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: Pentec Health, Inc.

Physical Address: 9 Creek Parkway

City: Boothwyn State: PA Zip Code: 19061

Telephone: 866-956-4376 Fax: 844-876-0017

Toll Free Number: 866-956-4376 (Required per NAC 639.708)

E-mail: jbickel@pentechealth.com Website: www.pentechealth.com

Supervising Pharmacist: Jean Bickel Nevada License #: 19764 ✓

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

100810

FEI Number (From FDA application): 3012746140

Please provide the name of the facility as registered with the FDA and the registration number:
Pentec Health

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
Pentec Health, Inc. is the only name used.

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Jean Bickel Nevada License Number: 19764

A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: _____

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required. (attached)

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

Joseph Cosgrove

Print Name of Authorized Person

04/03/2018

Date

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Pennsylvania

Parent Company if any: Pentech Holdings, Inc.

Address: 2711 Centerville Road, Suite 400

City: Wilmington State: DE Zip: 19808

Telephone: 800-927-9801 Fax: 302-636-5454

Contact Person: _____

For any corporation non publicly traded, disclose the following:

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

100% a) Pentech Holdings, Inc. 2711 Centerville Rd, Wilmington, DE 19808
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 167

3) What was the price paid per share? $55,000

4) What date did the corporation actually receive the cash assets? 05/04/2006

5) Provide a copy of the corporation's stock register evidencing the above information (please see 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.

✓ List of officers and directors

Nevada application for Outsourcing Facility Permit

Question 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?"

We are answering yes to this question, but also including explanation to avoid confusion. We think that the answer should be no, but because the question is so broad, we are including this information to avoid issues.

Pentec Health, as the applicant, was fined on their Colorado pharmacy license (OSP5533) $5500 in 2010 for failure to report to the PDMP of Colorado for a short period of time. This was rectified immediately, and Pentec Health has been 100% compliant with PDMP reporting in all states since then.

The above was for Pentec Health's pharmacy located at 4 Creek Parkway, **NOT** Pentec Health's outsourcing facility located at 9 Creek Parkway.

This attached application is for Pentec Health's new outsourcing facility at 9 Creek Parkway, and is completely unrelated to the pharmacy facility at 4 Creek Parkway.

The 9 Creek Parkway outsourcing facility is just starting up and has no sanctions or disciplinary actions on any licenses.

Debbie Flatch

National Practitioner Data Bank
Healthcare Integrity and Protection Data Bank
P.O. Box 10832
Chantilly, VA 20153-0832

http://www.npdb-hipdb.hrsa.gov

ADVERSE ACTION REPORT

STATE LICENSURE ACTION

Report Number: 5500000065613630

This report is maintained under the provisions of:

[ ] Title IV (NPDB) [ ] Section 1921 (NPDB) [X] Section 1128E (HIPDB)

The information contained in this report is maintained by the Healthcare Integrity and Protection Data Bank for restricted use under the provisions of Section 1128E of the Social Security Act, and 45 CFR Part 61. All information is confidential and may be used only for the purpose for which it was disclosed. Disclosure or use of confidential information for other purposes is a violation of Federal law. For additional information or clarification, contact the reporting entity identified in Section A.

A. REPORTING ENTITY

Entity Name:	COLORADO STATE BOARD OF PHARMACY
Address:	1560 BROADWAY, STE. 1300
City, State, Zip:	DENVER, CO 80202-0546
Country:	
Name of Office:	COLORADO STATE BOARD OF PHARMACY
Title or Department:	DORA/PROGRAM ASSISTANT
Telephone:	(303) 894-7754
Entity Internal Report Reference:	
Type of Report:	INITIAL

B. SUBJECT IDENTIFICATION INFORMATION (ORGANIZATION)

Organization Name:	PENTEC HEALTH, INC
Other Organization Name(s) Used:	
Business Address:	4 CREEK PKWY STE. A
City, State, ZIP:	BOOTHWYN, PA 19061
Organization Type:	PHARMACY (345)
Names and Titles of Principal Officers and Owners (POO):	
Federal Employer Identification Numbers (FEIN):	999999999
Social Security Numbers (SSN):	
Individual Taxpayer Identification Numbers (ITIN):	
State License Number, State of Licensure:	OSP 5533, CO
Is the Subject a health care entity that provides health care services and engages in a formal peer review process for the purpose of furthering quality health care?:	NO
Drug Enforcement Administration (DEA) Numbers:	
Clinical Laboratory Act (CLIA) Numbers:	
Food and Drug Administration (FDA) Numbers:	
National Provider Identifiers (NPI):	
Medicare Provider/Supplier Numbers:	
Name(s) of Health Care Entity (Entities) With Which Subject Is Affiliated or Associated (Inclusion Does Not Imply Complicity in the Reported Action.):	
Business Address of Affiliate:	
City, State, ZIP:	
Nature of Relationship(s):	

C. INFORMATION REPORTED

Type of Adverse Action:	STATE LICENSURE
Basis for Action:	VIOLATION OF FEDERAL OR STATE STATUTES, REGULATIONS OR RULES (A6)
Name of Agency or Program That Took the Adverse Action Specified in This Report:	COLORADO STATE BOARD OF PHARMACY
Adverse Action Classification Code(s):	PUBLICLY AVAILABLE FINE/MONETARY PENALTY (3233)

National Practitioner Data Bank
Healthcare Integrity and Protection
Data Bank
P.O. Box 10832
Chantilly, VA 20153-0832

://www.npdb-hipdb.hrsa.gov

Date Action Was Taken:	03/24/2010
Date Action Became Effective:	03/24/2010
Total Amount of Monetary Penalty, Assessment and/or Restitution:	$ 5,500.00
Is Subject Automatically Reinstated After Adverse Action Period Is Completed?:	YES
Description of Subject's Act(s) or Omission(s) or Other Reasons for Action(s) Taken and Description of Action(s) Taken by Reporting Entity:	STIPULATION AND FINAL AGENCY ORDER, EFFECTIVE 03/24/10, CASE 2010-2886, FOR FAILURE TO COMPLY WITH DATA SUBMISSION REQUIREMENTS OF COLORADO'S PRESCRIPTION DRUG MONITORING PROGRAM. PHARMACY PAID THE FINE, AND THE ACTION WAS COMPLETED ON 03/24/10

☐ Subject identified in Section B has appealed the reported adverse action.

D. SUBJECT STATEMENT

If the subject identified in Section B of this report has submitted a statement, it appears in this section.

E. REPORT STATUS

Unless one or more boxes below are checked, the subject of this report identified in Section B has not contested this report.

☐ If box is checked, this report has been disputed by the subject identified in Section B.

☐ If box is checked, at the request of the subject identified in Section B, this report is being reviewed by the Secretary of the U.S. Department of Health and Human Services to determine its accuracy and/or whether it complies with reporting requirements. No decision has been reached.

☐ If box is checked, at the request of the subject identified in Section B, this report was reviewed by the Secretary of the U.S. Department of Health and Human Services. The Secretary's decision is shown below:

Date of Original Submission: 11/29/2010
Date of Most Recent Change: 11/29/2010

END OF REPORT

Dora
Department of Regulatory Agencies

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2010-002886

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF PENTEC HEALTH, INC., REGISTRATION NO. OSP 5533,

RESPONDENT PHARMACY.

IT IS HEREBY STIPULATED by and between the Colorado State Board of Pharmacy ("Board") and Pentec Health, Inc. ("Respondent Pharmacy"), to resolve all matters pertaining to Board Case Number 2010-002886 as follows:

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of title 12, article 22, C.R.S. (2009), otherwise known as the Pharmaceuticals and Pharmacists Act.

2. Respondent Pharmacy has been registered by the Board as a non-resident prescription drug outlet in the State of Colorado at all times relevant to this disciplinary action.

3. Respondent Pharmacy's address of record with the Board and current location is 4 Creek Pkwy, Ste. A, Boothwyn, PA 19061.

4. Respondent Pharmacy does not contest these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent failed to submit required data into Colorado's Prescription Drug Monitoring Program (PDMP) for the January 16, 2010, through January 25, 2010, reporting period.

6. On January 28, 2010, the Board initiated a complaint against Respondent Pharmacy because Respondent Pharmacy failed to comply with the data submission requirements of the PDMP.

7. Respondent Pharmacy does not contest that the conduct described above constitutes a violation of section 12-22-125(1)(c)(I), (II) and (III) and 12-22-708, C.R.S., and that such conduct provides grounds for disciplinary action against Respondent Pharmacy's non-resident prescription drug outlet registration.

Dora Department of Regulatory Agencies

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DISPOSITION

$5,000.00 Fine with Surcharge and Terms

8. Fine with Surcharge. Pursuant to section 12-22-125.2(5), C.R.S., Respondent Pharmacy shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total amount of Five Thousand, Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.

9. Compliance. Respondent Pharmacy shall at all times comply with the data submission requirements of the PDMP.

10. Advisements and Waivers. Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, whether or not Respondent Pharmacy has consulted with legal counsel. Respondent Pharmacy acknowledges its understanding that it has the following rights:

   a. To have a formal notice of hearing and charges served upon it;
   b. To respond to said formal notice of charges;
   c. To have a formal disciplinary hearing pursuant to section 12-22-125, C.R.S.; and
   d. To appeal this Board order.

   Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

11. Acknowledgments. The undersigned authorized agent of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent Pharmacy has consulted with legal counsel, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

12. Violations. Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under

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Last Modified: November 13th, 2008

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section 12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.

13. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

14. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

15. Effective Date. This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Joseph S Marinelli
Authorized Agent of Respondent Pharmacy

Dated: 03/16/2010

Subscribed and sworn to before me in the County of DELAWARE, State of PENNSYLVANIA, this 16th day of MARCH, 2010 by JOSEPH MARINELLI, in his/her capacity as an authorized agent of Penten Health, Inc.

Notary Public

NOTARIAL SEAL
Public
Twp of Upper Chichester, Delaware County
My Commission Expires

My commission expires:

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Last Modified: November 13th, 2008

Dora
Department of Regulatory Agencies

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FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

DONE AND EFFECTIVE THIS 24th DAY OF March, 2010.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

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Last Modified: November 13th, 2008

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.

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

LICENSE VERIFICATION

Name: Pentec Health, Inc

Address: 9 Creek Parkway

City: Boothwyn State: PA Zip: 19061

I hereby authorize the Pennsylvania Board of Health to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
1000003778	active	11/9/16	11/30/18

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]	Drug Program Specialist	PA	3/9/18	

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.

