good sanitation and health habits.

Specifically, your firm does not have handwashing facilities near the gowning areas for entry into compounding areas, including entry into ISO 7 Cleanrooms/ISO 5 Glove Box. In addition, your written procedures regarding gowning do not require hand washing.

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm has not validated the incubation temperature and time for growth promotion of media and the environmental and personnel monitoring plates. Your firm is incubating the plates at 20-25 degrees C first and then 30-35 degrees C.

OBSERVATION 7

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, you compound drug products that: a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Add Continuation Page

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	Margaret M. Annes	Margaret M. Annes, CSO Aqualia L. Nelson, CSO	3/14/19

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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	FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Alicia L. Ashford, Director of Manufacturing Operations

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	5920 S. General Bruce Drive
CITY, STATE AND ZIP CODE Temple, TX 76502	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

- Neostigmine methylsulfate 1mg/1ml
- Glycopyrrolate 0.2mg/ml
- Midazolam PF 1mg/ml

OBSERVATION 8

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

a) The statement "This is a compounded drug";

b) ~~The name, address, and phone number of the outsourcing facility;~~ MMA 3/14/19

c) The dosage form and ~~strength;~~ MMA 3/14/19

d) ~~The quantity or volume;~~ MMA 3/14/19

e) The National Drug Code number, if available;

f) The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only";

g) ~~A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient~~. MMA 3/14/19

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Margaret M. Annes	Margaret M. Annes, CSO Aqualia L. Nelson, CSO	3/14/19

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Alicia L. Ashford, Director of Manufacturing Operations

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	5920 S. General Bruce Drive
CITY, STATE AND ZIP CODE Temple, TX 76502	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

Examples of your drug product labels that do not contain this information include:

- Fentanyl 10mcg/mL Preservative Free (PF) 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
- Diltiazem HCL 1mg/mL PF 3000mL bag
- Amiodarone HCL 1.8mg/mL 3000mL bag

OBSERVATION 9

The containers of your outsourcing facility's drug products does not include information required by section 503B (a)(10)(B). Specifically, your containers do not include the following information:

a) Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088;

Examples of your container labels that do not contain this information include:

- Fentanyl 10mcg/mL PF 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
- Diltiazem HCL 1mg/mL PF 3000mL bag
- Amiodarone HCL 1.8mg/mL 3000mL bag

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Alicia L. Ashford, Director of Manufacturing Operations

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	5920 S. General Bruce Drive
CITY, STATE AND ZIP CODE Temple, TX 76502	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

b) Route of administration.

Examples of drug product containers that do not contain this information:

- Fentanyl 10mcg/mL PF 3000mL bag
- Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag
- Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag
- Diltiazem HCL 1mg/mL PF 3000mL bag
- Amiodarone HCL 1.8mg/mL 3000mL bag

Add Continuation Page

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	Margaret M. Annes	Margaret M. Annes, CSO Aqualia L. Nelson, CSO	3/14/19

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 judgement, 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."

QuVa PHARMA

April 5, 2019

Monica Maxwell
U.S. Food and Drug Administration
4040 North Central Expressway, Suite 300
Dallas, TX 75204
(214) 253-5200

April 5, 2019

Subject: **Response to the Department of Health and Human Services Food and Drug Administration (FDA) Inspection Report (FEI 3002468086) issued March 14, 2019**

Dear Ms. Monica Maxwell,

Attached please find the QuVa Pharma, Inc. response to the FDA 483 Inspection Observations Report issued on March 14, 2019 by Investigators Margaret M. Annes and Aqualia L. Nelson at the completion of their inspection of the manufacturing facility located in Temple, Texas. The FDA inspection took place on February 26th, 27th, 28th, March 1st, 4th, 5th, 6th, 7th, and 8th. QuVa Pharma is registered as a 503B outsourcing facility manufacturing Compounded Sterile Products.

We would like to acknowledge and thank the FDA investigators who performed the inspection for their professionalism and thoroughness. Please be assured that the entire management team at QuVa Pharma, Inc. is fully committed to ensuring that enhancements are appropriately made and implemented to further strengthen the integrated Pharmaceutical Management System at the Temple, Texas site.

Details regarding the specific actions taken are included within our response to the FDA 483 Inspectional Observations Report. Timelines for the completion of remaining actions are included accordingly, and these commitments have been integrated into our site Quality Management System for continued tracking at the site.

QuVa Pharma remains committed in continuing to work with the Agency in a cooperative and responsible manner to ensure that effective system enhancements are accomplished to support sustainable cGMP compliance at the Temple facility.

Darren Hassey
Senior Director, Quality
darren.hassey@quvapharma.com
phone: (281) 644-9655

Alicia Ashford
Director, Manufacturing Operations
alicia.ashford@quvapharma.com
phone: (248) 882-0335

April 5, 2019

OBSERVATION 2

There are no established written methods of cleaning or methods of processing to remove pyrogenic properties.

Specifically, your firm has not validated the depyrogention process for the glass vessels/carboys used in compounding sterile drug products. Your firm has not demonstrated that the washing process you have implemented is adequate for endotoxin removal. Your firm had a confirmed endotoxin failure in January 2019 (Finished product lot #10019623 of Heparin PF 0.25 U/mL 48 mL 0.5 NS - Bulk lot# TTX000000003663).

RESPONSE 2

QuVa Pharma understands that Observation 2 is related to the lack of specific Log reduction validation for the carboy rinsing process' capability of removing endotoxin load. Post the inspection QuVa Pharma has collaborated with external industry subject matter experts, Charles River Laboratories, in designing a study protocol to best supplement the existing validation in a single discreet protocol. This protocol will be executed by 30 June 2019.

During the Inspection, QuVa Pharma presented the Investigator Engineering study, FR-ENG-2017-048, from 2017 which was performed to evaluate the DI water system and glassware cleaning process utilized by the QuVa Pharma Temple, TX Facility.

Additionally, QuVa Pharma performed a retrospective review of Historical data to determine the occurrence of the confirmed Heparin Endotoxin OOS result. Based upon the information reviewed from the manufacturing process, DI water rinse process evaluation, routine DI water sampling program, and historical endotoxin data for products with a similar specification to that of Heparin there was no indication of a systematic trend related to endotoxin bioburden levels exceeding product specifications at the QuVa Pharma Temple Facility. This data confirms the current processes for Endotoxin control is sufficient and that there is no risk to our products. See attachment 2A.

April 5, 2019

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a) In January 2019, your firm removed the pass thrus in all three (3) ISO 7 Cleanrooms that were between the unclassified hallway and the ISO 7 Cleanroom. As part of the change control, your firm did not perform an assessment to justify how you are bringing the materials into the cleanroom or if any changes were needed to the environmental monitoring program as a result of the change.

b) Your firm is not sampling sites that are frequently touched during production such as the surface of the Baxter Repeater Pump and the door handle from the ISO 7 Cleanroom into the ISO 8 Gowning/ Ante Room.

RESPONSE 3

3A

Though QuVa Pharma completed an extensive Change Control and Training for the pass thru decommissioning and removal, it is acknowledged that the specific assessment mentioned in the observation did not occur. This assessment was completed during the audit, to confirm suitability of the current plan, see attachment 3A, and was verbally acknowledged as acceptable by the Investigator.

3B

QuVa Pharma acknowledges that not every site that are frequently touched are sampled. QuVa Pharma has performed an additional risk assessment for each of the ISO 8 Gowning rooms and ISO 7 cleanrooms to identify additional sites that are frequently touched and a report of such has been generated, TEM-RA-R-00003, see attachment 3B. Further to this, the sampling sites identified in the observation, plus two others (airlock handles and airlock purge buttons) will be incorporated into the environmental sampling program via Change Control CR-0437. The additional sites will be incorporated by 3 May 2019.

QuVa Pharma has a series of contamination controls designed to minimize risk of microbial contamination ingress into the aseptic manufacturing environment, (Contained ISO 5). The aseptic manufacturing process itself is contained within an ISO 5 Compounding Isolator found within the ISO 7 Clean Room. All

QuVa PHARMA

April 5, 2019

materials are processed into each isolator using attached pass thru boxes that use a purge mechanism to clear the internal air prior to introducing into the interior area of the Isolator.

The ISO 7 cleanrooms (CR2, 3, and CSCR) are used as buffer areas that support aseptic manufacturing with an enclosed compounding isolator unit, which is used to establish the ISO 5 environment.

A review of the environmental monitoring data was performed and documented as "Risk Assessment of Current Environmental Monitoring sites for Classified Areas" during the Inspection, please refer attachment 3A. The review covered historical viable and non-viable environmental data for ISO 5 (Isolator), ISO 7 (Clean rooms), and ISO 8 (ante room) areas from 2017, 2018, and Q1 of 2019 and demonstrated that the current sampling plan provides suitable and robust data produced from monitoring the conditions of the ISO 7 cleanrooms and associated ISO 8 anterooms.

The design of the ISO 8 Gowning rooms, ISO 7 cleanrooms, and ISO 5 Isolators along with the robust aseptic gowning program QuVa Pharma has put into place provides the required environmental controls to prevent environmental contamination from aseptic manufacturing. The environmental program currently in place demonstrates that the environment is in control to produce sterile bulk product.

April 5, 2019

OBSERVATION 4

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, rust and residue could be seen on the metal hinges of the totes used to hold and bring items into and out of the ISO 7 Cleanrooms and/or the ISO 8 Gowning/Ante Rooms, including empty sterile bags used for filling and sterilized product into; packages containing sterile tubing, filters, and environmental monitoring plates; and bags with the unfiltered and filtered drug product. Rust was also noted on the wheels of the trash cart in the ISO 7 Cleanroom 3 and the inside of the lid on the trash can in the ISO 8 Gowning /Ante Room for Cleanroom 3.

RESPONSE 4

QuVa Pharma understands Observation 4, that rust and residue was observed on the metal hinges of the totes used to transfer disinfected materials into the ISO 8 and ISO 7 cleanroom areas as well as waste receptacles in the ISO 8 and ISO 7 cleanroom areas.

During the inspection, immediate actions were taken to ensure full compliance:

- Work order FM000702 was generated on 1 March 2019 during the inspection to address the stainless-steel trash cart in the Ante Room and the stainless-steel trash cart in the cleanroom.
- The trash carts in the Ante Room were replaced on the day of observation, and the Cleanroom trash carts were evaluated on 4 March 2019, with removal of the wheel canisters from the trash carts completed on that same day.

The work order is provided, see attachment 4A. To further remediate the use of materials, with metal parts (affected by cleaning agents), QuVa has sourced plastic totes without metal hinges, and all prior totes have been removed. The totes selected, align with disinfectant efficacy study completed in March 2017, see attachment 4B.

To prevent reoccurrence, the work instructions governing the disinfection and preparation of materials for introduction into the cleanroom have been revised. TEM-WI-SA-0002, Preparation of Compounding and Cleanroom Supplies, has been revised to include the use of the newly selected totes for cleanroom processing. Also, TEM-WI-SA-0003 Cleanroom Cleaning and TEM-FM-SA-0001, Cleanroom Cleaning/Prep Chart, has been revised to include requirement to inspect equipment for damage, degradation; and cleaning residue; removal; replacement and repair. The form, TEM-FM-SA-0001, is completed in the

QuVa PHARMA

April 5, 2019

cleanroom, prior to all compounding activities. This form enhancement allows operators to evaluate, report and escalate any equipment or material concerns. See attachments 4C, 4D and 4E.

As a continuous improvement opportunity, QuVa Pharma had an outside resource, and Industry Subject Matter Experts, Contec, Inc., to evaluate any opportunities for improvement of the current cleaning processes. On 25 March 2019, the technical representative from Contec, Inc. demonstrated proper cleaning techniques with our on-site trainers, Andrew Posey and Amanda Jarrett. Those techniques have been shared with the Temple site employees as an awareness training for proper cleaning techniques for disinfection and completeness of removal of disinfectants from equipment in the cleanroom. For evidence of training see attachment 4F and 4G.

April 5, 2019

OBSERVATION 5

Production personnel were not practicing good sanitation and health habits.

Specifically, your firm does not have handwashing facilities near the gowning areas for entry into compounding areas, including entry into ISO 7 Cleanrooms/ISO 5 Glove Box. In addition, your written procedures regarding gowning do not require hand washing.

RESPONSE 5

To further enhance sanitization practices, QuVa Pharma will implement a specific hand wash area. As such CR-0443 has been initiated for this change. See attachment 5A for evidence of engagement in work. This is a significant Engineering project to plan and complete properly without impact to our current excellent state of control. We anticipate this will complete by 30 September 2019.

QuVa Pharma complies with CFR211.52 with regard to providing adequate sanitation and handwashing facilities within the site. QuVa Pharma has long believed that the provision of city water close to controlled manufacturing environments may in fact present an increased Microbiological risk. To these ends, QuVa Pharma implemented the use of hand sanitant, gloving, and qualified sterile gowning procedures to assure cleanliness of operator's hands and to ensure high levels of general sanitization. During the inspection, the hand sanitant qualification technical qualification documentation detailing a 3 Log reduction in microbial load following use was presented.

April 5, 2019

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm has not validated the incubation temperature and time for growth promotion of media and the environmental and personnel monitoring plates. Your firm is incubating the plates at 20-25 degrees C first and then 30-35 degrees C.

RESPONSE 6

To ensure full validation of the incubation temperature and time for growth promotion of media and the environmental and personnel monitoring plates, a new study, (COR-ENG-P-00002) has been initiated to perform a specific validation of QuVa Pharma's current incubation strategy. See attachment 6A for the protocol. This protocol will be complete by 3 May 2019.

Based upon the below information QuVa Pharma's current dual incubation strategy is proven effective. See Attachment 6B.