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License Number	License Status	Date License Issued	Date License Expires
8000001736	active	5/17/06	6/30/18

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

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	Drug Program Specialist	PA	3/9/18	

NEVADA STATE BOARD OF PHARMACY

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☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

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☒ 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: PharMEDium Services, LLC

Physical Address: 913 North Davis Avenue

City: Cleveland State: MS Zip Code: 38732

Telephone: (662) 846-5969 Fax: (662) 846-2614

Toll Free Number: (800) 523-7749 (Required per NAC 639.708)

E-mail: Bwomack@pharmedium.com Website: http://pharmedium.com

Supervising Pharmacist: Barrett Karl Manning 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

100781

FEI Number (From FDA application): 961740623

Please provide the name of the facility as registered with the FDA and the registration number:
PharMEDium Services, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
PharMEDium Services, LLC

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Barrett Karl Manning 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 ☒

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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.

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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.

Brenda Womack

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

Brenda Womack, General Manager

Print Name of Authorized Person

4-6-18

Date

OWNERSHIP IS A PUBLICY TRADED COMPANY

State of Incorporation: Delaware

Parent Company if any: AmerisourceBergen Corporation is the Parent Company of PharMEDium Services, LLC

Corporation Name: AmerisourceBergen Corporation

Address: 1300 Morris Drive

City: Chesterbrook State: PA Zip: 19087

Telephone: 610-727-7000 Fax: (610) 647-0141

Contact Person:

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: 3/16/2001

Registration number issued: 3368747

Stock Exchange: NYSE (Ticker is ABC)

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.

List of officers and directors.

-Steven H. Collis, Chairman, President and Chief Executive Officer
-John G. Chou, Executive Vice President and Chief Legal & Business Officer
-Gina K. Clark, Executive Vice President and Chief Communications & Administration Officer
-James F. Cleary, Jr., Executive Vice President and Group President, Global Commercialization Services & Animal Health
-Dale Danilewitz, Executive Vice President and Chief Information Officer
-Kathy H. Gaddes, Executive Vice President and Chief Human Resources Officer
-Tim G. Guttman, Executive Vice President and Chief Financial Officer
-Peyton R. Howell, Executive Vice President and President, Health Systems & Specialty Care Solutions
-Robert P. Mauch, Executive Vice President and Group President, Pharmaceutical Distribution & Strategic Global Sourcing
-Sun Park, Executive Vice President, Strategy and Development

MISSISSIPPI BOARD OF PHARMACY

6360 I 55 North, Suite, 400, Jackson, Mississippi 39211
Phone 601-899-8880: Fax 601-899-8891

December 12, 2017

To Whom It May Concern:

The Mississippi Board of Pharmacy issued a Sterile Product Outsourcer Permit (Permit Number 13625/13.5) to Pharmedium Services, LLC, 913 North Davis Avenue, Cleveland, Mississippi, on August 18, 2014. This permit is current and in good standing and expires on December 31, 2019. There are no records of complaints or disciplinary action taken against this permit.

The Sterile Product Outsourcer Facilities are subject to the jurisdiction of the Food and Drug Administration and Drug Enforcement Administration.

If you have questions concerning this matter, please contact me at 601-899-8880.

Sincerely,

Cheri Atwood
Director of Compliance
Mississippi Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

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☐ 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: PharMEDium Services, LLC

Physical Address: 36 Stults Road

City: Dayton State: NJ Zip Code: 08810

Telephone: (609) 819-4100 Fax: (609) 655-7628

Toll Free Number: 800-523-7749 (Required per NAC 639.708)

E-mail: Wkelso@pharmedium.com Website: www.pharmedium.com

Supervising Pharmacist: Walter Kelso 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

100780

FEI Number (From FDA application): 079939389

Please provide the name of the facility as registered with the FDA and the registration number:
PharMEDium Services, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
PharMEDium Services, LLC

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Walter Kelso Nevada License Number: pendind

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.

Walter T. Kelso RPh.

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

Walter Kelso, General Manager

Print Name of Authorized Person

9/5/18

Date

OWNERSHIP IS A PUBLICY TRADED COMPANY

State of Incorporation: Delaware

Parent Company if any: AmerisourceBergen Corporation is the Parent Company of PharMEDium Services, LLC

Corporation Name: PharMEDium Services, LLC

Address: 1300 Morris Drive

City: Chesterbrook State: PA Zip: 19087

Telephone: (610) 727-7000 Fax: (610) 647-0141

Contact Person:

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: 3/16/2001

Registration number issued: 3368747

Stock Exchange: NYSE (Ticker is ABC)

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.

List of officers and directors.

-Steven H. Collis, Chairman, President and Chief Executive Officer
-John G. Chou, Executive Vice President and Chief Legal & Business Officer
-Gina K. Clark, Executive Vice President and Chief Communications & Administration Officer
-James F. Cleary, Jr., Executive Vice President and Group President, Global Commercialization Services & Animal Health
-Dale Danilewitz, Executive Vice President and Chief Information Officer
-Kathy H. Gaddes, Executive Vice President and Chief Human Resources Officer
-Tim G. Guttman, Executive Vice President and Chief Financial Officer
-Peyton R. Howell, Executive Vice President and President, Health Systems & Specialty Care Solutions
-Robert P. Mauch, Executive Vice President and Group President, Pharmaceutical Distribution & Strategic Global Sourcing
-Sun Park, Executive Vice President, Strategy and Development

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: PharMEDium Services, LLC

Physical Address: 6100 Global Drive

City: Memphis State: TN Zip Code: 38141

Telephone: (901) 547-3900 Fax: (901) 367-6896

Toll Free Number: 800-523-7749 (Required per NAC 639.708)

E-mail: Emack@pharmedium.com Website: http://pharmedium.com

Supervising Pharmacist: Erica Mack 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

100TP

FEI Number (From FDA application): 961740649

Please provide the name of the facility as registered with the FDA and the registration number:
PharMEDium Services, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
PharMEDium Services, LLC

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Erica Mack 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.

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

Bruce Bagley, Interim General Manager

Print Name of Authorized Person

6 APR 2018

Date

OWNERSHIP IS A PUBLICY TRADED COMPANY

State of Incorporation: Delaware

Parent Company if any: AmerisourceBergen Corporation is the Parent Company of PharMEDium Services, LLC

Corporation Name: AmerisourceBergen Corporation

Address: 1300 Morris Drive

City: Chesterbrook State: PA Zip: 19087

Telephone: (610) 727-7000 Fax: (610) 647-0141

Contact Person:

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: 3/16/2001

Registration number issued: 3368747

Stock Exchange: NYSE (Ticker is ABC)

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.

List of officers and directors.

-Steven H. Collis, Chairman, President and Chief Executive Officer
-John G. Chou, Executive Vice President and Chief Legal & Business Officer
-Gina K. Clark, Executive Vice President and Chief Communications & Administration Officer
-James F. Cleary, Jr., Executive Vice President and Group President, Global Commercialization Services & Animal Health
-Dale Danilewitz, Executive Vice President and Chief Information Officer
-Kathy H. Gaddes, Executive Vice President and Chief Human Resources Officer
-Tim G. Guttman, Executive Vice President and Chief Financial Officer
-Peyton R. Howell, Executive Vice President and President, Health Systems & Specialty Care Solutions
-Robert P. Mauch, Executive Vice President and Group President, Pharmaceutical Distribution & Strategic Global Sourcing
-Sun Park, Executive Vice President, Strategy and Development

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: PharMEDium Services, LLC

Physical Address: 12620 W. Airport Boulevard, Suite 130

City: Sugar Land State: TX Zip Code: 77478

Telephone: (281) 491-1900 Fax: (281) 491-1902

Toll Free Number: (800) 523-7749 (Required per NAC 639.708)

E-mail: Bbagley@pharmedium.com Website: www.pharmedium.com

Supervising Pharmacist: Bamidele Dauda Abdullahi Nevada License #: ~~N/A~~ 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

100782

FEI Number (From FDA application): 961740664

Please provide the name of the facility as registered with the FDA and the registration number:
PharMEDium Services, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
PharMEDium Services, LLC

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Bamidele Dauda Abdullahi Nevada License Number: **

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 by Reciprocation as a Pharmasict is being completed. Pharmacist license number in the state of TX is 54260.

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

Bruce Bagley, General Manager

Print Name of Authorized Person

6 APR 2018

Date

OWNERSHIP IS A PUBLICY TRADED COMPANY

State of Incorporation: Delaware

Parent Company if any: AmerisourceBergen Corporation is the Parent Company of PharMEDium Services, LLC

Corporation Name: AmerisourceBergen Corporation

Address: 227 Washington Street

City: Conshohocken State: PA Zip: 19428

Telephone: (610) 727-7000 Fax: (800) 640-5221

Contact Person:

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: 3/16/2001

Registration number issued: 3368747

Stock Exchange: NYSE (Ticker is ABC)

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.

List of officers and directors.

-Steven H. Collis, Chairman, President and Chief Executive Officer
-John G. Chou, Executive Vice President and Chief Legal & Business Officer
-Gina K. Clark, Executive Vice President and Chief Communications & Administration Officer
-James F. Cleary, Jr., Executive Vice President and Group President, Global Commercialization Services & Animal Health
-Dale Danilewitz, Executive Vice President and Chief Information Officer
-Kathy H. Gaddes, Executive Vice President and Chief Human Resources Officer
-Tim G. Guttman, Executive Vice President and Chief Financial Officer
-Peyton R. Howell, Executive Vice President and President, Health Systems & Specialty Care Solutions
-Robert P. Mauch, Executive Vice President and Group President, Pharmaceutical Distribution & Strategic Global Sourcing
-Sun Park, Executive Vice President, Strategy and Development

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
☐ Partnership - Pages 1-3 & 6
☒ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: SCA Pharmaceuticals LLC

Physical Address: 8821 Knoedl Court

City: Little Rock State: AR Zip Code: 72205

Telephone: 877-550-5059 Fax: 860-831-1101

Toll Free Number: 877-550-5059 (Required per NAC 639.708)

E-mail: lderton@scausa.net Website: www.scausa.net

Supervising Pharmacist: Matthew L. White Nevada License #: 19818 ✓

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

100350

FEI Number (From FDA application): 90-0622763

Please provide the name of the facility as registered with the FDA and the registration number:
SCA Pharmaceuticals LLC #037559301

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: Matthew L. White Nevada License Number: 19818

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

James Milton Boyer, CEO
Print Name of Authorized Person

12/1/2017
Date

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: SCA Pharmaceuticals Holdings LLC

Address: 601 Lexington Avenue, 55th Floor

City: New York State: NY Zip: 10022

Telephone: 877-550-5059 Fax: 860-831-1101

Contact Person: Matthew L. White

For any corporation non publicly traded, disclose the following:

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

a) EHP-SCA, LLC 601 Lexington Ave, 55th Floor, New York, NY 10022
Name Address

b) EHP-SCA CO-INVEST, LLC 601 Lexington Ave, 55th Floor, New York, NY 10022
Name Address

c) EHP CO-INVEST, LLC 601 Lexington Ave, 55th Floor, New York, NY 10022
Name Address

d) SCA HOLDINGS, LLC 8821 Knoedl Court, Little Rock, Arkansas 72205
Name Address

2) Provide the number of shares issued by the corporation. 17,952,500

3) What was the price paid per share? $1.00

4) What date did the corporation actually receive the cash assets? 10/20/2016

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 ✓

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: Stokes Healthcare Inc.

Physical Address: 8000 Commerce Parkway, Suite 600

City: Mt. Laurel State: NJ Zip Code: 08054

Telephone: 800-754-5222 Fax: 856-505-5899

Toll Free Number: 800-754-5222 (Required per NAC 639.708)

E-mail: licensing@stokespharmacy.com Website: www.stokespharmacy.com

Supervising Pharmacist: Emmett McVey Nevada License #: 19796 ✓

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

1000216

FEI Number (From FDA application): 3002815949

Please provide the name of the facility as registered with the FDA and the registration number:
Stokes Healthcare Inc. 3002815949

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

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Emmett McVey Nevada License Number: 19796

A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: NA

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

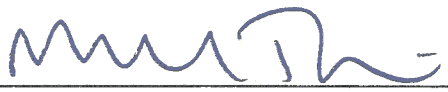
I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized Outsourcing Facility may be grounds for the revocation of this permit.

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

Michael Tursi

Print Name of Authorized Person

1-30-18

Date

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: New Jersey

Parent Company if any: _____

Address: 8000 Commerce Parkway, Suite 600

City: Mt. Laurel State: NJ Zip: 08054

Telephone: 800-754-5222 Fax: 856-505-5899

Contact Person: Michael Tursi

For any corporation non publicly traded, disclose the following:

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

a) See attached.
Name Address

b) _____
Name Address

c) _____
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

Stokes Pharmacy®
ABOVE AND BEYOND

8000 Commerce Parkway, Suite 600, Mount Laurel, NJ 08054
p: 800-754-5222 f: 800-440-5899

Stokes Healthcare Inc. Corporate Officers are as follows:

Emmett McVey, RPh – 50%
T: 609-471-1326
E. Monterey Ave., #601
Wildwood Crest, NJ 08260
Vice President/Owner
Pharmacist – In – Charge

Michael Tursi – 50%
T: 609-471-1295
Union Mill Road
Mt. Laurel, NJ 08054
President/Owner

Stokes Pharmacy®
ABOVE AND BEYOND

8000 Commerce Parkway, Suite 600, Mount Laurel, NJ 08054
p: 800-754-5222 f: 800-440-5899

April 13, 2018
Nevada Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509

Re: Stokes Pharmacy, Nevada Pharmacy License # PH02713 - Notice of Disciplinary Action

To Whom It May Concern:

This letter and the attached documentation is to provide notice of a disciplinary action taken against Stokes Healthcare Inc. d/b/a Stokes Pharmacy, Nevada Pharmacy License #PH02713.

On April 5, 2016 the Colorado Board of Pharmacy issued a Letter of Admonition against our Non Resident Pharmacy License for failing to disclose a 2012 disciplinary action from the North Carolina Board of Pharmacy. Attached is the Letter of Admonition from the Colorado Board which serves as the final version. There was no penalty assessed other than the letter, however Colorado does consider it a reportable disciplinary action.

As a result of the Colorado disciplinary action it has also come to our attention that the disciplinary action from the North Carolina Board that resulted in the above mentioned Letter of Admonition may not have been disclosed to the Nevada Board of Pharmacy. In an effort to ensure complete transparency, we have opted to now disclose that disciplinary action. Attached is the finalized consent order from North Carolina and below is a brief summary of the matter.

As the final consent order from North Carolina details, we had failed to renew our non-resident pharmacy license in North Carolina for 2009. This was unintentional at the time. Through 2009 and 2010 we had continued to ship prescriptions sporadically to patients in North Carolina believing that our license was active and current. By the end of 2010 during an annual review of our licenses we had determined that the license was not renewed. At this point we promptly submitted a new license application to the North Carolina Board and fully disclosed our previous mistake in attempt to remedy the situation as best possible which included providing a complete list of all medications sent into North Carolina during the lapsed license period, approximately 250 prescriptions total for roughly 25 month period. North Carolina did not have a "de minimis" provision that permits non-resident pharmacies to ship small numbers of prescriptions to patients without a license, so even the small volume we shipped was not permitted.

Stokes Pharmacy®
ABOVE AND BEYOND

8000 Commerce Parkway, Suite 600, Mount Laurel, NJ 08054
p: 800-754-5222 f: 800-440-5899

Upon discovery of the lapsed license we opted to immediately stop shipping any prescriptions to North Carolina patients until the matter was sorted.

Shortly after the submission of our new application in January of 2011, we received a letter from the Board to cease shipping into North Carolina which we had already done. We proceeded to work with the Board to finalize that consent order to have our new license approved. The consent order was finalized and permitted our new license to be granted in 2013 along with a stay of the suspension called for in the consent order.

Our interpretation at the time, now admittedly incorrect, was that since the suspension was stayed and not put in place we had no duty to disclose the matter to any state boards unless the suspension was later enacted. We had a similar belief for our more recent issue of the 2015 fine from our resident board of pharmacy. We do not deny that we failed to disclose the matter, however, our same misconception that resulted in our failure to disclose the more recent issue from New Jersey resulted in our failure to disclose this matter in 2013. We disclosed our mistake to the North Carolina Board in 2010 when discovered and we are taking a proactive approach to disclose the matter now. We maintain that these errors were not done intentionally and when given the opportunity Stokes has always provided all information to help aid in quick and complete conclusions to these issues so that we may continue to provide the best product possible to our patients.

If you have any questions or concerns regarding this matter you may contact me directly or you may speak with our in-house counsel, Nick Masino. Our contact info is provided at the bottom of this letter.

Regards,

Michael Tursi
Stokes Healthcare, Inc – Owner, President
T: 609-471-1295
E: MTursi@StokesPharmacy.com

Nick Masino
T: 856-988-1889
E: NMasino@StokesPharmacy.com

COLORADO
Department of
Regulatory Agencies
Divis on of Profes ions and Occupations

State Board of Pharmacy

LETTER OF ADMONITION

April 05, 2018

Stokes Healthcare Inc
Attn: Pharmacist Manager
8000 Commerce Pkwy Ste 600
Mount Laurel, NJ 08054-2211

And via email to: Licensing@StokesPharmacy.com

RE: Case 2018-973

Dear Pharmacist Manager:

The Colorado State Board of Pharmacy ("Board") reviewed the above-referenced complaint. After careful consideration, the Board determined that you failed to report a disciplinary action issued in North Carolina on 11/20/2012. Board Rule 9.00.10(b) requires licensees and registrants to notify the Board in writing within 30 days of any disciplinary action against them in another state.

Therefore, pursuant to Board Policy 30-14, the Board hereby admonishes you for violating the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act and Board Rules. This admonishment shall be a permanent, public record and reportable as a disciplinary action. It may also be considered as an aggravating factor if a future violation occurs.

You have the right to request, in writing, within twenty days after receipt of this letter, formal disciplinary proceedings to adjudicate the propriety of the conduct upon which this letter of admonition is based. If such a request is made, this letter will be vacated and the Board will process the matter by means of formal disciplinary proceedings in accordance with sections 24-4-104 and 105, C.R.S.

FOR THE COLORADO STATE BOARD OF PHARMACY

Wendy Anderson
Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **LETTER OF ADMONITION** upon all parties herein by depositing copies of same in the United States mail, certified, postage prepaid, at Denver, Colorado this 5 day of April 2018, addressed as follows:

Stokes Healthcare Inc
Attn: Pharmacist Manager
8000 Commerce Pkwy Ste 600
Mount Laurel, NJ 08054-2211

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF OUT-OF-STATE PERMIT APPLICATION OF STOKES HEALTHCARE, INC. d/b/a STOKES PHARMACY	)	**FINAL CONSENT ORDER**

THIS MATTER came on to be heard before the North Carolina Board of Pharmacy (the "Board") at a prehearing conference on November 19, 2012, on the consent of the parties. Both parties stipulate and agree to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, the permit applicant, Stokes Healthcare, Inc. ("Stokes") waives its right to appeal this Final Consent Order. Stokes also stipulates that the findings of fact and conclusions of law are legally sufficient to support this Final Consent Order and agrees not to challenge the legal adequacy of the findings and conclusions in any potential future proceeding regarding this Final Consent Order. With the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. Stokes is a corporation organized on January 3, 2002 and existing under the laws of the State of New Jersey. Stokes holds a pharmacy permit in the State of New Jersey and holds out-of-state pharmacy permits in a number of other states.

2. Stokes held an out-of-state pharmacy permit in North Carolina from November 1, 2007 to December 31, 2008 pursuant to North Carolina General Statutes § 90-85.21A. Stokes did not renew its North Carolina out-of-state pharmacy permit for 2009 and thereafter.

3. Stokes makes the following representations: Stokes' failure to renew its out-of-state pharmacy permit for 2009 and thereafter was inadvertent. Although it was unreasonable to do so, Stokes failed to recognize that it had not renewed its permit and it continued shipping prescription drugs into the State of North Carolina without a current out-of-state pharmacy permit. Between January 2009 and January 2011, Stokes shipped prescription drugs into the State of North Carolina on approximately 250 occasions in violation of North Carolina General Statutes §§ 90-85.21A and 90-85.38(b). The vast majority of those drugs were compounded veterinary drugs.

4. On December 6, 2010, the Board received a new permit application from Stokes. Stokes represents that the application was submitted because Stokes had only recently realized that it had failed to renew its out-of-state pharmacy permit for 2009 and 2010. On its North Carolina permit application, Stokes truthfully disclosed that it had previously shipped prescription drugs into the State of North Carolina without an out-of-state pharmacy permit.

5. On January 19, 2011, the Board staff denied Stokes's permit application because of its prior shipments into the State of North Carolina without an out-of-state permit and informed Stokes that it could not make further shipments into the State of North Carolina until a permit was granted.

6. Stokes represents that, upon receipt of that letter, Stokes immediately ceased shipping into the State of North Carolina in violation of North Carolina General Statutes §§ 90-85.21A and 90-85.38(b). The Board accepts that Stokes has made no shipments since it received the January 19, 2011 request from the Board staff.

7. Following the staff denial of Stokes's application in 2011, Stokes initially requested reconsideration of that denial. But Stokes subsequently allowed that request to become inactive.

8. On July 31, 2012, Stokes submitted a new application for an out-of-state pharmacy permit which, again, truthfully disclosed that it had previously shipped prescription drugs into the State of North Carolina without an out-of-state pharmacy permit between January 2009 and January 2011.

9. As of the date of this order, Stokes does not operate an Internet Pharmacy as defined in 21 NCAC 46 .1317(17).

10. With respect to the prior prescriptions shipped into North Carolina, the Board is unaware of instances where Stokes and its pharmacists actually knew or reasonably should have known that the order was issued without a physical examination of the patient and in the absence of a prior prescriber-patient relationship in violation of 21 NCAC 46 .1801(b) or otherwise was not a valid prescription, and Stokes represents that there were no such instances.