- QuVa Pharma Temple Feasibility Study (TEM-RPT-QC-0005), was provided and discussed during the audit, based upon the outcome of the study it was determined that both, the TSA media and the dual incubation strategy were satisfactory in supporting enumeration of bacterial organisms and met growth acceptance criteria.

- A review of the growth promotion testing requirements currently established for Environmental (EM) and Personnel Monitoring (PM) media was performed, which demonstrated 100% effectiveness.

April 5, 2019

OBSERVATION 7

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, you compound drug products that: a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

- *Neostigmine Methylsulfate 1mg/1ml*
- *Glycopyrrolate 0.2mg/ml*
- *Midazolam PF 1 mg/ml*

RESPONSE 7

QuVa understands the FDA has concerns that finish product is not in compliance with the FDA 503B Guidance document for Essential Copies (*Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, January 2018).

QuVa's Pharmacy Services team and the hospital's DOP collaborated in evaluating the Neostigmine Methylsulfate 1mg/1ml, Glycopyrrolate 0.2mg/ml, and Midazolam PF 1mg/ml with respect to Essential Copy following the 503B guidance document. Following this collaborative discussion, QuVa Pharma has initiated a change control, (CR-0449) to convert those CSPs made by QuVa Pharma from the Glycopyrrolate bulk drug substance source to only be made from bulk drug substance if the commercially available drug product is on the FDA Drug Shortage list. This CR will be completed by 3 May 2019.

The CSP needed by the practitioner for Neostigmine Methylsulfate 1mg/ml and Midazolam PF 1mg/mL must be compounded by drug substance because of the difference in formulation with the commercially available drug product. Please see the attached, (attachment 7A and 7B) hospital's clinical need justification for Neostigmine Methylsulfate 1mg/ml and Midazolam PF 1mg/mL.

April 5, 2019

The Glycopyrrolate 0.2mg/ml CSPs would be considered an Essential Copy if compounded from drug substance because there is not a difference in formulation that is needed by the practitioner. The practitioner does have a clinical need for the product to be in a syringe rather than the commercially available vial. Please see the attached (attachment 7C) clinical need justification for Glycopyrrolate 0.2mg/ml.

April 5, 2019

OBSERVATION 8

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(l0) (A). Specifically, the following information is not found on your drug product labels:

a) The statement "This is a compounded drug";
~~b) The name, address, and phone number of the outsourcing facility;~~
c) The dosage form and ~~strength~~;
~~d) The quantity of volume~~
e) The National Drug Code number, if available;
f) The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only";
~~g) A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient~~

**line out donates items removed by investigator during close out meeting*

RESPONSE 8

For clarification, these items are an Intermediate Bulk solution that are not for commercial sale but are further processed into compounded sterile preparations (CSP) such as syringes, cassettes, or IV bags. QuVa Pharma transports the Bulk Intermediate from the Temple, TX facility to one of two QuVa Pharma 503B Outsourcing facilities for further processing into the finish CSP. QuVa Pharma understands the DQSA labeling requirements for a product leaving a 503B facility to include the additional detail in the above observation.

QuVa Pharma will make the following changes to our existing bulk intermediate label information:

1. Change "In-Process Bulk Bag" to **"Intermediate In-Process Bulk Bag"**
2. Add the statement **"This is a compounded drug"**
3. The dosage form will be added as **"injection."** We will add this statement; **"Injection Solution-Not for Resale-Office Use Only"**

April 5, 2019

QuVa Pharma does not have bulk bags listed NDC numbers with the FDA. We use an 11-digit item code for internal tracking. As a result, we do not name the 11-digit item code as an NDC number on the label.

All bulk labels will be updated. This process has been initiated under CR-0446 and will complete by 30 June 2019.

April 5, 2019

OBSERVATION 9

The containers of your outsourcing facility's drug products does not include information required by section 503B (a)(lO)(B). Specifically, your containers do not include the following information:

a) Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088; Examples of your container labels that do not contain this information include:

- *Fentanyl 10mcg/mL PF 3000mL bag*
- *Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag*
- *Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag*
- *Diltiazem HCL 1mg/mL PF 3000mL bag*
- *Amiodarone HCL 1.8mg/mL 3000mL bag*

b) Route of administration.

Examples of drug product containers that do not contain this information:

- *Fentanyl l0mcg/mL PF 3000mL bag*
- *Morphine Sulfate Pentahydrate 1mg/mL PF 3000mL bag*
- *Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag*
- *Diltiazem HCL 1mg/mL PF 3000mL bag*
- *Amiodarone HCL 1.8mg/mL 3000mL bag*

RESPONSE 9

9A

QuVa would like to clarify that the labels referenced in this observation are for intermediate bulk batches that are not for sale and will be further compounded into a CSP at a QuVa 503B outsourcing facility. To meet the DQSA labeling requirements, QuVa will add to our intermediate bulk bag labels the adverse event reporting statement: *To Report Suspected adverse reactions, contact QuVa Pharma at 877-296-0190 or FDA at www.fda.gov/medwatch and 1-800-FDA-1088.*

April 5, 2019

9B

QuVa Pharma understands the DQSA labeling requirements for a product leaving a 503B facility to include the route of administration on the label. In the clinical setting, route of administration is used on a finished compounded sterile preparation (CSP) to instruct the practitioner on administration. The QuVa labels referenced in this observation are for intermediate bulk bags that are not for sale but will be further processed to a CSP at a QuVa 503B outsourcing facility. QuVa may use the same intermediate bulk batch to compound different CSPs. For example, one intermediate bulk batch may be used to compound one CSP for a local nerve block and another CSP for epidural use. To comply with the DQSA labeling requirements, we will add the potential CSP routes of administration on the intermediate bulk bag label, one example is shown below.

Fentanyl/Ropivacaine HCL PF 2mcg/ml/0.2% 3000mL bag **"Not for direct Infusion, further processing required for epidural use"**

All bulk labels will be updated. This process has been initiated under CR-0446 and will complete by 30 June 2019

15H

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (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 Publicly 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: Sincerus Florida, LLC

Physical Address: 3265 W McNab Road

City: Pompano Beach State: FL Zip Code: 33069

Telephone: 954-228-6632 Fax: 954-256-5043

Toll Free Number: 800-604-5032 (Required per NAC 639.708)

E-mail: elicense@sincerususa.com Website: www.sincerususa.com

Supervising Pharmacist: Jenny Liu Nevada License #: ~~Pending~~ 20340 exp 10/31/21

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

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

FEI Number (From FDA application): 3012384835

Please provide the name of the facility as registered with the FDA and the registration number:
3012384835 - Sincerus Florida, LLC

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: Jenny Liu Nevada License Number: 20340

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

Jonathan Fenster

Print Name of Authorized Person

May 5, 2020

Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Sincerus, LLC

Address: 3265 W McNab Road

City: Pompano Beach State: FL Zip: 33069

Telephone: 561-404-8885 Fax: 561-503-4131

Contact Person: Maria Yeager

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Sincerus, LLC 3265 W. McNab Road, Pompano Beach, FL 33069
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 100 Membership Units

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

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

Arizona Board of Pharmacy
Complaint No: 180170

Sincerus Florida, LLC (Sincerus) received a request for records from the Arizona Board of Pharmacy in connection with a consumer complaint. The complaint was the result of miscommunication between the consumer and the prescriber, the consumer's inaccurate research, and the prescriber's failure to properly label the dispensed medication. The complaint alleged that the practitioner's office orders ingredients from Sincerus to later compound in-office. This explanation was incorrect. Sincerus ships all compounded medications as final products and not as individual ingredients. The consumer also found a wholesaler license for Sincerus and assumed that Sincerus was shipping product into Arizona under that license. Sincerus is an FDA registered 503B Outsourcing Facility. The facility is licensed in Arizona as a Non-resident Manufacturer, as is required for any out-of-state 503B Outsourcing Facility doing business in Arizona. No further permits/licenses are required under Arizona law.
Please see the enclosed copy of the complaint and the response submitted on July 16, 2018, the matter was heard before the Arizona Board of Pharmacy on July 31, 2019 . Vice-President Snair moved for dismissal.

Nevada Board of Pharmacy
Case 17-011

Sincerus Florida, LLC (Sincerus) received an investigative Letter from the Nevada Board of Pharmacy based on misinformation received by the Board. Specifically, the Letter states that Sincerus "sells bulk and compounded products in conjunction with Prescriber's Choice (PC Operations, LLC) to physician groups in Nevada [that] are then re-compounded and/or repackaged for final sale to patients by the practitioner". As Sincerus response indicates, this is an inaccurate description of Sincerus' business. Sincerus submitted its response on June 2019, and an updated response on February 2020; the matter is pending.

Jonathan Foster - COO
5-5-20

Arizona State Board of Pharmacy
Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
p) 602-771-2727 f) 602-771-2749
www.azpharmacy.gov

April 5, 2019

Sincerus Florida, LLC
3265 W. McNab Road
Pompano Beach, FL 33069

RE: Arizona Board of Pharmacy Complaint Number 18-0170

Dear Sir or Madam,

On April 4, 2019, the Board office sent a notice regarding the conference scheduled for Board Case No. 18-0170, which was set for May 9, 2019. That conference has been rescheduled. It is now scheduled for:

July 31, 2019
1:00 – 5:00 P.M.
Arizona State Board of Pharmacy Meeting
Arizona State Board of Pharmacy Office
1616 W. Adams, Suite #120 – Board Room
Phoenix, AZ 85007

Please review the circumstances surrounding this complaint and come prepared to discuss the pertinent facts and answer questions from Board members.

Please be present by 1:00 P.M. Please remain in the audience until your name is called by the President to come forth to speak with the Board Members. Your case will be heard between 1:00-5:00 P.M.

Pursuant to A.R.S. § 32-1927.02(K) there are a number of options available to the Board after a conference, including but not limited to dismissing the matter, filing an advisory letter, mandating continuing education, or entering into a consent agreement that could include a letter of reprimand, a decree of censure, practice restrictions or referring the matter to a formal hearing for the revocation or suspension of the license.

If you have any questions regarding this matter, please contact this office.

Sincerely,

Elizabeth Dodge, PharmD
Deputy Director
edodge@AZPharmacy.gov

ED/jcm

C: Roger Morris, Esq.

SINCERUS FLORIDA
a Subsidiary of Sincerus Pharmaceuticals, Inc.

Sandy Sutcliffe, RPh, JD
Arizona Board of Pharmacy
Compliance Officer
1616 West Adams Street
Suite 120
Phoenix, Arizona 85007
ssutcliffe@azpharmacy.gov

RE: Complaint 180170

Dear Ms. Sutcliffe:

We are in receipt of the above-referenced complaint ("Complaint") and provide the attached documents in response. Sincerus Florida, LLC ("Outsourcing Facility") denies the allegations in the Complaint and offers the below as rebuttal.

- Outsourcing Facility is a Delaware limited liability company registered with the U.S. Food and Drug Administration ("FDA") as an "outsourcing facility" pursuant to Section 503B of the Food, Drug & Cosmetic Act. Outsourcing Facility is not registered, nor is required to be registered, with FDA as a repackager.
- As noted in your letter dated June 29, 2018, Outsourcing Facility currently holds in Arizona a non-resident manufacturer permit (#M0008206) based on its federal registration. Outsourcing Facility also holds in Arizona a non-resident, full-service wholesaler permit (#W002841). We were initially instructed by the AZ BOP that we required both licenses, but on review, it appears that our operations do not require a wholesaler permit. Unless we hear otherwise from you, we will prepare to relinquish it and maintain only the non-resident manufacturer permit in connection with our federal 503B registration.
- Outsourcing Facility compounds and ships medications ordered by physicians. All compounded medications are shipped as the final product and not as individual ingredients. The compounded medication that Outsourcing Facility ships are labeled properly in accordance with Federal law. We have attached a sample label for your convenience. Included on the label is the Beyond Use Date (BUD) appropriate for the product. For the product mentioned in the complaint, the appropriate BUD is 6-months. Physicians are expected to apply a state-specific label prior to dispensing.

Please let us know if you have any further questions.

Sincerely,

Deirdre J. Boling-Lewis*
General Counsel

Encl.

Sincerus

Sincerus Florida, LLC
3265 W McNab Road
Pompano Beach, FL 33069
(800)-604-5032

081033 LIDOCAINE 2% / MUPIROCIN 2% / TRANILAST 1% OINTMENT

QUANTITY: 400 ML
LOT:
MFG/CD:
BUD:

ACTIVE INGREDIENTS:

MUPIROCIN USP 2%
LIDOCAINE USP 2%
TRANILAST 1%

INACTIVE INGREDIENTS:

ALOE VERA 0.2%
PETROLATUM 94.8%

Directions for Use: As Directed by Physician
Route of Administration: Topical
Store at Controlled Room Temperature (20-25C)
This is a Compounded Drug
Office Use Only/Not for Resale
Wash Hands After Use
For External Use Only
RX Only
To report suspected adverse reactions, contact Sincerus Florida, LLC at 800-604-5032, or FDA at www.FDA.gov/MedWatch or 1-800-FDA-1088.

SAMPLE LABEL

2005

MOTION PASSED.

25.e. 18-0170
Compounded medication (503b) sold by a practitioner to a patient.

Compliance Officer Sutcliffe summarized for the Board that in May of 2018, the complainant's wife received a compounded medication from a dermatologist that did not contain a label with a beyond-use date. She presented photos of cartridges provided by Prescriber's Choice that are to be used in a device provided by Prescriber's Choice. She added that documentation was requested from the company including policies and procedures regarding removal of medication from the cartridge. Board staff discovered that the beyond-use date on the label did not match the log formula worksheet provided by the company, as the label indicated a beyond-use date of 60 days rather than the 30 days.