11. Stokes represents and the Board accepts that Stokes has never had any disciplinary action or investigation by any federal or state pharmacy regulatory authority involving the pharmacy or any of the pharmacists associated with Stokes.

CONCLUSIONS OF LAW

Based on the above findings, the Board concludes as a matter of law:

1. Stokes violated North Carolina General Statutes §§ 90-85.21A and 90-85.38(b) by shipping prescription drugs into the State of North Carolina without an out-of-state pharmacy permit from January 2009 and January 2011.

2. Stokes admits that the conduct in this matter violated North Carolina law and constitutes sufficient grounds for disciplinary action in connection with its permit application under North Carolina General Statutes § 90-85.38.

3. The Board has considered the following as substantial mitigating factors in this case:

a Stokes ceased shipment for a period of nearly two years after it was informed that it could not ship without an out-of-state permit.

b. The Board has no information that Stokes and its pharmacists have ever shipped prescription drugs into the State of North Carolina in circumstances where they actually knew or reasonably should have known that the order was issued without a physical examination of the patient and in the absence of a prior prescriber-patient relationship in violation of 21 NCAC 46 .1801(b) or otherwise was not a valid prescription.

c. Stokes is not an Internet Pharmacy and otherwise does not have a business model that is likely to encourage or facilitate the shipment of drugs based on invalid prescriptions or other violations of the pharmacy laws.

Based upon the foregoing, and with the consent of the parties, IT IS THEREFORE ORDERED that the permit application of Stokes Healthcare, Inc. d/b/a Stokes Pharmacy is hereby GRANTED, with a 2013 permit to be issued on January 1, 2013 (or within one week thereafter). Stokes Healthcare, Inc. may not ship into North Carolina until after that 2013 permit is issued. However, the permit of Stokes Healthcare, Inc. is hereby INDEFINITELY SUSPENDED, but that suspension is stayed for a period of ten (10) years, upon the following conditions:

1. Respondent's permit is conditioned upon the accuracy of the information in its permit application, the information that it previously provided to the Board in connection with the review of the permit application, and the stipulated Findings of Fact above;

2. Respondent shall violate no laws governing the practice of pharmacy or the distribution of drugs, whether federal, North Carolina or the laws of any other state;

3. Respondent shall violate no rules and regulations of the Board;

4. Respondent shall cooperate with the Board, its attorneys, investigators and other representatives in any investigation and compliance with the provisions of this Consent Order.

This the 20th day of November, 2012.

NORTH CAROLINA BOARD OF PHARMACY

By: _____
Jack W. Campbell, IV
Executive Director

Stokes Healthcare, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Final Consent Order. The undersigned understands and agrees that by entering into this Final Consent Order, it certifies that it has read the foregoing Final Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter. The undersigned further understands that should it violate the terms and conditions of this Final Consent Order, the Board may take additional disciplinary action. The undersigned understands and agrees that this Final Consent Order will not become effective unless and until approved by the Board. The undersigned understands that it has the right to have counsel of its choice review and advise it with respect to its rights and this Final Consent Order, and represents that it enters this Final Consent Order after consultation with its counsel or after knowingly and voluntarily choosing not to consult with counsel.

The undersigned certifies that its agent executing this Final Consent Order is duly authorized to accept the Final Consent Order on behalf of Stokes Healthcare, Inc. and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

STOKES HEALTHCARE, INC.

Emmett McVey Date 9-10-12

By: Emmett H. McVey

Title: Pharmacist in charge

STATE OF New Jersey

Burlington COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that personally appeared before me this day, and each acknowledged the due execution of the foregoing document: Emmett McVey

[PRINT NAME OF INDIVIDUAL SIGNING]

Date: 9.10.12

A Lazzaro

Notary Public

S I Lazzaro

S I LAZZARO
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 8/1/2015
9.10.12

My commission expires: 8.1.2015

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: Wells Pharmacy Network, LLC.

Physical Address: 450 US HWY 51 BYP N

City: Dyersburg State: TN Zip Code: 38024

Telephone: (731) 882-7000 Fax: (731) 882-7100

Toll Free Number: (800) 852-5689 (Required per NAC 639.708)

E-mail: RegulatoryAffairsTenneWellsRx.com Website: www.WellsRx.com

Supervising Pharmacist: John Guthrie Nevada License #: 19762 ✓

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

100472

FEI Number (From FDA application): 3012526962

Please provide the name of the facility as registered with the FDA and the registration number:
Wells Pharmacy Network, 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: John Guthrie Nevada License Number: 19762

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

William E. McMillen

Print Name of Authorized Person

3/22/2018

Date

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: FL

Parent Company if any: N/A

Address: 3420 Fairlane Farms Rd Suite 300

City: Wellington State: FL Zip: 33414

Telephone: (561) 793-1568 Fax: (561) 223-3885

Contact Person: _____

For any corporation non publicly traded, disclose the following:

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

a) Shirley Ann Fis (Name) 364 Woodbine Rd Stamford, CT 06903 (Address)

b) Rachel Shapiro McKim (Name) 145 Corte Madera Center Suite 169 Corte Madera, CA 94925 (Address)

c) Douglas Keith Garvey (Name) 3420 Fairlane Farms Rd Ste 300 Wellington FL 33414 (Address)

d) William Edward McMillen (Name) 22107 Martella Ave Boca Raton, FL 33433 (Address)

2) Provide the number of shares issued by the corporation. 3,212,630

3) What was the price paid per share? .01 per share par value

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

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive, Second Floor
Nashville, TN 37243
http://tn.gov/health

Tennessee Board of Pharmacy
Manufacturer/Wholesaler/Distributor
1-800-778-4123 or 6152531299

June 7, 2017

TO WHOM IT MAY CONCERN:

This verification can be considered primary source. To expedite the verification process, this is the standard format used by the Tennessee Board of Pharmacy. We are pleased to furnish the following information from our files:

PROFESSION:	Manufacturer/Wholesaler/Distributor
NAME:	WELLS PHARMACY NETWORK, LLC.
ADDRESS:	450 US Hwy 51 BYP N, Dyersburg TN 38024
LICENSE NUMBER:	4828
ISSUE DATE:	May 05, 2017
EXPIRATION DATE:	May 31, 2019
CURRENT STATUS:	Licensed
STATUS DATE:	May 05, 2017
SPECIAL ENDORSEMENT:	Controlled Substance Registration Sterile Compounding

COMMENTS: There is no derogatory information in our files concerning this facilty.

Sincerely,

Keshia Evans

Tennessee Board of Pharmacy

VERFFACLTY

wells pharmacy network
superior science & service

450 US Highway 51 Bypass North | Dyersburg, TN 38024 | 800.852.5689

Disciplinary Explanation

On October 24th, 2014 Wells Pharmacy Network LLC., **Ocala, FL** accepted a consent agreement with a warning and fine from the Maine Board of Pharmacy for failure to notify of PIC change within 7 days.

On March 31st, 2015 Wells Pharmacy Network LLC., **Ocala, FL** accepted a consent agreement from the Arizona Board of Pharmacy based on the subsequent inspection by the Arizona Board of Pharmacy after receipt of a 483 from FDA.

On November 1st, 2016 Wells Pharmacy Network LLC., **Ocala, FL** accepted a consent agreement from the Texas Board of Pharmacy **reprimanding its license based upon review of the Arizona Consent Agreement.**

On September 28th, 2016 Wells Pharmacy Network, LLC., **Ocala, FL** executed a Voluntary Agreement to Restrict Sterile Compounding with the Florida Department of Health and that restriction was noted on the FDOH website. This Agreement was faxed to all Board's of Pharmacy on September 28th, 2016. The FDOH and Wells agreed that once Wells gave the FDOH a detailed explanation of the corrective actions and remedial measures taken (and documentation confirmation of same) that the voluntary inspection would be lifted within 72 hours of notice to resume sterile compounding. On November 4th, 2016, Wells submitted its corrected actions and 72 hour notice to the FDOH. On November 5th, 2016, the sterile compounding restriction was lifted by the FDOH and Wells sterile compounding license was returned to "active" on the FDOH website. Wells Pharmacy Network notified all non-resident pharmacy boards on September 28, 2016 via facsimile.

In April 2017, Wells Pharmacy Network LLC, **Ocala, FL** accepted a settlement agreement from the Hawaii Board of Pharmacy agreeing to pay administrative costs after Wells Pharmacy Network reported disciplinary action taken by Maine, Arizona and Florida. The Hawaii Board of Pharmacy approved the settlement as its June 15, 2017 meeting and mailed such referenced agreement on June 20, 2017.

The California Board of Pharmacy filed an accusation against Wells Pharmacy Network, LLC., **Dyersburg, TN** facility dated October 21st, 2016. This matter has been resolved. Please see attached letter from Wells Pharmacy Network's outside counsel for an explanation.

On November 4th, 2016, the Alabama Board of Pharmacy issued Wells Pharmacy Network, LLC., **Ocala, FL** a notice of emergency suspension of license as to sterile compounding to stay in effect for 120 days and set the matter for hearing on January 24th, 2017. This hearing was postponed with the emergency suspension left in place. On January 20th, 2017 Wells Pharmacy Network LLC., **Dyersburg, TN** received Notice of Emergency Suspension of License as to Sterile Compounding from the Alabama Board of Pharmacy dated January 10th, 2017. Wells Pharmacy Network met informally with the General Counsel and Executive Secretary of the Board to resolve the concerns from both ESO's. The informal meeting had productive results which were presented to the Board in Executive Session. From Executive Session, the Alabama Board of Pharmacy conveyed to Wells Pharmacy Network that patient access to customized medications was unimportant to the Board. General Counsel for the Board offered Wells Pharmacy Network request a voluntary surrender of its Alabama permits with payment of $10,000 in costs with all charges dismissed with prejudice from the Board. This request was granted by the Board and a Consent Order reflecting this Agreement has been executed by Wells Pharmacy Network The Board countersigned on June 13, 2017 and was received by Wells Pharmacy Networks outside counsel on June 21, 2017.

wells pharmacy network
superior science & service

450 US Highway 51 Bypass North | Dyersburg, TN 38024 | 800.852.5689

The New Hampshire Board of Pharmacy denied Wells Pharmacy Network, LLC., **Ocala, FL** license renewal on February 15, 2017. Wells Pharmacy Network, LLC appeared before the Board of Pharmacy on April 4, 2017 to appeal the New Hampshire Board of Pharmacy decision and provided additional information requested at the appearance to the Board including its NABP inspection report. The New Hampshire Board of Pharmacy issued its decision to Wells Pharmacy Network on July 20, 2017reaffirming its denial.

On May 17, 2017, Wells Pharmacy Network , LLC., **Ocala, FL** received the adoption of the Imposition of Civil Fine Order by the Alaska Board of Pharmacy in the amount of $1,000 for a technical violation of its professional licensing statutes and regulations. Wells Pharmacy Network disputed the allegation of neglecting to reveal derogatory information concerning criminal convictions of employees as the information was greater than 15 years old (a violation of the FCRA), a misdemeanor not covered by standard background checks, the NABP or FBI background checks. Wells Pharmacy Network voluntarily accepted the fine as an employee did not follow policy on reporting employee disciplinary matters and waived its rights to a hearing.

On May 18, 2017 Wells Pharmacy Network, LLC., **Ocala, FL** received the attached copy of the fully executed Letter of Admonition from the Colorado Board of Pharmacy. This Letter was based on findings that the June 9, 2015 Arizona Consent Order, previously disclosed to all pharmacy boards, provided grounds for disciplinary action.

On June 6, 2017 Wells Pharmacy Network, LLC., **Ocala, FL** signed a Consent Order from the Kentucky Board of Pharmacy agreeing to pay a fine for failing to timely report the June 9, 2015 Arizona Board of Pharmacy Consent Order.

On August 14, 2017 Wells Pharmacy Network, LLC., **Ocala, FL** accepted a reprimand and payment of costs of $468.00 from the Wisconsin Pharmacy Examining Board. The Wisconsin Pharmacy Examining Board concluded Wells Pharmacy Network, LLC. engaged in unprofessional conduct as defined by the Wisconsin Administration Code by having been subject to other disciplinary action by the State of Florida Board of Pharmacy. Wells Pharmacy Network, LLC. has paid the costs to the Wisconsin Pharmacy Examining Board.

On October 5th, 2017 Wells Pharmacy Network, LLC., **Ocala, FL** agreed to the attached Stipulation and Consent Order with the Board of Pharmacy State of Idaho. Wells Pharmacy Network was willing to settle and comply going forward with all the requirements of the Idaho Telehealth Access Act including paying a fine, reviewing the licenses for any provider sending a prescription for an Idaho resident, and refusing to fill any prescription for an Idaho resident from a provider who is not fully licensed in Idaho. However, the Board and Wells Pharmacy Network agreed Wells Pharmacy Network would not expressly admit to violations for these interpretations that are not clear under the Act and for which Wells Pharmacy Network did not know in advance following the recent enactment of the Act.

Wells Pharmacy Network, LLC ("WPN") submitted to the Utah Board of Pharmacy an application for a Pharmacy Class C Pharmaceutical Wholesaler, Manufacturer, Distributor for its Dyersburg, Tennessee 503b facility. As part of the application package, WPN included its disciplinary explanation for both the Dyersburg, Tennessee and Ocala, Florida facilities which had been previously submitted to the Utah Board of Pharmacy in prior years renewals. The Utah Board of Pharmacy pended review of the Pharmacy Class C application and issued the attached Stipulation and Consent Orders against the Dyersburg, Tennessee Class D license and the Ocala, Florida Class D license for 2 disciplinary actions that had been timely submitted to the Utah Board of Pharmacy – one in 2015 and one in mid-2017 each of which have been fully corrected. On January 16th, 2018 Wells Pharmacy Network, LLC agreed to accept the fine of $500.00 which has been paid for each of the Orders as the Utah Board of Pharmacy was within its rights to discipline WPN.

MAIL ORDER PHARMACY— CHANGE OF PHARMACIST IN CHARGE—Checklist affirmation
Please check mark each box to affirm that you have enclosed the information and documents required for this application. This affirmation checklist does not replace the requirements outlined in the Board of Pharmacy Laws and Rules. Please review them carefully for more detailed and clarifying information. This checklist is designed as a tool to confirm that your application is complete and ready to forward to our office.

CHECKLIST—please checkmark as an indicator that you have completed the following.

- [X] Each section of the application has been completed.
- [X] Each page of the application, where noted, has been initialed.
- [X] Signature present where noted.
- [X] Check made payable to: Treasurer State of Maine in the amount of $100.00 is enclosed, or Credit card authorization completed.
- N/A A copy of the consent agreement or order issued by the Board or jurisdiction is enclosed if licensure discipline has been indicated.
- N/A A copy of the Court Judgment and Decision is enclosed if convicted of a crime, including a written statement, in your words, regarding the details of the crime.

SECTION 4: CERTIFICATION AND SIGNATURES

Read the statement below and sign where indicated as your certification of the information provided on this application.

By my signature, I hereby certify that the information provided on this application and in accompanying documents is true and accurate to the best of my knowledge and belief. By submitting this application I understand that the Maine Board of Pharmacy will rely upon this information as truthful and factual. I also acknowledge that an incomplete, altered (including the use of any white out substance), defaced, including use of white out, or compromised application will not be accepted and will be returned and fees forfeited. This includes, but not limited to, unanswered questions, lack of appropriate signature, illegible, missing supporting documents, and/or missing or wrong fee.

Printed Name of Mail Order Pharmacy Owner or Officer	Title
BEN DAVID	CEO
Signature of Mail Order Pharmacy Owner or Officer	Date
[signature]	10/22/13

Also, as the Pharmacist in Charge certify by my signature that I have read and understand the Maine Board of Pharmacy laws and rules and related laws and rules as it applies to a Mail Order Pharmacy. I also certify that the management of the pharmacy will be vested with the pharmacist in charge in all matters directly or indirectly related to the practice of pharmacy or in any matters related to health, welfare, and safety of the public, as required by laws and rules.

Printed Name of PIC	Title
Robert Pruneau	PIC
Signature of PIC	Date
[signature]	10/22/13

SECTION 2 Con't—PHARMACIST IN CHARGE INFORMATION

THIS SECTION MUST BE COMPLETED BY THE PHARMACIST IN CHARGE ("PIC"). Check appropriate response to the questions below. Any YES response must be fully explained by written statement on a separate sheet of paper, signed and dated, and submitted with your application.

CRIMINAL BACKGROUND DISCLOSURE *NOTE: Failure to disclose criminal convictions may result in denial, fines, suspension and/or revocation of a license.*

Have you ever been denied registration by the U.S. Drug Enforcement Administration (DEA) or have you ever had a DEA Registration modified, restricted, suspended or revoked? Has any state or province denied, restricted, modified, suspended or revoked your state permit to prescribe or dispense controlled substances? If yes: 1. ☐ DEA action ☐ Other State of Province (Name) _____ 2. Submit a copy of the official action by the entity. 3. Provide a detailed explanation in your own words on a separate sheet of paper.	☐ Yes ☒ No
Have you ever received a sanction from Medicare or from a state Medicaid program? 1. Medicare OR Medicaid Program (State) _____ 2. Submit a copy of the official action by the entity. 3. Provide a detailed explanation in your own words on a separate sheet of paper. Clarification on programs: • Medicare – Health program administered by the United States government for people that are (1) ages 65 or older, (2) under the age of 65 with certain disabilities, and/or (3) all ages with end-stage renal disease. • Medicaid – Health program administered by the United States government for people with limited incomes. • MaineCare – Health program administered by the State of Maine with similar eligibility requirements as Medicaid.	☐ Yes ☒ No
Have you ever been convicted by any court of any crime? If yes, enclose a detailed description of what happened (including dates) and a copy of the court judgment.	☐ Yes ☒ No
Has any jurisdiction taken disciplinary action against any professional license you hold or have held, or denied your application for licensure? If yes, enclose a detailed explanation and copies of all documents.	☐ Yes ☒ No

BP
INITIALS OF APPLICANT

RECEIVED
OCT 23 2013

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION

RECEIVED
OCT 23 2013

COMPANY APPLICATION

APPLICANT INFORMATION (please print)

NAME OF MAIL ORDER PHARMACY: Wells Pharmacy Network, LLC

FEIN OR SSN: [redacted]

PHYSICAL LOCATION OF THE MAIL ORDER PHARMACY: 1210 SW 33rd Ave

CITY: Ocala | STATE: FL | ZIP: 34474 | COUNTY: Marion

MAILING ADDRESS: 1210 SW 33rd Ave

CITY: Ocala | STATE: FL | ZIP: 34474 | COUNTY: Marion

PHONE # (352) 622-2913 | FAX # (352) 401-5650

PERSON RESPONSIBLE FOR COMPLETING AND SUBMITTING APPLICATION (must be an owner or officer of the entity): Ben David CEO

By my signature, I hereby certify that the information provided on this application is true and accurate to the best of my knowledge and belief. By submitting this application, I affirm that the Office of Professional and Occupational Regulation will rely upon this information for issuance of my license and that this information is truthful and factual. I also understand that sanctions may be imposed including denial, fines, suspension or revocation of my license if this information is found to be false.

SIGNATURE [signature], CEO DATE 10/22/13

Board of Pharmacy
Change of Pharmacist in Charge
for a Mail Order Pharmacy
Required Fee: $100.00 (Non Refundable)

Maine Mail Order Pharmacy License #
MO 40001342

Expiration Date 12/31/13

Office Use Only:
1457 - $100.00

Office Use Only:
Check # 3975
Amount: 100.--
Cash #
Lic. # 99143
Issue Date
Exp. Date

PAYMENT OPTIONS:

Make checks payable to "Maine State Treasurer" - If you wish to pay by Mastercard or Visa, fill out the following:

NAME OF CARDHOLDER (please print name on card)

I authorize the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation to charge my ☐ VISA ☐ MASTERCARD the following amount: $

Card number: Expiration Date /

SIGNATURE DATE

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
BOARD OF PHARMACY
COMPLAINTS AND INVESTIGATION
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Paul R. LePage
GOVERNOR

Anne L. Head, Esq.
COMMISSIONER

Geraldine L. Betts
ADMINISTRATOR

October 30, 2013

Colleen Shapiro, Managing Member/Secretary/Director
11101 S. Crown Way, Suite 5
Wellington, FL 33414

Re: Complaint #2013 PHA 9589 License #MO 40001342 | Expiration Date: 12/31/2013

Against: Wells Pharmacy Network L.L.C.
1210 SW 33rd Ave, Ocala, FL 34474-2853

Pharmacist-in-charge: No Pharmacist-in-charge on record at the time of the alleged incident.

NOTICE OF COMPLAINT

Dear Ms. Shapiro:

Thomas Avery, Chief Field Investigator, has filed a complaint against the license issued to the above named pharmacy by the Board of Pharmacy. A copy of the complaint is enclosed. Please mail to this office a detailed response to the complaint within 33 days of your receipt of this letter.

Be sure to include the complaint number shown above on your response. A copy of your response will be forwarded to the complainant, who will have 15 days to file an optional reply. If the complainant does file a reply, we will send you a copy. A complete description of the complaint process is included in the Administrative Complaint Procedures enclosed with this letter.

If you have any questions, feel free to call me. Do not contact any members of the board. This prohibition is necessary to prevent board members bias.

Sincerely,

Kelly L. McLaughlin, Senior Consumer Assistant Specialist
(email:kelly.l.mclaughlin@maine.gov)

cc: Michael Miller, Assistant Attorney General
Geraldine L. Betts, Board Administrator
Thomas Avery, Chief Field Investigator
Shane Savage, Complaint Officer

Enc.