The CEO was present with Counsel, including Mr. Roger Morris. Mr. Morris explained that this is an outsourcing facility that is FDA approved and holds an Arizona manufacturing permit. He stated that the outsourced product that is sold to practices is then dispensed to patients pursuant to the law. The CEO explained that the cartridges displayed in the photos that were submitted within the complaint never made it production as the physicians lacked the technical knowledge from a pharmaceutical perspective to modify the medication in the office as originally planned. He stated that the device referenced in the complaint is a historical relic that is no longer used as the current process involves shipment to physicians in a final container without the need for compounding in the office.

Mr. Morris stated that the company used USP guidelines for the beyond-use dates that were clearly listed on the label. He stated that it was not the outsourcing facility's fault that the medication was dispensed after the beyond-use date expired as it was properly labeled, and that the physician should not have dispensed the medication. Ms. Walmsley noted that the Florida license is in good standing and has not had any compliance issues with respect to inspections, and that there have been no other formal investigations or discipline in any other state.

After hearing the process from start to finish from the company's CEO, the Board questioned Board staff as to the obligations of a prescriber to dispense the medication under Arizona law. Mr. Morris clarified that there was no compounding being performed by the physicians in the office as they were receiving a finished mixed product that they had the ability to portion out into a different container. Ms. Walmsley spoke in favor of dismissing the case and referring the matter to the Arizona Medical Board for review as physician prescribing practices are not under the jurisdiction of the Pharmacy Board.

Mr. Blaire stated that since the passage of DQSA, the Board has seen an enormous movement of compounding from pharmacies into physicians' offices. He stated that while compounding continues to evolve, the laws that regulate compounding were developed when there were very few people engaging in such practice. Mr. Blaire stated that the Board at some point will need to address or revisit their general opinion on the practice of compounding. He added that he was impressed with the model presented for the Board's review in this matter, and that while it may conform to the letter of the law, he was not sure that it was the spirit of the law. He stated that the Board needs to bring the regulation of compounding into the current time. President Leyba stated that the interpretation of the law could be clarified by the FDA.

MOTION: Vice-President Snair moved for dismissal and for the matter to be referred to the Arizona Medical Board.
SECOND: Mr. Blaire

3265 W McNab Road
Pompano Beach, FL 33069
Phone: (561) 404-8885
Fax: (561) 503-4131

March 19, 2019

Monica R. Maxwell
Acting Program Division Director
U.S. Food and Drug Administration
Office of Pharmaceutical Quality Operations (OPQO), Division II
4040 N. Central Expressway, Suite 900
Dallas, TX 75204

RE: Update to Sincerus Florida, LLC (Sincerus) Response to FDA Form 483 issued September 17, 2018

Dear Director Maxwell:

This letter is being sent to update you on the progress that Sincerus Florida has made since our response to the FDA form 483 observations made during the last FDA inspection of our facility at 3265 McNab Road, Pompano Beach, FL 33069. The inspection was conducted on August 30, 2018, August 31, 2018, and September 17, 2018. Our last response to your observations during that inspection was sent to you on October 9, 2018.

Sincerus Florida takes cGMP concerns very seriously and continues to make great strides in taking the necessary steps to comply with those regulations as well as the new 503B draft guidelines (Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Draft Guidance for Industry December 2018) to the best of our ability. We are also planning to modify our facility in 2019 to comply with the new USP <800> and USP <795> regulations. And while we are currently developing potency methods, due to the number of APIs at multiple strengths in our compounded drug formulations, we have additional work that must be completed. Our efforts to address all of these concerns are described in this update. Lastly, Sincerus Florida has recently decided that as soon as practical in 2019, our packaging will change from cartridges to final containers (i.e., airless pumps). This will help to maintain product stability and allow us to extend our compounds' BUDs. These changes have caused delays in our progress as we work through the processes needed to implement these beneficial changes. However, we truly believe that all these improvements are necessary to provide our customers with the best compounded products available. Our plan is to send you routine updates on our progress towards satisfying all of the observations noted during the inspection.

Respectfully submitted,

Spencer Malkin
President
Sincerus Florida, LLC
Email: smalkin@sincerususa.com

Joanne Hoefling
Director of Regulatory Compliance and Quality
Sincerus Florida, LLC
Email: jhoefling@sincerususa.com

OBSERVATION 1
Each lot of components is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically, non-pharmaceutical grade components are used in the formulation of non-sterile drug products. Your firm uses Distilled Water or Preserved Water (Parabens) Solution in the formulation of your nonsterile drug products. However, your firm did not provide any documentation supporting this component, which is not USP grade. Your firm does not conduct any microbial testing on any drug products that use D1 water or Preserved Water (Parabens).

RESPONSE 1:
In response, CAPA18-25 was issued. Sincerus recognizes that prior to the execution of CAPA18-25, Sincerus utilized commercially available purified water in the compounding of 42 non-sterile formulations. Sincerus now uses only USP grade purified water in the compounding of its non-sterile products. Forty-two (42) master formulation records have been updated to include this change. See attachment 1 for the list of the 42 affected formulations, COA for the USP grade purified water and an example of the change in the master formulation records.

Please see Attachment 1, CAPA18-25 with attachments, which was closed on 10/09/2018.

2019-Q1 UPDATE: CAPA18-25 was closed on 10/09/2018 and copy of closed CAPA18-25 was attached to Sincerus' 10/09/2018 response. No further action planned at this time.

OBSERVATION 2
Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm has failed to perform release testing for potency on each batch of drug product produced at your facility. Examples include, but are not limited to the following:

- Product 031041- Fluocinolone Acetonide 0.01% / Minoxidil 5% / Tretinoin 0.025%, Lot 031041AIBFCABI@l4, BUD 09/14/18
- Product 031089- Fluocinolone Acetonide 0.0 l % / Minoxidil 7% / Progesterone 0.1% / Tretinoin 0.025%, Lot 031089AFDBCABI@5, BUD 06/30/18
- Product 031070- Tacrolimus 0.1%, Lot 031070AIDACABI@14, BUD 09/29/18
- Product 031101- Ketoconazole 2% / Minoxidil 7% / Tretinoin 0.05%, Lot 031101AHBGCABI@14, BUD 08/15/18
- Product 041013- Betamethasone Dipropionate 0.05% / Menthol 2% / Pramoxine HCL 1% / Tranilast 0.5%, Lot 041013AICJCABI@14, BUD 09/27/18
- Product 141030- Hydroquinone 8%, Lot l41030AJAFCABI@l4, BUD 10/05/18
- Product 201017- Lidocaine 23% / Prilocaine 5% (Oleabase), Lot 201017AIBGCABI@l, BUD 02/12/19

RESPONSE 2:
In response, CAPA18-26 was issued. Sincerus recognizes that it is only using pharmacist discretion according to Board of Pharmacy standards to release non-sterile drug products. Sincerus has a Quality Control lab that includes 4-HPLCs and employs 2 full-time method development chemists. Method development for potency testing in order to establish final specifications for the release of our non-sterile drug products according to GMP regulations was in-process prior to inspection. In order to expedite this process, Sincerus will take a two-phase approach. Phase One will entail developing sound potency methods and utilizing accelerated stability results to first assess our non-sterile products and then establishing potency specifications. There is a target date of 4-months to complete Phase One. Phase Two will be a fully compliant stability assessment including real-time studies. It is expected that Phase Two will require an additional 5-months to complete.

Please see Attachment 2, CAPA18-26. There is a 9 month target date for the completion of this project.

2019-Q1 UPDATE: Due to the number of APIs at multiple strengths in our compounded medication formulations, we have additional work before we can finalize reliable, sound methods to extract the actives from our compounds. We must accurately measure their content in our products which contain from one to seven active ingredients. This abundance of caution in providing the best possible outcome has caused some delays in our aggressive plan to complete Phase One during the 4 months period previously targeted. We are moving the original 4 month target date to 9 months for Phase 1. To date we have developed potency methods covering 38 of our non-sterile formulations which are currently being validated.

OBSERVATION 3
The in-process control procedures were deficient in that they did not include an examination of the adequacy of mixing to assure uniformity and homogeneity.

Specifically, your firm failed to validate your current formulary procedures are in accordance with your reference procedures to ensure homogeneity and blend uniformity are obtained.

RESPONSE 3:
In response, CAPA18-27 was issued. Sincerus recognizes the need to examine the adequacy of mixing to ensure uniformity and homogeneity. Sincerus has a Quality Control lab that includes 4-HPLCs and employs 2 full-time method development chemists. Method development for potency testing in order to establish final specifications for the release of our non-sterile drug products according to GMP regulations was in-process prior to inspection. Once method development is complete the adequacy of compounding mixing processes will be assessed ASAP after potency specifications are approved.

Please see Attachment 3, CAPA18-27. There is a 12-month target date to complete this project for our current 210 non-sterile formulations.

2019-Q1 UPDATE: Due to the aforementioned work described in Observation 2 – 2019 Q1 Update above that is needed prior to the actions required to resolve this observation, it is necessary to move the 12 month target out 3 months for CAPA18-27 which addresses the adequacy of mixing to ensure uniformity and homogeneity. In addition, Sincerus has been evaluating several commercially available options for automating our mixing process. We engaged engineers at Schold Manufacturing, Chicago, IL to design a specialized bowtie type blade for their LMX mixer. It is a custom fit for our batch containers to help ensure thorough, even mixing of our non-sterile compounded drug products. See attached product information, blade diagram and PO.

Please see 2019-Q1 Attachment 1, Schould Products LMX Mixer Information, Blade Diagram and PO

OBSERVATION 4
There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm has not performed stability testing on any drug product to ensure the shelf-life of the drug products. Examples include, but are not limited to:

- Product 501010- Magnesium sulfate in 5% Dextrose, Lot 501010SAGBDCABI@l, BUD 06/22/18
- Product 141030- Hydroquinone 8%, Lot 141030AJAFCABI@14, BUD 10/05/18

RESPONSE 4:
In response, CAPA18-28 was issued. Sincerus recognizes that currently, there are no stability studies performed on our non-sterile compounded products and USP standards are being utilized for the BUD (Beyond Use Dates) assigned to our non-sterile products. Sincerus has a Quality Control lab that includes four HPLCs and two stability chambers and employs 2 full-time method development chemists, a senior quality chemist, and a lab technician. Method development for potency testing in order to establish final specifications for the release of our non-sterile drug products according to GMP regulations was in-process prior to inspection. In order to expedite this process, Sincerus will take a two-phase approach. Phase One will entail developing sound potency methods and utilizing accelerated stability results to first assess our non-sterile products and then establishing potency specifications. There is a target date of 4 months to complete Phase One. Phase Two will be a fully compliant stability assessment including real-time studies. It is expected that Phase Two will require an additional 5 months to complete.

Sincerus did perform stability studies on our sterile product, 2G Magnesium Sulfate in 5% Dextrose 50 ML Bag Injection. While the protocol called for a 28-day study, Sincerus only sells this sterile product with a 9-day BUD. Sincerus was able to confirm 14-days. An Addendum Report to the Original Process Validation has been issued and is attached. (Attachment 5)

Please see Attachment 4, CAPA18-28.
Please see Attachment 5, Addendum to Process Validation Report for the Compounding of Medium Risk Sterile Preparations (14 Day Stability Results) 2 GM Magnesium Sulfate in 5% Dextrose 50 ML Bag Injection.

2019-Q1 UPDATE: A 14-day stability study report for our sterile product, 2G Magnesium Sulfate in 5% Dextrose 50 ML Bag Injection, was attached to Sincerus' 10/09/2018 response. No further action planned at this time.

Due to the aforementioned work described in Observation 2- 2019 Q1 Update for developing reliable, sound potency methods to determine the level of actives in Sincerus' non-sterile products, it is necessary to move the 4 month target date for Phase 1 to 9 months in CAPA18-28 which addresses non-sterile compounded drug product stability studies.

OBSERVATION 5
There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. Specifically, multiple complaint investigations into adverse events lacked a thorough investigation into the root cause for the complaint. Examples include, but are not limited to:

- Complaint 18-52- Five patients experienced redness during use of Product 201019-Lidocaine 23% / Tetracaine 7%, Lot 201019ABAECABI@6, BUD 05/09/18. There was no root cause or potential root cause identified.
- Complaint 18-84- Four patients experienced a rash after use of Product 011009- Niacinamide 4% / Tretinoin 0.05%, Lot 011009BBCBCABH@8, BUD 12/21/17. There was no root cause or potential root cause identified.
- Complaint 18-138- Multiple patients experienced redness, hives, itching, or swelling within five (5) minutes of applying Product 201016- Lidocaine 7% / Tetracaine 7%, Lot 201016ADCJCABI@2, BUD 09/25/18. There was no root cause or potential root cause identified.

RESPONSE 5:
In response, CAPA18-29 was issued. Although Sincerus performs a thorough investigation of customer complaints including, but not limited to, batch record reviews, review of similar prior complaints and checking our retains, Sincerus recognizes that we did not always request the return of consumers' products that were subject to a quality complaint and/or adverse reaction. Sincerus did not have designated sections in our complaint investigation report for "root cause" or "evaluation notes for returned product." SOP QA-10 Management of Customer Complaints and/or Adverse/Adverse Events has been updated to address these concerns.

Sincerus recognizes that the potency testing of returned products would provide better insight to the root cause of a legitimate quality complaint, including those involving adverse events. For non-sterile products, potency testing of returned products with legitimate quality and/or adverse events will commence once potency specifications have been established. For sterile products, Sincerus has not received any complaints. Although not previously documented in our SOPs, Sincerus' plan has always been to test sterile products returned for legitimate quality complaints and/or adverse reactions. SOP QA-10 Management of Customer Complaints and/or Adverse/Adverse Events has been revised to address these issues.

Please see Attachment 5, CAPA18-29 and Attachment 6, SOP QA-10 Management of Customer Complaints and/or Adverse/Adverse Events

2019-Q1 UPDATE: CAPA18-29 was closed on 12/21/2018 and copy of closed CAPA18-29 is attached to this update. No further action planned at this time. See Attachment 2.