Board Staff (207)624-8621
Main Receptionist (207)624-8603
TTY users call Maine relay 711

PRINTED ON RECYCLED PAPER
www.maine.gov/professionallicensing

OFFICE LOCATION: GARDINER ANNEX
76 NORTHERN AVENUE, GARDINER, MAINE

Geraldine.L.Betts@maine.gov
Direct line: (207) 624-8625
Fax: (207)624-8637

Law Offices of
SUSAN B. MORRISON, P.A.
Admitted to Practice in Florida, New York and Pennsylvania

1200 W. Platt Street, Suite 100
Tampa, Florida 33606 USA
Telephone 813 902 9293
Facsimile 813 902 9275
Email smorrisonlaw@tampabay.rr.com

December 13, 2013

Via U.S. Mail / Email/ kelly.l.mclaughlin@maine.gov

Kelly L. McLaughlin
Senior Consumer Assistant Specialist
State of Maine
Department of Professional
and Financial Regulations
Office of Professional and Occupational Regulation
Board of Pharmacy
Complaints and Investigation
35 State House Station
Augusta, Maine 04333-0035

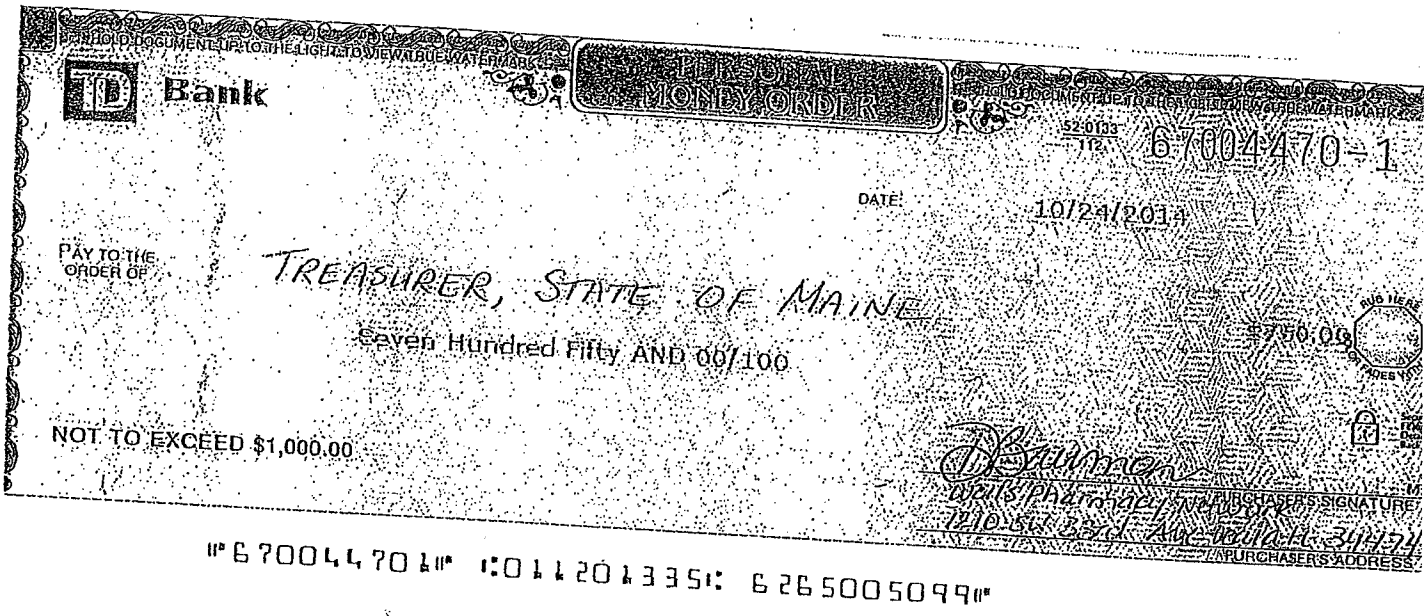
Re: Complaint # 2013PHA9589
License # MO 40001342

Dear Ms. McLaughlin:

This letter is submitted on behalf of this firm's client, Wells Pharmacy Network, L.L.C. ("Wells") in response to your October 30, 2013, letter with enclosed Complaint addressed to Colleen Schapiro, Wells' Managing Member.

The letter was not received by Ms. Schapiro until November 11th. Thus, Wells' response contained herein is timely submitted within the 33 day response window referenced in your letter.

Wells' October 22, 2013 Change of Pharmacist in Charge Application identified Robert Pruneau as the new pharmacist in charge ("PIC") with an effective date of change of October 3, 2013, as so noted in the Complaint by Board of Pharmacy Investigator and Complainant, Thomas Avery. Mr. Pruneau was hired by Wells as Vice President of Pharmacy and intended to assume the role of PIC at the commencement of his employment. However, Mr. Pruneau had advised Wells' management prior to accepting his position that he had a pre-planned two week European vacation scheduled for the middle two weeks of October. Wells prepared the application, but was unable to submit it to the Board until October 22, 2013, because the Application required Mr. Pruneau's signature, and he was unavailable to sign it until he returned to the office on the 22nd.


HOLD DOCUMENT UP TO THE LIGHT TO VIEW WATERMARK
TD Bank
PERSONAL MONEY ORDER
52-0133
112
6700470-1
DATE
10/24/2014
PAY TO THE ORDER OF
TREASURER, STATE OF MAINE
Seven Hundred Fifty AND 00/100
$750.00
NOT TO EXCEED $1,000.00
PURCHASER'S SIGNATURE
PURCHASER'S ADDRESS
"670047011" :011201335: 626500509911"

b. A CIVIL PENALTY in the amount of seven hundred fifty dollars ($750.00), payment which shall be made by certified check or money order payable to the "Treasurer, State of Maine" and delivered to Kelly McLaughlin, Senior Consumer Assistance Specialist, Maine Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333, within thirty (30) days of the execution of this Consent Agreement.

10. This Consent Agreement is not appealable and is effective until modified or rescinded by the parties hereto.

11. Violation of any of the terms or conditions of this Consent Agreement by Wells Pharmacy shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

12. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

13. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408.

14. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

15. Wells Pharmacy acknowledges by its authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
WELLS PHARMACY NETWORK LLC	)	CONSENT AGREEMENT
	)	
Complaint No. 2013 PHA 9589	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order pharmacy license of Wells Pharmacy Network LLC in the State of Maine. The parties to this Consent Agreement are: Wells Pharmacy Network LLC ("Wells Pharmacy"), the State of Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times relevant to this matter, Wells Pharmacy was licensed by the Board as a mail order pharmacy, license no. MO40001342, located at 1210 SW 33rd Avenue, Ocala, Florida.
2. The Board received a change in Pharmacist in Charge application from Wells Pharmacy on October 23, 2013, which disclosed that on October 3, 2013, Robert J. Pruneau took over as the Pharmacist in Charge of Wells Pharmacy.
3. Board Investigator Thomas Avery filed a complaint with the Board alleging that Wells Pharmacy had failed to timely notify the Board of the change in the Pharmacist in Charge as required, which the Board docketed as Complaint No. 2013 PHA 9589.

L. MITCHELL JONES (U.S.B. 5979)
Assistant Attorney General
SEAN D. REYES (U.S.B. 7969)
Utah Attorney General
Commercial Enforcement Division
Heber M. Wells Building
Box 140872
Salt Lake City, UT 84114-6741
Telephone: (801) 366-0310

BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

OF THE DEPARTMENT OF COMMERCE

OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSES OF WELLS PHARMACY NETWORK UTAH LICENSE #8392997-1708 & 8913 TO OPERATE AS A PHARMACY AND TO DISPENSE CONTROLLED SUBSTANCES IN THE STATE OF UTAH	)	STIPULATION AND ORDER CASE NO. DOPL 2018-14

WELLS PHARMACY NETWORK, LLC ("Respondent") and the DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING of the Department of Commerce of the State of Utah ("Division") stipulate and agree as follows:

1. Respondent admits the jurisdiction of the Division over Respondent and over the subject matter of this action. Stacy Shapiro is an officer of Respondent pharmacy and is authorized to act as agent for and enter into binding agreements on behalf of Respondent pharmacy.

and Order, and will release other information about this disciplinary action against Respondent's license, to other persons and entities.

7. Respondent admits the following facts are true:

   a. Respondent was first licensed to operate as a pharmacy and to dispense controlled substances in the State of Utah on or about November 26, 2012.

   b. On or about March 31, 2015, Respondent entered into a "Consent Agreement for Probation, Civil Penalty, Costs, and Inspection" with the Board of Pharmacy of the State of Arizona, a copy of which is incorporated by reference to this Stipulation and Order and attached as Exhibit A, sanctioning Respondent's Arizona pharmacy license.

   c. The allegations contained in Exhibit A would constitute misconduct in the State of Utah.

   d. Respondent shipped compounded drugs to Utah during the time period described in Exhibit A.

8. Respondent admits that Respondent's conduct described above is unprofessional conduct as defined in Utah Code Ann. § 58-1-501(2)(a) and (d); and that said conduct justifies disciplinary action against Respondent's license pursuant to Utah Code Ann. § 58-1-401(2)(a). Respondent agrees that an Order, which constitutes disciplinary action against Respondent's licenses by the Division pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2), shall be entered in this matter as follows:

   (a) Respondent shall pay a fine to the Division in the amount of $500.00 (five hundred dollars), pursuant to Utah Code Ann. § 58-17b-401(6), § 58-17b-504(5), and Utah Administrative Code R156-17b-402, within 90 days of the effective date of this Stipulation and Order.

   (b) Respondent's license shall be publicly reprimanded for the conduct described above.

   (c) Respondent shall successfully complete all the requirements of Exhibit A.

subject Respondent to revocation or other sanctions.

13. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law. Such sanction may include revocation or suspension of Respondent's license, or other appropriate sanction.

14. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

15. Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order. Respondent has no questions about any paragraph or provision contained in this Stipulation and Order.

ORDER

THE ABOVE STIPULATION, in the matter of WELLS PHARMACY NETWORK, LLC, is hereby approved by the Division of Occupational and Professional Licensing, and constitutes my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is disciplinary action pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2). The terms and conditions of the Stipulation are incorporated herein and constitute my final Order in this case.

DATED this 16 day of January 2018

DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

MARK B. STEINAGEL
Director

Investigator: Sharilee McIntyre

RECITALS

1. Respondent has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Respondent understands that it has a right to a public administrative hearing concerning the above-captioned matter, at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Respondent knowingly and voluntarily relinquishes all right to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Respondent affirmatively agrees that this Consent Agreement shall be irrevocable.

4. Respondent understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board.

5. Respondent understands this Consent Agreement deals with Board Complaint No. 4338 involving allegations of unethical conduct against Respondent. The investigation into these allegations against Respondent shall be concluded upon the Board's adoption of this Consent Agreement.