Please see 2019-Q1 Attachment 2, CAPA18-29. No further action planned at this time.

OBSERVATION 6
Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, hazardous drugs, hormones, and antibiotics were produced in your firm's non-sterile suite area without providing adequate cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination. However, your firm does not have a cleaning procedure for these drug products to ensure cross-contamination does not occur. In addition, your firm places dedicated utensils in the dishwasher with non-dedicated utensils used in production. On 08/30/2018, we observed hazardous/antibiotics being produced under the same hood as non-hazardous drugs. We also observed powdered residue on your firm's Exakt Rolling Mill used in the production of cream and emollient drug products. According to your firm's Pharmacist-In-Charge, this equipment's status was clean.

RESPONSE 6:
In response, CAPA18-30 was issued. Sincerus recognizes that utensils and labware marked for use with antibiotics or hormones were comingled with general labware during washing. SOP NC-04, Operation of the Hobart LXeR Dishwasher has been updated to use separate wash cycles for antibiotics, hormones, and general labware.

NOTES:

- Train all compounding personnel on preventing cross-contamination and improved cleaning procedures

Sincerus recognizes the fact that while hormone containing products were compounded in a dedicated hood, products containing antibiotics were not. Sincerus is in the process of certifying a separate hood that will be dedicated to compounding products containing antibiotics. SOP NC-15, "General cleaning procedure - pharmacies - non-sterile areas" is currently being drafted to address the cleaning of non-sterile compounding areas and will include swab testing and cleaning non-sterile powder containment hood areas to the level used for hazard drugs. In the meantime, a cleaning log has been created to document the cleaning of non-sterile hood after the compounding of each lot. In addition, Sincerus has created usage and cleaning logs for the ointment mills used in the compounding of non-sterile drug products to capture the use, cleaning, and cleaning verification of ointment mills. All compounding personnel will be trained by a Pharmacist on preventing cross-contamination and improved cleaning procedures including blanketing all hood surfaces by spraying 70% IPA spray then wiping and wiping down all equipment with wipes saturated with 70% IPA.

Please see Attachment 8, CAPA18-30
Please see Attachment 9, SOP NC-04, Operation of the Hobart LXeR Dishwasher
Please see Attachment 10, Ointment Mill Use and Cleaning Log
Please see Attachment 11, Non-Sterile Powder Hood Cleaning Log

2019-Q1 UPDATE: SOP NC-04, Operation of the Hobart LXeR Dishwasher, the Ointment Mill Use and Cleaning Log, and the Non-Sterile Powder Hood Cleaning Log were addressed in Sincerus' 10/09/2018 response and are currently in use. See Attachments 3 and 4. A powder containment hood dedicated to compounding products containing antibiotics is now in use. See Attachment 5. SOP F-09, General Cleaning of Sincerus' Non-Sterile cGMP Areas has been drafted. See Attachment 6. An SOP is currently being drafted to address the operation, use and cleaning procedures for ointments mills.

Please see 2019-Q1 Attachment 3, Example of a Powder Containment Hood Use and Cleaning Log
Please see 2019-Q1 Attachment 4, Example of an Ointment Mill Use and Cleaning Log
Please see 2019-Q1 Attachment 5, Pictures of Hood Dedicated to Compounding Products Containing Antibiotics
Please see 2019-Q1 Attachment 6, SOP F-09, General Cleaning of Non-Sterile cGMP Areas DRAFT

Information of Organization

Sincerus Florida, LLC, Sole owner and operator of facility
EIN: 30-0891087

Mailing Address: 3265 W McNab Road, Pompano Beach FL 33069
Phone No: 561-404-8893
legal@sincerususa.com

Officers of Applicant:
Spencer Malkin, CEO of Sincerus Florida, LLC (0% direct ownership)
Jonathan Fenster, COO of Sincerus Florida, LLC (0% direct ownership)

2013

AC# 8771491

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
02/01/2019	PH 29976	111165

The PHARMACY named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2021**

SINCERUS FLORIDA, LLC
Sincerus Florida, LLC
3265 W MCNAB ROAD
POMPANO BEACH, FL 33069

QUALIFICATION(S):
SPECIAL STERILE COMPOUNDING

Ron DeSantis
GOVERNOR

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE
AC# 8771491

DATE	LICENSE NO.	CONTROL NO.
02/01/2019	PH 29976	111165

The PHARMACY named below has met all requirements of the laws and rules of the state of Florida.
Expiration Date: FEBRUARY 28, 2021

SINCERUS FLORIDA, LLC

LICENSEE SIGNATURE

QUALIFICATION(S):
Special Sterile Compounding

EXPIRATION DATE: **FEBRUARY 28, 2021**

Your license number is PH 29976. Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

Medical Quality Assurance has a new and improved Online Services Portal. In the new system, you have the ability to renew your license, update your mailing and practice location addresses, request a name change, request a duplicate license and update your profile information all from the convenience of your online account.

1. Go to www.FLHealthSource.gov.
2. Click on "Provider Services" and select "Manage Your License."
3. Select your profession and license type and click "Submit."
4. The question "Have you Renewed or Applied Online Since 2015?" will display.
   a. Click on "No" if you have not registered for an account in the new system and follow the instructions provided for new user registration.
   b. Click on "Yes" if you are a returning user. Enter the user ID and password you selected during the registration process, then select "Sign In" to access your MQA Online Services Portal account.

IMPORTANT ANNOUNCEMENTS

Are You Renewal Ready?

Grounds for Discipline

2014

B14EZ0050

AC#8771490

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
02/01/2019	PH 29905	111156

The **PHARMACY**
named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28 2021**

SINCERUS FLORIDA, LLC
SINCERUS FLORIDA, LLC
3265 W MCNAB ROAD
POMPANO BEACH, FL 33069

QUALIFICATION(S):
COMMUNITY PHARMACY
3:1 PHARMACY TECHNICIAN RATIO APPROVED

Ron DeSantis
GOVERNOR

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE
AC# 8771490

DATE	LICENSE NO.	CONTROL NO.
02/01/2019	PH 29905	111156

The PHARMACY named below has met all requirements of the laws and rules of the state of Florida.
Expiration Date: FEBRUARY 28, 2021

SINCERUS FLORIDA, LLC

LICENSEE SIGNATURE

QUALIFICATION(S):
Community Pharmacy
3:1 Pharmacy Technician Ratio Approved

EXPIRATION DATE: **FEBRUARY 28, 2021**

Your license number is PH 29905. Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

Medical Quality Assurance has a new and improved Online Services Portal. In the new system, you have the ability to renew your license, update your mailing and practice location addresses, request a name change, request a duplicate license and update your profile information all from the convenience of your online account.

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   a. Click on "No" if you have not registered for an account in the new system and follow the instructions provided for new user registration.
   b. Click on "Yes" if you are a returning user. Enter the user ID and password you selected during the registration process, then select "Sign In" to access your MQA Online Services Portal account.

Department of Health

License Number: PH29976

Data As Of 5/5/2020

Profession	Pharmacy
License	PH29976
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2021
License Original Issue Date	03/23/2016
Address of Record	3265 W MCNAB ROAD POMPANO BEACH, FL 33069 UNITED STATES
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.

Official license certifications have been ordered from FL BOP, they will be forwarded to your office immediately upon receipt. Please accept this on-line verification in the interim

Department of Health

License Number: PH29905

Data As Of 5/5/2020

Profession	Pharmacy
License	PH29905
License Status	CLEAR/
Qualifications	Community Pharmacy
License Expiration Date	2/28/2021
License Original Issue Date	02/19/2016
Address of Record	3265 W MCNAB ROAD POMPANO BEACH, FL 33069
Discipline on File	No
Public Complaint	No

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Maria Yeager

From: DoNotReply_CDER@fda.hhs.gov
Sent: Wednesday, January 29, 2020 12:25 PM
To: elicense
Cc: CDERCollections@fda.hhs.gov; Compounding@fda.hhs.gov; EDRLS@fda.hhs.gov
Subject: FY2020 Outsourcing Facility Acknowledgment - Sincerus Florida, LLC

Good Afternoon,

We have received the establishment registration fee for Sincerus Florida, LLC in the amount of $18,288. Effective January 01, 2020, your facility located at 3265 West McNab Road Pompano Beach, FL 33069 is now registered as a human drug outsourcing facility through December 31, 2020.

For more information on the Compounding Quality Act, visit FDA's Compounding Website:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm

Thanks
CQA User Fee Staff

Revision Bulletin
Official January 1, 2014

⟨795⟩ PHARMACEUTICAL COMPOUNDING—NONSTERILE PREPARATIONS

INTRODUCTION

The purpose of this chapter is to provide compounders with guidance on applying good compounding practices for the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals. Compounding is an integral part of pharmacy practice and is essential to the provision of healthcare. This chapter and applicable monographs on formulation help define good compounding practices. Furthermore, this chapter provides general information to enhance the compounder's ability in the compounding facility to extemporaneously compound preparations that are of acceptable strength, quality, and purity. Pharmacists, other healthcare professionals, and others engaged in the compounding of drug preparations should comply with applicable state and federal compounding laws, regulations, and guidelines.

DEFINITIONS

Active Pharmaceutical Ingredient (API)—Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

Added Substances—Ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredients, excipients,* and *pharmaceutical ingredients.*

Beyond-Use Date (BUD)—The date after which a compounded preparation should not to be used; determined from the date the preparation is compounded.

Component—Any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation.

Compounder—A professional authorized by the appropriate jurisdiction to perform compounding pursuant to a prescription or medication order by a licensed prescriber.

Compounding—The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

- Preparation of drug dosage forms for both human and animal patients
- Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients
- Preparation of drugs or devices for the purposes of, or as an incident to, research (clinical or academic), teaching, or chemical analysis
- Preparation of drugs and devices for prescriber's office use where permitted by federal and state law

Hazardous Drug—Any drug identified by at least one of the following six criteria:

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Genotoxicity
- New drugs that mimic existing hazardous drugs in structure or toxicity [for examples see current National Institute for Occupational Safety and Health (NIOSH) publications]

Manufacturing—The production, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction of the drug from substances of natural origin or by means of chemical or biological synthesis. Manufacturing may also include any packaging or repackaging of the substance(s) or labeling or relabeling of containers for resale by pharmacies, practitioners, or other persons.

Preparation—For the purposes of this chapter, a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations; the term *product* will be used to describe manufactured pharmaceutical dosage forms. (For the definitions of *official substance* and *official products,* see *General Notices and Requirements.*)

Stability—The extent to which a preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding (see *Stability Considerations in Dispensing Practice* ⟨1191⟩, the table *Criteria for Acceptable Levels of Stability*).

Vehicle—A component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers, and proprietary products.

CATEGORIES OF COMPOUNDING

In the three general categories of nonsterile compounding described in this section, different levels of experience, training, and physical facilities are associated with each category.

Criteria used to determine overall classification include:

- degree of difficulty or complexity of the compounding process
- stability information and warnings
- packaging and storage requirements
- dosage forms
- complexity of calculations
- local versus systemic biological disposition
- level of risk to the compounder
- potential for risk of harm to the patient

See *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩ for risk levels associated with sterile preparations. Specialty areas such as radiopharmaceuticals require special training and are beyond the scope of this chapter. Compounders shall acquire and maintain knowledge and skills in all areas (e.g., dosage form, patient population, and medical specialty) for which they compound.

Description of Categories

Simple—Making a preparation that has a *United States Pharmacopeia* (*USP*) compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs; or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. Examples include *Captopril Oral Solution, Indomethacin Topical Gel,* and *Potassium Bromide Oral Solution, Veterinary.*

Moderate—Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available. Examples include *Morphine Sulfate Suppositories,* diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.

Complex—Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.

RESPONSIBILITIES OF THE COMPOUNDER

The compounder is responsible for compounding preparations of acceptable strength, quality, and purity and in accordance with the prescription or medication order. The compounder is also responsible for dispensing the finished preparation, with appropriate packaging and labeling, and in compliance with the requirements established by the applicable state agencies, state boards of pharmacy, federal law, and other regulatory agencies where appropriate. Individuals who are engaged in drug or dietary supplement compounding shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature. They shall be knowledgeable about the contents of this chapter and should be familiar with *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩, *Pharmaceutical Dosage Forms* ⟨1151⟩, *Pharmaceutical Calculations in Prescription Compounding* ⟨1160⟩, *Quality Assurance in Pharmaceutical Compounding* ⟨1163⟩, *Prescription Balances and Volumetric Apparatus* ⟨1176⟩, *Stability Considerations in Dispensing Practice* ⟨1191⟩, *Written Prescription Drug Information—Guidelines* ⟨1265⟩, and all applicable compounding laws, guidelines, and standards.

To ensure the quality of compounded preparations, compounders shall adhere to the following general principles (additional information on these general principles is provided in the sections that follow).

General Principles of Compounding

1. Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties. Such training should be documented.
2. Compounding ingredients of the appropriate identity, purity, and quality are purchased from reliable sources and are properly stored according to manufacturer specifications or *USP* standards.
3. Bulk component containers are labeled with appropriate Occupational Safety and Health Administration (OSHA) hazard communication labels (see OSHA.gov), and Material Safety Data Sheets (MSDSs) are available to compounding personnel for all drugs and chemicals used in compounding.
4. All equipment used in compounding is clean, properly maintained, and used appropriately.
5. The compounding environment is suitable for its intended purpose; and procedures are implemented to prevent cross-contamination, especially when compounding with drugs (e.g., hazardous drugs and known allergens like penicillin) that require special precautions.
6. Only authorized personnel are allowed in the immediate vicinity of the drug compounding operations.
7. There is assurance that processes are always carried out as intended or specified and are reproducible.
8. Compounding conditions and procedures are adequate for preventing errors.
9. All aspects of compounding are appropriately documented.
10. Adequate procedures and records exist for investigating and correcting failures or problems in compounding, testing, or the preparation itself.

COMPOUNDING PROCESS

The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section (additional information on these criteria is provided in the sections that follow).

Criteria When Compounding Each Drug Preparation

1. The dose, safety, and intended use of the preparation or device has been evaluated for suitability in terms of:
   - the chemical and physical properties of the components
   - dosage form
   - therapeutic appropriateness and route of administration, including local and systemic biological disposition
   - legal limitations, if any
2. A Master Formulation Record should be created before compounding a preparation for the first time. This record shall be followed each time that preparation is made. In addition, a Compounding Record should be completed each time a preparation is compounded.
3. Ingredients used in the formulation have their expected identity, quality, and purity. If the formulation is for humans, ingredients are not on a list of federally recognized drugs or specific drug products that have been withdrawn or removed from the market for safety or efficacy reasons (see www.FDA.gov). If the formulation is for food-producing animals, ingredients are not on a list of components prohibited for use in food-producing animals. Certificates of Analysis, when applicable, and MSDSs have been consulted for all ingredients used.
4. Compounding is done in an appropriately clean and sanitized area dedicated to this activity (see the section *Compounding Facilities*).
5. Only one preparation is compounded at one time in a specific workspace.
6. Appropriate compounding equipment has been selected and inspected for cleanliness and correct functioning and is properly used.

7. A reliable BUD is established to ensure that the finished preparation has its accepted potency, purity, quality, and characteristics, at least until the labeled BUD.
8. Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination.
9. The preparation is made in accordance with this chapter, other official standards referenced in this chapter, and relevant scientific data and information.
10. Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.
11. The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record (see chapter ⟨1163⟩).
12. The preparation is packaged as recommended in the *Packaging and Drug Preparation Containers* section of this chapter.
13. The preparation container is labeled according to all applicable state and federal laws. The labeling shall include the BUD and storage and handling information. The labeling should indicate that "this is a compounded preparation."
14. The Master Formulation Record and the Compounding Record have been reviewed by the compounder to ensure that errors have not occurred in the compounding process and that the preparation is suitable for use.
15. The preparation is delivered to the patient or caregiver with the appropriate consultation.

COMPOUNDING FACILITIES

Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions. This space shall provide for the orderly placement of equipment and materials to prevent mixups among ingredients, containers, labels, in-process materials, and finished preparations and is designed, arranged, and used to prevent adventitious cross-contamination. Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area (see *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩, *Environmental Quality and Control*).

Potable water shall be supplied for hand and equipment washing. This water meets the standards prescribed in the Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR Part 141). *Purified Water* (see *Purified Water* monograph) shall be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water. *Purified Water* should be used for rinsing equipment and utensils. In those cases when a water is used to prepare a sterile preparation, follow the appropriate monographs and general chapters (see *Water for Pharmaceutical Purposes* ⟨1231⟩).

The plumbing system shall be free of defects that could contribute to contamination of any compounded preparation. Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas. Such facilities shall include, but are not limited to, hot and cold water, soap or detergent, and an air-drier or single-use towels. The areas used for compounding shall be maintained in clean, orderly, and sanitary conditions and shall be maintained in a good state of repair. Waste shall be held and disposed of in a sanitary and timely manner and in accordance with local, state, and federal guidelines.

The entire compounding and storage area should be well lighted. Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Storage Temperature and Humidity*; and the manufacturers' labeled storage conditions). Appropriate temperature and humidity monitoring should be maintained as required for certain components and compounded dosage forms. All components, equipment, and containers shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area.

Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel. The following are references for the safe handling of antineoplastic and hazardous drugs in healthcare settings:

- OSHA Technical Manual—Section VI: Chapter 2, *Controlling Occupational Exposure to Hazardous Drugs*
- NIOSH Alert: *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* (DHHS (NIOSH) Publication No. 2004-165) and updates.

Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.

COMPOUNDING EQUIPMENT

The equipment and utensils used for compounding of a drug preparation shall be of appropriate design and capacity. The equipment shall be of suitable composition that the surfaces that contact components are neither reactive, additive, nor sorptive and therefore will not affect or alter the purity of the compounded preparations. The types and sizes of equipment depend on the dosage forms and the quantities compounded (see chapter ⟨1176⟩ and equipment manufacturers' instruction manuals).

Equipment shall be stored to protect it from contamination and shall be located to facilitate its use, maintenance, and cleaning. Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance. Immediately before compounding operations, the equipment shall be inspected by the compounder to determine its suitability for use. After use, the equipment shall be appropriately cleaned.

Extra care should be used when cleaning equipment used in compounding preparations that require special precaution (e.g., antibiotics and cytotoxic and other hazardous materials). When possible, special equipment should be dedicated for such use, or when the same equipment is being used for all drug products, appropriate procedures shall be in place to allow meticulous cleaning of equipment before use with other drugs. If possible, disposable equipment should be used to reduce chances of bioburden and cross-contamination.

COMPONENT SELECTION, HANDLING, AND STORAGE

The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations.

1. A *United States Pharmacopeia* (*USP*), *National Formulary* (*NF*), or *Food Chemicals Codex* (*FCC*) substance is the recommended source of ingredients for compounding all preparations.
2. Compounders shall first attempt to use components manufactured in an FDA-registered facility. When components cannot be obtained from an FDA-registered facility, compounders shall use their professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, which should include Certificate of Analysis, manufacturer reputation, and reliability of source.
3. Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided. These preparations may be labeled *USP* or *NF* as appropriate.
4. When components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, or American Chemical Society–certified may be used. However, these components should be used cautiously because the standards for analytical reagents or American Chemical Society–grade materials do not consider whether any impurity present raises human or animal safety concerns.
5. For components in containers that have an expiration date from the manufacturer or distributor, the material may be used in compounding before that expiration date (a) when the material is stored in its original container under conditions to avoid decomposition of the chemicals (see chapter ⟨1191⟩ and *Packaging and Storage Requirements* ⟨659⟩, unless other conditions are noted on the label), (b) when there is minimal exposure of the remaining material each time material is withdrawn from the container, and (c) when any withdrawals from the container are performed by those trained in the proper handling of the material. If the component has been transferred to a different container, that container shall be identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container.
6. For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date*) based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions.
7. If a manufactured drug product is used as the source of active ingredient, the drug product shall be manufactured in an FDA-registered facility, and the manufacturer's product container shall be labeled with a batch control number and expiration date. When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components.
8. If the preparation is intended for use as a dietary or nutritional supplement, then the compounder must adhere to this chapter and must also comply with any federal and state requirements. Generally, dietary supplements are prepared from ingredients that meet *USP, FCC,* or *NF* standards. Where such standards do not exist, substances may be used in dietary supplements if they have been shown to have acceptable food-grade quality using other suitable procedures.
9. When a component is derived from ruminant animals (e.g., bovine, caprine, ovine), the supplier shall provide written assurance that the component is in compliance with all federal laws governing processing, use, and importation requirements for these materials.
10. When compounding for humans, the compounder should consult the list of components that have been withdrawn or removed from the market for safety or efficacy reasons by FDA (see www.FDA.gov). When compounding for food-producing animals, the compounder should consult the list of components prohibited for use in food-producing animals.
11. All components used in the compounding of preparations must be stored as directed by the manufacturer, or according to *USP, NF,* or *FCC* monograph requirements, in a clean area, and under appropriate temperature and humidity conditions (controlled room temperature, refrigerator, or freezer). All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. All containers shall be properly labeled.

Change to read:

STABILITY CRITERIA AND BEYOND-USE DATING

The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their BUDs are assigned on the basis of criteria different from those applied to assigning expiration dates to manufactured drug products.

BUDs should be assigned conservatively. When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available and should consider:

- the nature of the drug and its degradation mechanism
- the dosage form and its components
- the potential for microbial proliferation in the preparation
- the container in which it is packaged
- the expected storage conditions
- the intended duration of therapy (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date*).

When a manufactured product is used as the source of the API for a nonsterile compounded preparation, the product expiration date cannot be used solely to assign a BUD for the compounded preparation. Instead, the compounder shall refer to the manufacturer for stability information and

to the literature for applicable information on stability, compatibility, and degradation of ingredients; shall consider stability factors in chapter ⟨1191⟩; and shall use his or her compounding education and experience. All stability data shall be carefully interpreted in relation to the actual compounded formulation.

At all steps in the compounding, dispensing, and storage process, the compounder shall observe the compounded drug preparation for signs of instability. For more specific details of some of the common physical signs of deterioration (see chapter ⟨1191⟩, *Observing Products for Evidence of Instability*). However, excessive chemical degradation and other drug concentration loss due to reactions may be invisible more often than visible.

General Guidelines for Assigning Beyond-Use Dates

In the absence of stability information that is applicable to a specific drug and preparation, the following table presents maximum BUDs recommended for •• (RB 1-Jan-2014) nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated •• (RB 1-Jan-2014) (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling*). Drugs or chemicals known to be labile to decomposition will require shorter BUDs.

BUD by Type of Formulation[a]
For Nonaqueous Formulations—The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
For Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures.
For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days.

[a] These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

Susceptible preparations should contain suitable antimicrobial agents to protect against bacteria, yeast, and mold contamination inadvertently introduced during or after the compounding process. When antimicrobial preservatives are contraindicated in such compounded preparations, storage of the preparation at controlled cold temperature is necessary; to ensure proper storage and handling of such compounded preparations by the patient or caregiver, appropriate patient instruction and consultation is essential. Antimicrobial preservatives should not be used as a substitute for good compounding practices.

For information on assigning BUDs when repackaging drug products for dispensing or administration, see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date*, and *Packaging and Repackaging—Single-Unit Containers* ⟨1136⟩.

Assurance of sterility in a compounded sterile preparation is mandatory. Compounding and packaging of sterile drugs (including ophthalmic preparations) requires strict adherence to guidelines presented in chapter ⟨797⟩ and in the manufacturers' labeling instructions.

PACKAGING AND DRUG PREPARATION CONTAINERS

The compounder shall ensure that the containers and container closures used in packaging compounded preparations meet *USP* requirements (see *Packaging and Storage Requirements* ⟨659⟩; *Containers—Glass* ⟨660⟩; *Containers—Plastics* ⟨661⟩; *Containers—Performance Testing* ⟨671⟩; chapter ⟨1136⟩); and when available, compounding monographs. Compounders are not expected to perform the tests described in these chapters but should be knowledgeable about the standards described in them. Container suppliers shall supply, upon request, verification of *USP* container compliance. Containers and container closures intended for the compounding of sterile preparations must be handled as described in chapter ⟨797⟩.

The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded drug preparation. The container used depends on the physical and chemical properties of the compounded preparation. Container–drug interaction should be considered for substances that have sorptive or leaching properties.

The containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. The containers and container closures shall be stored in such a way as to permit inspection and cleaning of the storage area.

COMPOUNDING DOCUMENTATION

Documentation, written or electronic, enables a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation. All compounders who dispense prescriptions must comply with the record-keeping requirements of their state boards of pharmacy. When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section.

These records should be retained for the same period of time that is required for any prescription under state law. The record may be a copy of the prescription in written or machine-readable form and should include a Master Formulation Record and a Compounding Record.

Master Formulation Record

This record shall include:

- official or assigned name, strength, and dosage form of the preparation
- calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients
- description of all ingredients and their quantities
- compatibility and stability information, including references when available
- equipment needed to prepare the preparation, when appropriate
- mixing instructions that should include:
    1. order of mixing
    2. mixing temperatures or other environmental controls
    3. duration of mixing
    4. other factors pertinent to the replication of the preparation as compounded
- sample labeling information, which shall contain, in addition to legally required information:

1. generic name and quantity or concentration of each active ingredient
2. assigned BUD
3. storage conditions
4. prescription or control number, whichever is applicable

- container used in dispensing
- packaging and storage requirements
- description of final preparation
- quality control procedures and expected results

Compounding Record

The Compounding Record shall contain:

- official or assigned name, strength, and dosage of the preparation
- Master Formulation Record reference for the preparation
- names and quantities of all components
- sources, lot numbers, and expiration dates of components
- total quantity compounded
- name of the person who prepared the preparation, name of the person who performed the quality control procedures, and name of the compounder who approved the preparation
- date of preparation
- assigned control or prescription number
- assigned BUD
- duplicate label as described in the Master Formulation Record
- description of final preparation
- results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)
- documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver

Standard Operating Procedures

All significant procedures performed in the compounding area should be covered by written standard operating procedures (SOPs). Procedures should be developed for the facility, equipment, personnel, preparation, packaging, and storage of compounded preparations to ensure accountability, accuracy, quality, safety, and uniformity in compounding. Implementing SOPs establishes procedural consistency and also provides a reference for orientation and training of personnel.

Material Safety Data Sheets File

MSDSs shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility premises. Employees should be instructed on how to retrieve and interpret needed information.

QUALITY CONTROL

The safety, quality, and performance of compounded preparations depend on correct ingredients and calculations, accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment. As a final check, the compounder shall review each procedure in the compounding process. To ensure accuracy and completeness, the compounder shall observe the finished preparation to ensure that it appears as expected and shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient.

Compounding Controls

1. The Master Formulation Record, the Compounding Record, and associated written procedures shall be followed in execution of the compounding process. Any deviation in procedures shall be documented.
2. The compounder shall check and recheck each procedure at each stage of the process. If possible, a trained second person should verify each critical step in the compounding process.
3. The compounder shall have established written procedures that describe the tests or examinations conducted on the compounded preparation (e.g., the degree of weight variation among capsules) to ensure their uniformity and integrity.
4. Appropriate control procedures shall be established to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations.
5. For further guidance on recommended quality control procedures, see chapter ⟨1163⟩.