6. Respondent understands that this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

7. Respondent also understands that acceptance of this Consent Agreement does not preclude any other agency, subdivision, or officer of this State from instituting any other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.

ACCEPTED AND AGREED BY RESPONDENT

Wells Pharmacy Network Dated: 3.31.15

Ben David, CEO

by Ben David, CEO on behalf of Wells Pharmacy Network

Subscribed and sworn to before me in the County of Palm Beach, State of Florida, this 31st day of March, ~~2014~~ 2015, by Ben David, on behalf of Wells Pharmacy Network.

BRET JONATHAN PHILLIPS
NOTARY PUBLIC
STATE OF FLORIDA
Comm# FF173681
Expires 11/4/2018

NOTARY PUBLIC

My Commission expires: 11/4/2018

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Respondent is the holder of Pharmacy Permit Number Y005709.

3. From February 21, 2014 through March 7, 2014 representatives of the United States Food and Drug Administration ("FDA") conducted an inspection of Respondent's facility located at 1210 SW 33rd Ave., Ocala, Florida. As a result of that inspection, the FDA issued a report on March 7, 2014 which contained eleven (11) observations detailing potential violations. Based upon its concerns regarding the observations identified in the FDA report the Board directed its staff to conduct an inspection of Respondent's facility in Ocala, Florida.

4. On or about October 7 and 8, 2014 Board compliance officers conducted an inspection of Respondent's facility located at 1210 SW 33rd Ave., Ocala Florida and on

complex preparation which is then verified and approved by a pharmacist (quality manager).

10. At the October 7 and 8, 2014 inspection Board compliance officers reviewed ten (10) random prescription/orders from the Arizona report which revealed Respondent failed to maintain proper compounding records of quality assurance verification, documentation of procedures for obtaining samples for testing, documentation of filter lot number/expiration date and bubble point testing in the compounding record, documentation of the sampling plan for sterility/endotoxin testing and failure to follow proper procedures/protocols for sterility and endotoxin testing sampling.

11. Board compliance officers reviewed additional documents requested from Respondent and received on or about October 15, 2014 which revealed additional discrepancies regarding the records, documentation, compliance with standard operating procedures, testing procedures, sampling procedures and shipping procedures involving Rx 6009925, Rx 6038319, Rx 6038321, Rx 6021313, Rx 605 1741 and Rx 6004621 as more fully set forth in the compliance officers' report dated October 15, 2014, a copy of which is attached and is incorporated by this reference.

CONCLUSIONS OF LAW

1. The Board possesses jurisdiction over the subject matter and over Respondent pursuant to A.R.S. § 32-1901 *et seq*.

2. The Board may discipline permit holder if the Board determines that the permittee or the permittee's employee has engaged in unethical conduct. A.R.S. § 32-1927.02(A) (1).

required unannounced random inspection in paragraph 4 of this Order prior to the expiration of the one (1) year probationary period, Respondent may petition the Board for early termination of the probation by submitting such a request in writing and appearing before the Board at a regularly scheduled meeting.

6. If Respondent violates this Order in any way or fails to fulfill the requirements of this Order, the Board, after giving the Respondent notice and the opportunity to be heard, make take disciplinary action against Respondent's permit. The issue at such a hearing will be limited solely to whether this Order has been violated.

DATED this 09 day of June, ~~2014~~ 2015

ARIZONA STATE BOARD OF PHARMACY

(Seal)

By: _____
KAMLESH GANDHI
EXECUTIVE DIRECTOR

ORIGINAL OF THE FOREGOING FILED
this 09 day of June, ~~2014~~ 2015 with:

Arizona State Board of Pharmacy
1616 W. Adams St.
Phoenix, Arizona 85007

COPY OF THE FOREGOING MAILED
BY CERTIFIED MAIL
this 09 day of June, ~~2014~~ 2015

Wells Pharmacy Network
1210 SW 33rd Ave.
Ocala, Florida 34474
Respondent

CERTIFICATE OF SERVICE

I hereby certify that on the 16 day of January, 2018, a true and correct copy of the foregoing STIPULATION AND ORDER has been served on the parties of record in this proceeding by mailing a copy thereof, properly addressed by first class mail with postage prepaid, to the following:

WELLS PHARMACY NETWORK
1210 SW 33RD AVENUE
OCALA FL 34474

and caused a copy to be electronically mailed to:

L. Mitchell Jones, Assistant Attorney General
(mitchelljones@agutah.gov)

Carol Inglesby
Administrative Assistant
Division of Occupational
and Professional
Licensing

L. MITCHELL JONES (U.S.B. 5979)
Assistant Attorney General
SEAN D. REYES (U.S.B. 7969)
Utah Attorney General
Commercial Enforcement Division
Heber M. Wells Building
Box 140872
Salt Lake City, UT 84114-6741
Telephone: (801) 366-0310

BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

OF THE DEPARTMENT OF COMMERCE

OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSES OF **WELLS PHARMACY NETWORK, LLC** UTAH LICENSE #8473516-1708 & 8913 TO OPERATE AS A PHARMACY AND TO DISPENSE CONTROLLED SUBSTANCES IN THE STATE OF UTAH	)))))))	STIPULATION AND ORDER CASE NO. DOPL 2016-15

WELLS PHARMACY NETWORK, LLC ("Respondent") and the **DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING** of the Department of Commerce of the State of Utah ("Division") stipulate and agree as follows:

1. Respondent admits the jurisdiction of the Division over Respondent and over the subject matter of this action. Stacy Shapiro is an officer of Respondent pharmacy and is authorized to act as agent for and enter into binding agreements on behalf of Respondent pharmacy.

and Order, and will release other information about this disciplinary action against Respondent's license, to other persons and entities.

7. Respondent admits the following facts are true:

a. Respondent was first licensed to operate as a pharmacy and to dispense controlled substances in the State of Utah on or about November 26, 2012.

b. On or about May 23, 2017, Respondent entered into a "Stipulated Settlement and Disciplinary Order for Public Reproval" with the Board of Pharmacy of the State of California, a copy of which is incorporated by reference to this Stipulation and Order and attached as Exhibit A, sanctioning Respondent's California pharmacy license. Exhibit A also contains an "Accusation" which describes the allegations of misconduct against Respondent.

c. The allegations contained in Exhibit A would constitute misconduct in the State of Utah.

8. Respondent admits that Respondent's conduct described above is unprofessional conduct as defined in Utah Code Ann. § 58-1-501(2)(a) and (d); and that said conduct justifies disciplinary action against Respondent's license pursuant to Utah Code Ann. § 58-1-401(2)(a). Respondent agrees that an Order, which constitutes disciplinary action against Respondent's licenses by the Division pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2), shall be entered in this matter as follows:

(a) Respondent shall pay a fine to the Division in the amount of $500.00 (five hundred dollars), pursuant to Utah Code Ann. § 58-17b-401(6), § 58-17b-504(5), and Utah Administrative Code R156-17b-402, within 90 days of the effective date of this Stipulation and Order.

(b) Respondent's license shall be publicly reprimanded for the conduct described above.

(c) Respondent shall successfully complete all the requirements of Exhibit A.

9. Upon approval by the Director of the Division this Stipulation and Order shall be the

13. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law. Such sanction may include revocation or suspension of Respondent's license, or other appropriate sanction.

14. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

15. Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order. Respondent has no questions about any paragraph or provision contained in this Stipulation and Order.

ORDER

THE ABOVE STIPULATION, in the matter of **WELLS PHARMACY NETWORK, LLC**, is hereby approved by the Division of Occupational and Professional Licensing, and constitutes my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is disciplinary action pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2). The terms and conditions of the Stipulation are incorporated herein and constitute my final Order in this case.

DATED this 16 day of January, 2018

DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

MARK B. STEINAGEL
Director

Investigator: Sharilee McIntyre

JURISDICTION

3. On or about May 28, 2013, the Board issued Original Non-Resident Pharmacy Permit No. NRP 1325 to Respondent. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5887, expired on May 1, 2017, and has not been renewed.

4. On or about July 1, 2013, the Board issued Original Non-Resident Sterile Compounding Permit Number NSC 99824 to Respondent to compound injectable sterile drug products. The Non-Resident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5887, expired on May 1, 2017, and has not been renewed.

5. Accusation No. 5887 was filed before the Board and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on October 21, 2016. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 5887 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5887. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

///

14. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that both Non-Resident Pharmacy Permit No. NRP 1325 and Non-Resident Sterile Compounding Permit No. NSC 99824 issued to Respondent Wells Pharmacy Network LLC shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 5887, attached as exhibit A.

Cost Recovery. Respondent shall pay $6,155.25 to the Board for its costs associated with the investigation and enforcement of this matter. Respondent shall be permitted to pay these costs in a payment plan approved by the Board. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew its Non-Resident Pharmacy Permit or its Non-Resident Sterile Compounding Permit until Respondent pays costs in full.

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///

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 5/23/2017

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General

DAVID E. BRICE
Deputy Attorney General
Attorneys for Complainant

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12687933.docx

CERTIFICATE OF SERVICE

I hereby certify that on the 16 day of January, 2018, a true and correct copy of the foregoing STIPULATION AND ORDER has been served on the parties of record in this proceeding by mailing a copy thereof, properly addressed by first class mail with postage prepaid, to the following:

WELLS PHARMACY NETWORK LLC
450 US HWY 51 BYPASS N
DYERSBURG TN 38024

and caused a copy to be electronically mailed to:

L. Mitchell Jones, Assistant Attorney General
(mitchelljones@agutah.gov)

Carol Inglesby
Administrative Assistant
Division of Occupational
and Professional
Licensing

LAWRENCE G. WASDEN
ATTORNEY GENERAL

S. KAY CHRISTENSEN
CHIEF OF CONTRACTS AND ADMINISTRATIVE LAW

LINCOLN STRAWHUN, ISB #8925
REBECCA OPHUS, ISB #7697
Deputy Attorneys General
Fair Hearings Unit
Contracts and Administrative Law
Office of the Attorney General
954 W. Jefferson, 2nd Floor
P. O. Box 83720
Boise, ID 83720-0010
Telephone: (208) 334-4555
Fax: (208) 854-8070

BEFORE THE BOARD OF PHARMACY STATE OF IDAHO

In the Matter of the License of:	)	
	)	Case No. BOP 16-071
WELLS PHARMACY NETWORK, LLC	)	
Mail Service Pharmacy License No. 19765MS	)	**PRELIMINARY ORDER**
Respondent.	)	

Per IDAPA 04.11.01.280, the above appeal is resolved, without a hearing on the merits of the appeal, by a Stipulation and Consent Order between the parties. The stipulation is attached (Exhibit A) and incorporated into this Order.