PATIENT COUNSELING

At the time of dispensing the prescription, the patient or the patient's agent shall be counseled about proper use, storage, handling, and disposal of the compounded preparation. The patient or the patient's agent shall also be instructed to report any adverse event and to observe and report to the compounder any changes in the physical characteristics of the compounded preparation (see *Stability Considerations in Dispensing* ⟨1191⟩, *Responsibility of Pharmacists*). The compounder shall investigate and document any reported problem with a compounded preparation and shall take corrective action.

TRAINING

All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained for the type of compounding conducted. It is the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing. Compounding personnel should be evaluated at least annually. Steps in the training procedure include the following:

- All employees involved in pharmaceutical compounding shall read and become familiar with this chapter. They should also be familiar with the contents of the *USP Pharmacists' Pharmacopeia* and other relevant publications, including how to read and interpret MSDSs.
- All employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing.
- All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs. For information on training for personnel who compound hazardous drugs, see the references in *Compounding Facilities* earlier in this chapter.
- All training activities shall be documented. The compounder shall meet with employees to review their

work and answer any questions the employees may have concerning compounding procedures.
- The compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee will then repeat the procedure without any assistance from, but under the direct supervision of, the compounder.
- When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then will the employee be permitted to perform the procedure without direct supervision. However, the compounder should be physically present and shall approve all ingredients and their quantities and the final preparation.
- When the compounder is satisfied with the employee's knowledge and proficiency, the compounder will sign the documentation records to show that the employee was appropriately trained.
- The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed.
- The compounder is solely responsible for the finished preparation.

COMPOUNDING FOR ANIMAL PATIENTS

A compounder's responsibility for providing patients with high-quality compounded preparations extends beyond the human species. All portions of this chapter apply to compounded preparations formulated for animal patients. Intended use of any animal patient (e.g., companion, performance, food) shall be determined before compounding for that patient.

Because humans can consume animal patients as food, care must be taken to prevent drug residues from entering the human food chain when compounded preparations are used in animal patients. For this reason, all compounders preparing formulations for animals shall possess a functional knowledge of drug regulation and disposition in animal patients. Veterinarians are required by law to provide food-producing animal caregivers with an accurate length of time to withhold treated animal tissues (e.g., meat, milk, eggs) from the human food supply. This length of time is referred to as a withdrawal time (WDT) and must also, by law, be included on the dispensing label of every prescription prepared for a food-producing species.

Drug use in any performance animal is strictly regulated by federal and state governments, in addition to the governing bodies of each of the specific disciplines. Penalties for violation of these rules may be severe for all contributing to the violation, including the veterinarian, pharmacist, and caregiver.

The pharmacist shall be knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations. For this reason, compounders making preparations for animals should use, when possible, formulations specifically developed for animal patients. If such formulations are not available, the compounder shall conduct a literature review to determine whether a specific component of the formula is toxic to the target species. Extrapolating compounding formulations intended for use in humans may not be appropriate for animal species and may contribute to negative outcomes.

Veterinarians and pharmacists making preparations for animal patients should be familiar with all state and federal regulations regarding drug use in animals, including but not limited to the Food, Drug, and Cosmetic Act; the Animal Drug Amendment; the Animal Medicinal Drug Use Clarification Act; and FDA's Compliance Policy Guideline for Compounding of Drugs for Use in Animal Patients.

Maria Yeager

From: Kay Mitchen
Sent: Tuesday, March 15, 2016 11:21 AM
To: Spencer Malkin; Alex Chervinsky; Marc Poirier
Cc: Lynn Swanson; Maria Yeager; Matthew Bernstein
Subject: FW: Confirmation of Registration: Sincerus Florida, LLC

Importance: High

Mazeltov!

From: CDER Electronic Drug Registration and Listing [mailto:EDRLS@fda.hhs.gov]
Sent: Tuesday, March 15, 2016 11:17 AM
To: Kay Mitchen <KMitchen@vividus.com>
Cc: Compounding <Compounding@fda.hhs.gov>
Subject: Confirmation of Registration: Sincerus Florida, LLC

Dear Ms. Mitchen,

We have received the establishment registration fee for Sincerus Florida, LLC in the amount of $16,465. Effective March 10, 2016, your facility located at 3265 West McNab Road, Pompano Beach, FL 33069 is now registered as a human drug outsourcing facility through December 31, 2016.

For more information on the Compounding Quality Act, visit FDA's Compounding Website:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm

Electronic Drug Registration and Listing (eDRLS Staff)
301-796-3100
eDRLS@fda.hhs.gov

Maria Yeager

From: CDER Collections <CDERCollections@fda.hhs.gov>
Sent: Thursday, December 28, 2017 2:42 PM
To: elicense
Cc: CDER Collections; Compounding; CDER Electronic Drug Registration and Listing
Subject: FY 2018 503B Registration Acknowledgement Letter - Sincerus Florida, LLC (CQA187000350)

Good Afternoon,

We have received the establishment registration fee for Sincerus Florida, LLC in the amount of $17,364. Effective January 01, 2018, your facility located at 3265 West McNab Road Pompano, FL 33069 is now registered as a human drug outsourcing facility through December 31, 2018.

For more information on the Compounding Quality Act, visit FDA's Compounding Website: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm

Thanks,
Frances Winters
CDER/OM/ DUFMBF
U.S. Food & Drug Administration

FDA U.S. FOOD & DRUG ADMINISTRATION

Please take a moment to provide specific, immediate, honest, and actionable feedback on the services received by taking this short survey.

Maria Yeager

From: DoNotReply@fda.hhs.gov
Sent: Wednesday, March 20, 2019 1:16 PM
To: elicense
Cc: CDERCollections@fda.hhs.gov; Compounding@fda.hhs.gov; EDRLS@fda.hhs.gov
Subject: FY2019 Outsourcing Facility Acknowledgement - Sincerus Florida, LLC

Good Afternoon,

We have received the establishment registration fee for Sincerus Florida, LLC in the amount of $18,375. Effective January 01, 2019, your facility located at 3265 West McNab Road Pompano Beach, FL 33069 is now registered as a human drug outsourcing facility through December 31, 2019.

For more information on the Compounding Quality Act, visit FDA's Compounding Website:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm

CDER Collections Staff

Please take a moment to provide specific, immediate, honest, and actionable feedback on the services received by taking a short survey at: https://fdacder.co1.qualtrics.com/jfe/form/SV_1MneD4auUHMi9ql

3265 W McNab Road
Pompano Beach, FL 33069

Phone: (561) 404-8885
Fax: (561) 503-4131

April 20, 2017

Sent Via Certified Mail
Nevada State Board of Pharmacy
431 W Plumb Ln
Reno, NV 89509

To Whom It May Concern:

Please allow this correspondence to serve as formal notification that Mr. Alex Chervinsky has determined that he will no longer hold a position as a corporate officer of Sincerus Florida, LLC, an out-of-state Wholesaler licensed in the state of Nevada permit No.: WH02257. Mr. Chervinsky will continue to be associated with the company as a pharmacist.

Please contact us, if you require additional information.

Cordially,

Maria Yeager
Legal Assistant
Sincerus Florida, LLC
3265 W. McNab Road
Pompano Beach, FL 33069
Phone: (561) 419-9250
Fax: (561) 503-4131
legal@vividus.com

Each sheet can be used for one Certified Mail piece, which can be sent without Physical Return Receipt Service (Option A) or with Physical Return Receipt Service (Option B).

CERTIFIED MAIL

Sincerus Florida, LLC
3265 W McNab Road
Pompano Beach, FL 33069

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U.S. Postal Service
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9414 8118 9956 4174 3476 32

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431 W Plumb Ln
Reno NV 89509-3766

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Postage per piece	$2.43
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B Certified Mail
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(Uses Return Receipt Card)
Instructions
1. Apply address label above to the back of this card.
2. Apply this card to the TOP EDGE of the mailpiece.

Certified Mail Labels (SDC-3910)
Covered by and/or for use with U.S. Patents 6,244,763; 6,868,406; 7,216,110; 7,236,956; 7,236,970; 7,490,065; 7,567,940; 7,613,639; 7,743,043; 7,882,094; 8,027,926; 8,027,927; 8,027,935; 8,041,644; 8,046,823; 8,103,647; 8,195,579; 8,301,572; 8,392,391; and 8,498,943

2029

VOID

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A. Signature: (☐ Addressee or ☐ Agent)
X

B. Received By: (Please Print Clearly)

C. Date of Delivery

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Delivery Address

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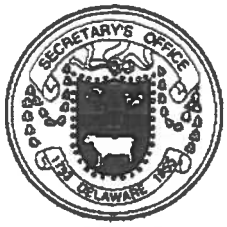
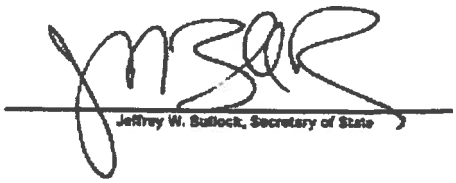
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SINCERUS FLORIDA, 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 JUNE, A.D. 2020.





5883753 8300

SR# 20205618176

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

Authentication: 203115462

Date: 06-16-20

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

May 20, 2020

Sincerus Florida, LLC
Maria Yeager
3820 NW 23rd Place
Coconut Creek, FL 33066

RE: License Certification for Sincerus Florida, LLC

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the above referenced Health Care Practitioner:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH29905
ORIGINAL CERTIFICATION:	02/19/2016
EXPIRATION DATE:	02/28/2021
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No
OTHER CERTIFICATIONS:	Community Pharmacy

To expedite the verification process, the above format is the standard format for all healthcare practitioners. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Gerlisia K. Still
Regulatory Specialist II

/gs

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Vision: To be the Healthiest State in the Nation

Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

May 14, 2020

Maria Yeager
3820 NW 23 Place
Coconut Creek, FL 33066

RE: License Certification for Sincerus Florida, Llc

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the above referenced Health Care Practitioner:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH29976
ORIGINAL CERTIFICATION:	03/23/2016
EXPIRATION DATE:	02/28/2021
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No

To expedite the verification process, the above format is the standard format for all healthcare practitioners. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Susan Harris

Susan Harris
Operations Analyst I

/sh

GREAT SEAL OF THE STATE OF FLORIDA · IN GOD WE TRUST ·

Florida Department of Health
Division of Medical Quality Assurance• Bureau of Operations
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3251
PHONE: (850) 488-0595 • FAX : (850) 245-4791

PHAB Accredited Health Department
Public Health Accreditation Board

15I

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 00020
☐ 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: Wedgewood Connect, LLC

Physical Address: 17 Great Oaks Blvd.

City: San Jose State: CA Zip Code: 95119

Telephone: 855-321-8477 Fax: 800-589-4250

Toll Free Number: 800-216-5005 (Required per NAC 639.708)

E-mail: pyamamoto@wedgewoodpharmacy.com Website: www.wedgewoodpharmacy.com/

Supervising Pharmacist: Paul K Yamamoto Nevada License #: 19734

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

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

FEI Number (From FDA application): 3003434972

Please provide the name of the facility as registered with the FDA and the registration number:
Previous name: LEITER'S ENTERPRISES, INC dba LEITER'S; New name: Wedgewood Connect, LLC

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: Paul K Yamamoto Nevada License Number: 19734

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

Marcy Ann Bliss

Print Name of Authorized Person

Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Wedgewood Village Pharmacy, LLC

Address: 405 Heron Dr., Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: 480-946-2223 Fax: 800-589-4250

Contact Person: Marcy Ann Bliss

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Address

b) N/A
Name Address

c) N/A
Name Address

d) N/A
Name Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? 05/31/2020

5) Provide a copy of the corporation's stock register evidencing the above information N/A

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

Within the last five (5) years:

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**.

Leiters
17 Great Oaks Blvd., San Jose, CA 95119
Summary of State Actions

- California Board of Pharmacy – CI 2018 83424

On October 8, 2019, the California Board of Pharmacy issued a notice of Citation and Fine for an alleged violation of California pharmacy law. California alleged that Leiters, located at 17 Great Oaks Blvd, San Jose, CA 95119, violated California pharmacy law by compounding cefuroxime 10mg/ml in 0.9% sodium chloride intravitreal injection, 1ml in a 2ml vial with sterile water for injection instead of 0.9% sodium chloride, as labeled. Leiters disagreed with the allegations, Leiters agreed to settle the matter with the California Board of Pharmacy and pay a fee of $2500. This agreement was finalized on January 10, 2020.

This is not a discipline by the California Board of Pharmacy, but it is disclosing it out of an abundance of caution.

- California Board of Pharmacy – CI 2016 75140 (LSC 100533); CI 2018 80747 (PHY 55311); CI 2018 80748 (RPH 43950)

On April 28, 2017 the California Board of Pharmacy received a complaint from a compounding pharmacist that Leiters was not a manufacturer and must label their sterile products to "discard 28 days after first use". Leiters was an FDA registered Outsourcing Facility following cGMP requirements. This complaint arose prior to Leiters' licensure as a California outsourcing facility (while Leiters was licensed as a sterile compounding pharmacy), but after the law mandating California Outsourcing licensure was enacted. The same allegation was made against Leiters' pharmacist-in-charge individually. Leiters disagreed with the allegations, but Leiters agreed to settle the matter with the California BOP and pay a fee of $1000 to the facility, $500 to the individual. This agreement was finalized on January 29, 2020.

This is not a discipline by the California DOJ, but it is disclosing it out of an abundance of caution.

Marcy Ann Bliss
CEO/President/Treasurer/Secretary

does not constitute any admission of wrongdoing by Wedgewood; however, it is being provided out of an abundance of caution. A copy of the citation is attached.

Marcy Ann Bliss
CEO/President/Treasurer/Secretary

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

October 08, 2019

DATED MATERIAL ENCLOSED

LEITERS
ATTN: ROBIN HOKE, PRS
17 GREAT OAKS BLVD
SAN JOSE, CA 95119

RE: CI 2018 83424
LEITERS
OSF 107

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:

- November 07, 2019: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 22, 2019: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 07, 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 Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

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 **November 07, 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
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

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 October 22, 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 November 07, 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) 518-3013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2018 83424	LEITERS, OSF 107

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 § 4129.1 subd. (b)/Title 21 CFR § 211.100(a)	**Outsourcing facilities; shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities. /Written procedures; deviations (a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.**	**$5,000.00**

CONDUCT:

Outsourcing Facility – License Required: Business and Professions Code section 4129.1 (b) states, an outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities. As related to the Code of Federal Regulations section, CFR 211.100 (a) Written procedures; deviations states; There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.
Leiters (OSF 107) was not compliant. Specifically, Leiters, located at 17 Great Oaks Boulevard, San Jose, CA 95119, on 11/2/2018, compounded cefuroxime 10mg/ml in 0.9% sodium chloride intravitreal injection, 1ml in a 2ml vial with sterile water for injection instead of sterile 0.9% sodium chloride, as labeled. This was a violation of pharmacy law.

CITATION ISSUED ON: October 08, 2019 | **TOTAL AMOUNT OF FINE(S): $5,000.00**

PAYMENT OF FINE(S) DUE BY: November 07, 2019

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: LEITERS

License No: OSF 107

Citation Number : CI 2018 83424

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
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3013

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:	Citation Case No : CI 2018 83424
LEITERS OSF 107 Respondent	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
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

January 29, 2020

CERTIFIED MAIL

LEITERS
ATTN: ROBIN HOKE, PRS
17 GREAT OAKS BLVD
SAN JOSE, CA 95119

RE: CI 2018 83424
LEITERS
OSF 107

As a result of the explanation and information you provided at the office conference, the amount of the fines assessed in Citation and Fine, CI 2018 83424 have been reduced.

The modified Citation is attached and is hereby issued pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (d).

If you desire a hearing to appeal the attached Citation, you must submit a written request for a hearing to the Board of Pharmacy ("Board") within 30 days of the date this Citation was issued. (See Bus. Prof. Code sec. 125.9, subd. (b)(4), and C.C.R., title 16, sec. 1775.4, subd. (d).). Unless the Board receives a written request within the 30 days, you will be deemed to have waived your right to a hearing in this matter and the Citation shall become the final order of the Board. If a hearing is not requested, the timely payment of the imposed fine(s) shall not constitute an admission of the violation(s) charged in the Citation.

Failure to pay any imposed fine(s) within 30 days of the date the Citation was issued may result in disciplinary action being taken.

If any fine(s) are not timely paid, then the full amount of the unpaid fine(s) shall be added to the fee for the renewal of your license. Your license shall not then be renewed without full payment of the renewal fee and the assessed fine(s).

If you have any questions regarding this Citation please contact Susan Cappello, Enforcement Manager at (916) 518-3008.

Sincerely

Thomas P. Lenox

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2018 83424	LEITERS, OSF 107

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 § 4129.1 subd. (b)/Title 21 CFR § 211.100(a)	Outsourcing facilities; shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities. /Written procedures; deviations (a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.	$2,500.00

CONDUCT:

Outsourcing Facility – License Required: Business and Professions Code section 4129.1 (b) states, an outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities. As related to the Code of Federal Regulations section, CFR 211.100 (a) Written procedures; deviations states; There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.
Leiters (OSF 107) was not compliant. Specifically, Leiters, located at 17 Great Oaks Boulevard, San Jose, CA 95119, on 11/2/2018, compounded cefuroxime 10mg/ml in 0.9% sodium chloride intravitreal injection, 1ml in a 2ml vial with sterile water for injection instead of sterile 0.9% sodium chloride, as labeled. This was a violation of pharmacy law.

CITATION ISSUED ON: January 29, 2020 | **TOTAL AMOUNT OF FINE(S): $2,500.00**

PAYMENT OF FINE(S) DUE BY: February 28, 2020

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2018 83424	LEITERS, OSF 107

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 § 4129.1 subd. (b)/Title 21 CFR § 211.100(a)	**Outsourcing facilities; shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities. /Written procedures; deviations (a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.**	**$2,500.00**

CONDUCT:

Outsourcing Facility – License Required: Business and Professions Code section 4129.1 (b) states, an outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities. As related to the Code of Federal Regulations section, CFR 211.100 (a) Written procedures; deviations states; There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.
Leiters (OSF 107) was not compliant. Specifically, Leiters, located at 17 Great Oaks Boulevard, San Jose, CA 95119, on 11/2/2018, compounded cefuroxime 10mg/ml in 0.9% sodium chloride intravitreal injection, 1ml in a 2ml vial with sterile water for injection instead of sterile 0.9% sodium chloride, as labeled. This was a violation of pharmacy law.

CITATION ISSUED ON: January 29, 2020 | **TOTAL AMOUNT OF FINE(S): $2,500.00**

PAYMENT OF FINE(S) DUE BY: February 28, 2020

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:	Citation Case No : CI 2018 83424
LEITERS OSF 107 Respondent	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: LEITERS, OSF 107
Citation and Fine CI 2018 83424

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 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On January 29, 2020, I served the attached:

Cover Letter, Citation, 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
LEITERS ATTN: ROBIN HOKE, PRS 17 GREAT OAKS BLVD SAN JOSE, CA 95119	7019 1120 0002 2777 0196

I declare under penalty of perjury that the forgoing is true and correct.

Executed on January 29, 2020, at Sacramento, California.

Susan Cappello

DECLARANT

Susan Cappello
Enforcement Manager

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.

September 10, 2018

DATED MATERIAL ENCLOSED

LEITER'S ENTERPRISES INC DBA LEITER'S
17 GREAT OAKS BLVD
SAN JOSE, CA 95119

LEITER'S ENTERPRISES INC DBA LEITER'S
C/0 ROBIN SMITH HOKE
2134 YORKSHIRE RD
COLUMBUS, OH 43221

RE: CI 2016 75140
LEITER'S ENTERPRISES INC DBA LEITER'S
LSC 100753 (CANCELED)

The attached Citation, ("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 Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. 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 IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- September 24, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- October 10, 2018: 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. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
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.

Unless contested, Citations are final 30 days from the date of service. Acceptance of a Citations 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 September 24, 2018 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 October 10, 2018 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, Enforcement Analyst, at (916) 574-7925.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2016 75140	LEITER'S ENTERPRISES INC DBA LEITER'S, LSC 100753 (CANCELED)

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4300.1 Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1751.9 subd.(c)	Single-Dose and Multi-Dose Containers; Limitations on Use; Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture

CONDUCT:

California Code of Regulations section 1751.9 (c) states in pertinent part: Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within 28 days from initial opening or puncture.Leiters was not compliant. Specifically, Leiter's enterprises Inc. DBA Leiter's Compounding located at 17 Great Oaks Boulevard, San Jose, CA 95119 did not label their multi-dose containers of atropine eye drops with a discard after 28 days notation. This was a violation of pharmacy law.

CITATION ISSUED ON: September 10, 2018

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2016 75140	LEITER'S ENTERPRISES INC DBA LEITER'S, LSC 100753 (CANCELED)

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CONDUCT:

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CITATION ISSUED ON: September 10, 2018

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: LEITER'S ENTERPRISES INC DBA LEITE

License No: LSC 100753 (CANCELED)

Citation Number : CI 2016 75140

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:	Citation Case No : CI 2016 75140
LEITER'S ENTERPRISES INC DBA LEITER'S LSC 100753 (CANCELED) Respondent	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: LEITER'S ENTERPRISES INC DBA LEITER'S, LSC 10075
Citation and Fine CI 2016 75140

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 September 10, 2018, 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
LEITER'S ENTERPRISES INC DBA LEITER'S 17 GREAT OAKS BLVD SAN JOSE, CA 95119	7017 0530 0000 7764 4850
LEITER'S ENTERPRISES INC DBA LEITER'S C/0 ROBIN SMITH HOKE 2134 YORKSHIRE RD COLUMBUS, OH 43221	7017 0530 0000 7764 4867

I declare under penalty of perjury that the forgoing is true and correct.

Executed on September 10, 2018, at Sacramento, California.

DECLARANT

Christina Metzen
Associate Enforcement Analyst

Within the last five (5) years:

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**.

Summary of Actions Related to Applicant's Owner Wedgewood Village Pharmacy, LLC

- Minnesota Board of Pharmacy; Michigan Department of Licensing and Regulatory Affairs; Alabama Board of Pharmacy

On March 19, 2015, the Minnesota Board of Pharmacy finalized a Stipulation and Consent Order ("Minnesota Consent Order") with Wedgewood Village Pharmacy ("Wedgewood-NJ"), located in Swedesboro, New Jersey. Wedgewood-NJ subsequently entered into consent orders with the Michigan Department of Licensing and Regulatory Affairs ("Michigan LARA") and the Alabama Board of Pharmacy to resolve "sister state" actions that arose out of the Minnesota Consent Order. All three orders are attached.

The underlying facts of the Minnesota Consent Order are as follows. Acting on a reasonable and good faith interpretation of Minnesota law, Wedgewood-NJ had dispensed compounds into Minnesota to a licensed veterinarian pursuant to a veterinarian's order for office use. The Minnesota Board of Pharmacy, however, asserted that Wedgewood-NJ needed a wholesaler license to dispense into Minnesota in this manner. For purposes of settlement only and admitting no wrongdoing, Wedgewood entered into the Minnesota Consent Order whereby it agreed to a $10,000 civil penalty. Wedgewood subsequently entered into a consent order with Michigan LARA to resolve a "sister state" matter based on the Minnesota Consent Order. Wedgewood-NJ entered into a similar consent order with the Alabama Board of Pharmacy to resolve a sister state action brought by the Alabama Board of Pharmacy based on the Minnesota Consent Order. There was not finding in the Michigan or Alabama consent order that Wedgewood NJ violated any provisions of Michigan or Alabama law outside of these state' prohibition on "sister State" actions.

- California Board of Pharmacy – CI 2018 82132; CI 2016 73882

On March 1, 2019, a citation was affirmed under each of Wedgewood-NJ's two California pharmacy licenses. Under California law these citations are not disciplinary actions and Wedgewood was not administered any fines in connection with the citations. Nonetheless, out of an abundance of caution Wedgewood is hereby notifying you of these citations. A copy of the citations are attached.

- California Board of Pharmacy – CI 2017 77042

On February 27, 2018, Wedgewood-NJ was issued an administrative citation and a $1,000 fine as a result of an investigation by the California Board of Pharmacy. The citation is not a discipline by the California Board of Pharmacy and payment of the fines

does not constitute any admission of wrongdoing by Wedgewood; however, it is being provided out of an abundance of caution. A copy of the citation is attached.

_____

Marcy Ann Bliss
CEO/President/Treasurer/Secretary

MINNESOTA BOARD OF PHARMACY

An Equal Opportunity Employer

2829 University Ave. SE., #530 • Minneapolis, MN 55414-3251 • Telephone: (651) 201-2825 • FAX: (651) 201-2837
MN RELAY SERVICE FOR HEARING/SPEECH IMPAIRED ONLY:
Metro and Non-Metro; 800-627-3529
E-Mail Address: Pharmacy.Board@state.mn.us
Web Site: www.pharmacy.state.mn.us

MAR 19 2015

PERSONAL & CONFIDENTIAL

March 16, 2015

Gregory P. Bulinski
Attorney
Bassford Remele
33 South Sixth Street, Suite 3800
Minneapolis, MN 55402-3707

Re: In the Matter of Wedgewood Pharmacy
License No. 262173

Dear Mr. Bulinski,

Enclosed and served upon you in the above-referenced matter is the fully executed Stipulation and Consent issued by the Board of Pharmacy.

Sincerely,

Cody Wiberg

Cody Wiberg, Pharm D, MS, RPh
Executive Director

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") 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 register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood 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 December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Bassford Remele and Rachael G. Pontikes, Esq., of Duane Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a **CIVIL PENALTY** in the amount of $10,000 for the conduct described in section III above. The civil penalty must 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 this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel 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 Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must 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 Review Panel, 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 Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel 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 Review Panel 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. 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 will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional 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 future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. 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.

13. 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.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. 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.

17. 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.

18. 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

19. 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 person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. 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:

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

MARCY BLISS, PRESIDENT
Wedgewood

Dated: 1/13/15

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a **CIVIL PENALTY,** and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

Wedgewood Village Pharmacy, Inc.
License No. 53-01-008041
_____/

Complaint No. 53-15-137238

CONSENT ORDER AND STIPULATION

CONSENT ORDER

An administrative complaint was filed with the Disciplinary Subcommittee of the Board of Pharmacy on July 24, 2015, charging Wedgewood Village Pharmacy, Inc. (Respondent) with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended, MCL 333.1101 *et seq*.

The parties have stipulated that the Disciplinary Subcommittee may enter this consent order. The Disciplinary Subcommittee has reviewed the stipulation contained in this document and agrees that the public interest is best served by resolution of the outstanding complaint. Therefore, the Disciplinary Subcommittee finds that the allegations of fact contained in the complaint are true and that Respondent has violated section 17768(2)(d) of the Public Health Code.

Accordingly, for this violation, IT IS ORDERED:

Respondent is FINED $500.00 (Five Hundred Dollars) to be paid by check, money order or cashier's check made payable to the State of Michigan (with complaint number 53-15-137238 clearly indicated on the check or money order), and

shall be payable within 60 days of the effective date of this order. The timely payment of the fine shall be Respondent's responsibility. Respondent shall mail the fine to: Sanction Monitoring, Bureau of Professional Licensing, Enforcement Division – Compliance Section, Department of Licensing and Regulatory Affairs, P.O. Box 30189, Lansing, Michigan 48909.

This order shall be effective on the date signed by the Chairperson of the Disciplinary Subcommittee or the Disciplinary Subcommittee's authorized representative, as set forth below.

Signed on 4-13-16

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

The parties stipulate as follows:

1. Respondent does not contest the allegations of fact and law in the complaint. Respondent understands that, by pleading no contest, it does not admit the truth of the allegations but agrees that the Disciplinary Subcommittee may treat the allegations as true for resolution of the complaint and may enter an order treating the allegations as true.

2. Respondent understands and intends that, by signing this stipulation, it is waiving the right under the Public Health Code, rules promulgated under the Public Health Code, and the Administrative Procedures Act of 1969, 1969 PA 306,

as amended, 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 to present a defense to the charges before the Disciplinary Subcommittee or its authorized representative. Should the Disciplinary Subcommittee reject the proposed consent order, the parties reserve the right to proceed to hearing.

3. The Disciplinary Subcommittee may enter the above Consent Order, supported by Board conferee Patti Smeelink, R.Ph. Ms. Smeelink or an attorney from the Licensing and Regulation Division may discuss this matter with the Disciplinary Subcommittee in order to recommend acceptance of this resolution.

4. Conferee Smeelink and the parties considered the following factors in reaching this agreement:

A. Respondent has fully cooperated in this matter and since initially licensed in 2004, Respondent has never had any disciplinary action taken against its Michigan Pharmacy license prior to this incident.

B. Respondent timely reported the Minnesota Board of Pharmacy Stipulation and Consent Order to the Department.

C. The violation of MCL 333.17768(d)(2) as alleged in the Complaint is based solely on a "sister-state" action taken against Respondent's Pharmacy license by the Minnesota Board of Pharmacy that was based on Respondent's former practice in 2012 of dispensing compounded veterinary medications for office-use to licensed veterinarians in Minnesota, which according to the Minnesota Board of Pharmacy, required a wholesaler's license. However, this practice did not implicate Respondent's practice of pharmacy in the State of Michigan and Respondent has not been found to have violated the Michigan Public Health Code or Board of Pharmacy Administrative Rules, except as provided herein.

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Elizondo

Kelly K. Elizondo (P45534)
Assistant Attorney General
Attorney for Complainant
Dated: 4-1-2016

AGREED TO BY:

Alison Lynch, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 3/31/16

Alan T. Rogalski (P44550)
Attorney for Respondent
Dated: 3/31/2016

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
WEDGEWOOD VILLAGE PHARMACY, LLC	)	
	)	
Non-Resident Pharmacy Permit Number: 112625	)	**CASE NO: 16-L-0066**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Wedgewood Village Pharmacy, LLC ("Wedgewood") 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 Board through its counsel and Wedgewood through its counsel engaged in negotiations and as a result 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 Wedgewood has violated the "sister-state" provisions of Alabama law as set out in the Statement of Charges.

2. Wedgewood shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) 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 either pharmacy attempt to discharge the same.

3. Wedgewood expressly waive 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. Wedgewood 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, Wedgewood 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. Wedgewood 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 Wedgewood's permit, including, but not limited to revocation.

6. Wedgewood acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Wedgewood acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 6th of June, 2017.

WEDGEWOOD VILLAGE PHARMACY, LLC

BY: [signature]

ITS: President & CEO

[signature]

Jennifer Clark, attorney for Wedgewood Village Pharmacy, LLC

DONE this the _____ of 6/13/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

By: Buddy Bunch

Buddy Bunch, R.Ph., President

By: [signature]

James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	
	)	BEFORE THE ALABAMA STATE
WEDGEWOOD VILLAGE PHARMACY, LLC	)	BOARD OF PHARMACY
	)	
	)	
Non-Resident Pharmacy Permit Number: 112625	)	CASE NO: 16-L-0066
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Wedgewood Village Pharmacy, LLC
405 Heron Drive
Suite 200
Swedesboro, New Jersey 08085

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) 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 _____ _____, 2016 at _____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 Wedgewood Village Pharmacy, LLC (Wedgewood) should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Wedgewood has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Stipulation and Consent Order by the Minnesota Board of Pharmacy on January 4,

2015 attached hereto as Exhibit "A" and/or the Facts set out therein that you shipped drugs to licensed veterinarians in Minnesota without patient specific prescriptions nor the required license to do so.

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 Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon the Consent Order entered by the State of Michigan Board of Pharmacy on April 13, 2016 as a result of the filing of an Administrative Complaint, these documents being attached hereto as Exhibits "B" and "C".

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 FOUR

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 any or all of

the allegations contained in 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 _____ day of _____, 2016.

ALABAMA STATE BOARD OF PHARMACY

_____

By: Susan Alverson
Secretary

EXHIBIT "A"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") 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 register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood 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 December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Hassford Reinele and Rachael G. Pontikes, Esq., of Duane Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must 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 this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel 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 Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must 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 Review Panel, 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 Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel 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 Review Panel 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. 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 will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional 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 future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. 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.

13. 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.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. 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.

17. 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.

18. 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

19. 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 person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. 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:

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

MARCY KLESS, PRESIDENT
Wadgewood

Dated: 1/13/15

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT "B"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") 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 register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood 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 December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Bassford Remele and Rachael O. Pontikes, Esq., of Duane Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

EXHIBIT A page 2 of 7

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must 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 this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel 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 Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

EXHIBIT A page 3 of 7

b. The Review Panel, 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 Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel 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 Review Panel 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. 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 will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional 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 future practice or suspension or revocation of Licensee's registration.

EXHIBIT A page 4 of 7

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. 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.

13. 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.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. 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.

17. 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.

18. 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

19. 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 person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. 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:

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

MARGY BLESS, PRESIDENT
Wedgewood

Dated: 1/13/15

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT A page 7 of 7

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Elizondo (P45554)
Assistant Attorney General
Attorney for Complainant
Dated: 9-1-2016

AGREED TO BY:

Alison Lynch, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 5/31/16

Alan T. Rogalski (P44660)
Attorney for Respondent
Dated: 8/31/2016

EXHIBIT "C"

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the matter of

WEDGEWOOD VILLAGE PHARMACY INC.
License Number: 53-01-008041 File Number: 53-15-137238

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs (Complainant) by Kim Gaedeke, Acting Director, Bureau of Health Care Services, files this Complaint against Wedgewood Village Pharmacy Inc. (Respondent Pharmacy) as follows:

1. The Michigan Board of Pharmacy (Board) is an administrative agency established by the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq. Pursuant to section 17768 of the Public Health Code, supra, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.

2. Respondent Pharmacy is licensed to practice as a pharmacy in the state of Michigan and has an address of record with Complainant of Swedesboro, New Jersey.

3. On January 21, 2015, the Minnesota Board of Pharmacy (Minnesota Board) executed a Stipulation and Consent Order which ordered Respondent Pharmacy

to pay a $10,000.00 civil penalty. The action was based on Respondent Pharmacy not being licensed as a drug wholesaler by the Minnesota Board and shipping drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. A copy of the Stipulation and Consent Order, marked Exhibit A, is attached and incorporated

COUNT I

The action by the Minnesota Board, as set forth above evidence a pharmacy, manufacturer, or wholesale distributor which has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty and constitutes a violation of section 17768(2)(d) of the Public Health Code, supra.

Complainant requests that this Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq.

Pursuant to section 16231(8) of the Public Health Code, supra, Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Complainant, Kim Geedeke, Acting Director, Bureau of Health Care Services, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

Pursuant to section 16231(9) of the Public Health Code, supra, Respondent Pharmacy's failure to submit a written response within 30 days, as noted above, shall be treated as an admission of the allegations contained herein and shall result in transmittal of this Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

DATED: 07/24/2015

Kim Gaedeke, Acting Director
Bureau of Health Care Services

Attachment

This is the final page of an Administrative Complaint in the matter of Wedgewood Village Pharmacy Inc., File Number 53-15-137238, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

DWC

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.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2016 73882
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation, ("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 Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. 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 IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 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. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold

Virginia Herold
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.

Unless contested, Citations are final 30 days from the date of service. Acceptance of a Citations 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 December 19, 2018 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 January 04, 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, Enforcement Analyst, at (916) 574-7925.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2016 73882	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2016 73882	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NSC 100970

Citation Number : CI 2016 73882

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:	Citation Case No : CI 2016 73882
WEDGEWOOD VILLAGE PHARMACY LLC NSC 100970 Respondent	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: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2016 73882

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 December 05, 2018, 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
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7938

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

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

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2018 82132
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("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 Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. 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 IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 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. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold
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.

Unless contested, Citations are final 30 days from the date of service. Acceptance of a Citations 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 December 19, 2018 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 January 04, 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, Enforcement Analyst, at (916) 574-7925.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2018 82132	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

COPY

Citation Number	Name, License No
CI 2018 82132	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NRP 1826

Citation Number : CI 2018 82132

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: WEDGEWOOD VILLAGE PHARMACY LLC NRP 1826 Respondent	Citation Case No : CI 2018 82132 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: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2018 82132

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 December 05, 2018, 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
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7945

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT

Christina Metzen
Associate Enforcement Analyst

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.

October 13, 2017

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2017 77042
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

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:

- November 12, 2017: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 27, 2017: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 12, 2017: 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 Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold

Virginia Herold
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 **November 12, 2017.**
- 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: Ericka Busby
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7731

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 October 27, 2017 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 November 12, 2017 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 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

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 § 4059.5 subd. (b)	A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board	$1,000.00

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017	TOTAL AMOUNT OF FINE(S): $1,000.00

PAYMENT OF FINE(S) DUE BY: November 12, 2017

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

1 OF 7

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
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CONDUCT:

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CITATION ISSUED ON: October 13, 2017	TOTAL AMOUNT OF FINE(S): $1,000.00

PAYMENT OF FINE(S) DUE BY: November 12, 2017

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NRP 1826

Citation Number : CI 2017 77042

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:	Citation Case No : CI 2017 77042
WEDGEWOOD VILLAGE PHARMACY LLC NRP 1826 Respondent	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: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2017 77042

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 October 13, 2017, 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
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7017 0530 0001 1516 2087

I declare under penalty of perjury that the forgoing is true and correct.

Executed on October 13, 2017, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

Wedgewood Connect, LLC
Officer List

Marcy Ann Bliss
Title: CEO/President/Treasurer/Secretary
Address: 405 Heron Drive, Suite 200, Swedesboro, NJ. 08085

Edward Michael Lhee
Title: Asst. Secretary
Address: 1240 Gregory Avenue, Wilmette, Illinois 60091

Jocelyn Rose Stanley
Title: Asst. Secretary
Address: 747 West Dickens Avenue, Chicago, Illinois 60614

Thomas Joseph Formolo
Title: Asst. Secretary
Address: 115 DeWindt Road, Winnetka, Illinois 60093

BOARD OF PHARMACY

LICENSING DETAILS FOR: OSF 107

NAME: LEITERS

LICENSE TYPE: OUTSOURCING FACILITY

LICENSE STATUS: CLEAR

ADDRESS
17 GREAT OAKS BLVD
SAN JOSE CA 95119
SANTA CLARA COUNTY

ISSUANCE DATE
OCTOBER 19, 2017

EXPIRATION DATE
OCTOBER 1, 2020

CURRENT DATE / TIME
APRIL 7, 2020
6:15:10 AM

BakerHostetler

Baker&Hostetler LLP

811 Main Street
Suite 1100
Houston, TX 77002-6111

T 713.751.1600
F 713.751.1717
www.bakerlaw.com

Simone O. Otenaike
direct dial: 713.646.1365
sotenaike@bakerlaw.com

April 27, 2020

VIA OVERNIGHT DELIVERY

Nevada Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, Nevada 89521

Re: LEITERS - License # PH03129

Dear Sir or Madam:

Enclosed is a change of ownership application, along with attachments to same and the applicable fees, for the Pharmacy License pertaining to Leiter's Enterprises, Inc., dba Leiter's ("Leiter's" or "Licensee"), a Delaware corporation, located at 17 Great Oaks Blvd., San Jose, CA 95119.

On December 27, 2019, Wedgewood Village Pharmacy, LLC, a Delaware corporation, entered into a Share Purchase Agreement (the "Agreement") with, among others, the Licensee. On June 8, 2020, pursuant to the terms and subject to the conditions set forth in the Agreement, Wedgewood Village Pharmacy, LLC will acquire a 100% ownership interest in the Licensee and convert the Licensee into a Delaware limited liability company with the name Wedgewood Connect, LLC. As such, effective on June 8, 2020, Wedgewood Village Pharmacy, LLC will have a 100% direct ownership interest in the Licensee and the Licensee's new name will be Wedgewood Connect, LLC.

Pursuant to this name change and change of ownership, Wedgewood Village Pharmacy, LLC submits this application on behalf of Wedgewood Connect, LLC. The Licensee will submit this application on or about the same time the Licensee submits a new application to the DEA. Since the Licensee's updated DEA registration has not yet been issued, the Licensee cannot provide a copy with this application. The Licensee will supplement this application once the new DEA registration is issued and such verification becomes available.

Since the Licensee's conversion into Wedgewood Connect, LLC will occur at closing, the Licensee will supplement this application with the following documents as soon as they become available:

- The Final Bill of Sale
- The Wedgewood Connect, LLC Certificate of Authority
- The Wedgewood Connect, LLC Statement of Information

Please note that while Wedgewood Village Pharmacy, LLC will be the new owner of the Licensee and Wedgewood Connect LLC will be the Licensee's new name, the Licensee's Pharmacist in Charge and Designated Representative will remain the same—thus the Licensee's operations will continue substantially unchanged from its pre-transaction operations. Additionally, the Licensee's FEIN and address will not change as a result of this transaction. If you require any additional information or follow-up, please contact me at (713) 646-1365 or by e-mail at sotenaike@bakerlaw.com.

Sincerely,

Simone Otenaike /ox

Simone O. Otenaike

Enclosures