Pursuant to Sections 67-5270 and 67-5272, Idaho Code, if this preliminary order becomes final, any party aggrieved by the final order or orders previously issued in this case may appeal the final order and all previously issued orders in this case to district court by filing a petition in the district court of the county in which a hearing was held; the final agency action was taken; the party seeking review of the order resides, or operates its principal place of business in Idaho, or; the real property or personal property that was the subject of the agency action is located.

This appeal must be filed within twenty-eight (28) days of this preliminary order becoming final. See Section 67-5273, Idaho Code. The filing of an appeal to district court does not itself stay the effectiveness or enforcement of the order under appeal.

* * * * * * * * * * * * *

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 6th day of November, 2017, I caused to be served a true and correct copy of the foregoing by the following method to:

Jed Manwaring
EVANS KEANE LLP
1161 W. River St., Suite 100
PO Box 959
Boise, ID 83701
jmanwaring@evanskeane.com
ckaes@evanskeane.com

☐ U.S. Mail
☐ Hand Delivery
☐ Facsimile:
☑ Email

Steven Olsen
Deputy Attorney General
Civil Litigation Division
PO Box 83720
Boise, ID 83720
steven.olsen@ag.idaho.gov

☐ U.S. Mail
☐ Hand Delivery
☐ Facsimile:
☑ Email

Alex J. Adams
Executive Director
Idaho Board of Pharmacy
1199 Shoreline Ln., Suite 303
Boise, ID 83702
alex.adams@bop.idaho.gov

☐ U.S. Mail
☐ Hand Delivery
☐ Facsimile:
☑ Email

SAM SEEVERS, PARALEGAL
FAIR HEARINGS UNIT

B. STIPULATED FACTS

1. In March 2015, Board staff reviewed its Prescription Monitoring Program ("PMP") and became concerned about Respondent's activity. In July 2016, Board staff prepared and reviewed a PMP dispensing report regarding Respondent for the time period of April 4, 2014, through July 5, 2016. This PMP dispensing report showed medications prescribed to Idaho residents by medical providers located in Arizona, California, Florida, Illinois, Maine, Massachusetts, and Virginia.

2. The Board requested and timely received prescription records from Respondent's Director of Quality Assurance. Board staff's review of the provided records revealed that Respondent issued prescription drugs to at least four residents of the state of Idaho which were the result of patient-doctor "Telehealth Service" consultations in which the prescriber/doctor was not licensed in Idaho. The Board alleges that these prescriber-doctors not licensed in Idaho was a violation of Idaho Code §54-5703(4), which interpretation of said statute, Respondent denies as not being clear in the statute's wording. Regardless, the Board alleges that these prescriptions were filled by Respondent in violation of Idaho Code, Title 54, Chapter 57 (the Idaho Telehealth Access Act), as follows:

a. Patient D.D. received six prescriptions for Schedule III controlled substances from two prescribers located in Maine and California, neither of whom were licensed to practice medicine nor registered for controlled substances in Idaho. The Board alleges that: Patient D.D. did not have an existing relationship with the prescribers; had no face-to-face interaction with the prescribers; and had no telephone interaction with the prescribers, only with a representative. Respondent denies these allegations. Patient D.D. did not have any contact with Respondent other than emails and receiving the prescribed medications by mail.

Enforcement Agency ("DEA") registration for controlled substances in Idaho. In addition, V.D. has been disciplined by the Idaho Board of Medicine for treating and prescribing to Idaho residents in violation of the Idaho Telehealth Access Act.

4. Respondent issued prescription drugs, including Schedule III controlled substances, under which the Board alleges were invalid prescriptions. These allegations are based upon the Board's position that the prescriptions were invalid because they were issued by physicians who claimed to be treating patients via telehealth but were not complying with the Idaho Telehealth Access Act, Title 54, Chapter 56, Idaho Code, nor complying with United States Code, Title 21, Section 802(54). Specifically, the Board alleges that: Idaho Code § 54-5703(4) requires telehealth providers to be licensed in the state of Idaho; Idaho Code § 54-5707(1) requires telehealth providers to have an established provider-patient relationship in order to issue prescription drug orders; and 21 U.S.C. § 802(54) requires telemedicine providers to possess a DEA controlled substance registration and a state controlled substance registration in the state where the patient is located. The Respondent denies these allegations and contends that: it requires prescriber-physicians to comply with all state and federal statutes; Idaho Code §54-5703(4) is ambiguous as to whether it requires physicians practicing telemedicine to be licensed in Idaho; and that all physicians requesting prescriptions from Respondent have a DEA controlled substance registration.

5. The Board alleges that Respondent had a duty to confirm the validity of the prescriptions it filled for the patients of its associated physicians. Specifically, the Board alleges that: Respondent failed to verify the information provided to it by its associated physicians with regard to (1) those physicians' licensing status in the states in which they prescribed drugs and controlled substances; (2) the patient-physician relationships that must exist; and (3) whether the actions taken by the physicians in treating their patients via telehealth complied with applicable

f. Pursuant to Idaho Code § 37-2723, no person shall fill, compound or dispense a prescription for a controlled substance unless it is in compliance with applicable federal law; including but not limited to Title 21, Chapter 13, U.S. Code, and 21 C.F.R. § 1306.04(a).

7. Respondent, in lieu of proceeding with a formal disciplinary hearing, hereby stipulates that the Board may enter a final order against its license as set forth in Section C below. By entering this stipulation, Respondent is not admitting to any violations or wrongdoing but rather simply seeks a settlement with compliance of the Board's demands going forward.

C. STIPULATED SETTLEMENT

1. The Board has authority pursuant to Idaho Code § 54-1728(c) to impose conditions restricting Respondent's license, and pursuant to § 54-1728(f) to impose administrative fines not to exceed $2,000 per violation, plus attorneys' fees and administrative costs. Respondent agrees to pay the Board $10,000 for the alleged violations outlined above in Section B(6). This fine shall become due only after the Board approves and executes the Order incorporating this Stipulation and shall be paid to the Board within 180 days of the date the Order is executed.

2. Going forward from the date the Order incorporating this Stipulation is executed, Respondent shall verify the appropriate Idaho medical or prescriber licenses and controlled substance registrations for all prescribers issuing prescriptions to Idaho residents. Documentation of such verifications shall be retained by Respondent for two years from the date they are obtained and shall be provided to the Board upon its written request.

3. Respondent shall designate a representative of its management to whom the Board should direct its communications and inquiries and who will be responsible for responding to such inquiries. This representative shall be designated in writing within thirty days of the date the Order incorporating this Stipulation is executed.

E. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

Respondent, by signature of its authorized representative hereto, hereby acknowledges the following:

1. Respondent understands these allegations constitute cause for disciplinary terms upon its license. Respondent agrees the Board has jurisdiction to proceed in this matter with its consent as indicated by signature on its behalf hereto.

2. Respondent has read the above Stipulation fully and has had the opportunity to discuss it with legal counsel. Respondent understands and acknowledges that by its terms it is waiving certain rights provided under Idaho law.

3. Respondent understands that it has, among other rights, the right to a full and complete hearing; the right to confront and cross-examine witnesses; the right to present evidence or to call witnesses, or to so testify on its own behalf; the right to reconsideration; the right to appeal this matter to district court; and all rights provided by the Idaho Administrative Procedure Act and the laws and rules governing the practice of pharmacy in Idaho. Respondent hereby freely and voluntarily waives these rights, without further process, in order to enter into this Stipulation as a resolution of the allegations contained herein.

4. Respondent understands that in signing this Stipulation, it is enabling the Board to impose disciplinary terms upon its license as set forth in Section C without further process.

5. Respondent understands the Board may approve this Stipulation as proposed, approve it subject to specified changes, or reject it. Respondent understands that, if approved as proposed, the Board will execute and issue this Stipulation and Consent Order according to the aforementioned terms, and Respondent hereby agrees to the above Stipulation for settlement. If the Board rejects this proposed Stipulation and Consent Order, this Stipulation and Consent Order will not have any effect and a new proposed Stipulation and Consent Order may be proposed and

DATED this 18th day of October, 2017.

WELLS PHARMACY NETWORK, LLC

By: [signature]
(Print Name)

Its: Secretary
Authorized Representative for Respondent

DATED this 16 day of October, 2017.

EVANS KEANE, LLP

[signature]
Jed W. Manwaring
Attorneys for Respondent

[The remainder of this page is intentionally blank.]

ORDER

Pursuant to Idaho Code § 54-1728 and § 37-2718, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order, and it is hereby ordered that Respondent comply with said terms and conditions.

DATED this 26th day of October, 2017.

Nicole Chopski

Nicole Chopski, PharmD
Board Chair

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
WELLS PHARMACY NETWORK LLC, RESPONDENT.	:	0005454

Division of Legal Services and Compliance Case No. 16 PHM 159

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

Wells Pharmacy Network LLC
1210 SW 33rd Avenue
Ocala, FL 34474

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

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

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

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

FINDINGS OF FACT

1. Respondent Wells Pharmacy Network LLC, is licensed in the state of Wisconsin as an out-of-state pharmacy, having license number 805-43, first issued on August 9, 2012, and current through May 31, 2018. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 1210 SW 33rd Avenue, Ocala, Florida 34474.

2. Respondent is an out-of-state pharmacy located in Ocala, Florida.

2. Respondent Wells Pharmacy Network LLC, is REPRIMANDED.

3. Within ninety (90) days from the date of this Order, Respondent Wells Pharmacy Network LLC, shall pay COSTS of this matter in the amount of 468.00.

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

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

5. In the event that Respondent violates any term of this Order, Respondent's out-of-state pharmacy license (no. 805-43) in the state of Wisconsin, may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of the Order. The Board may, in addition and/or in the alternative refer any violation of this Order to the Division of Legal Services and Compliance for further investigation and action.

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

WISCONSIN PHARMACY EXAMINING BOARD

by: _____ 9/21/17
A Member of the Board Date

of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

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

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

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

14Aug17
Wells Pharmacy Network LLC, Respondent — Date
Melissa Stefko
1210 SW 33rd Avenue
Ocala, FL 34474
License no. 805-43

8-21-17
Gretchen Mrozinski, Prosecuting Attorney — Date
Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190

Tracking # for payment: EV858918288US

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE

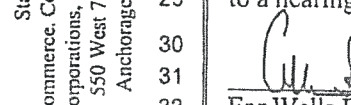
Case # 2016-001006

Wells Pharmacy Network, LLC, admits and agrees the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of their license in Alaska and over this Imposition of Civil Fine.

1. On June 9, 2014, Wells Pharmacy Network submitted a Biennial Out-of-State Pharmacy License Renewal for Alaska License # PHAO1183.
2. Wells Pharmacy Network neglected to reveal derogatory information concerning criminal convictions of employees, as well as disciplinary action of an employee.
3. On May 10, 2016, Wells Pharmacy Network submitted a Biennial Out-of-State Pharmacy License Renewal for Alaska License # PHAO1183.
4. Wells Pharmacy Network neglected to reveal derogatory information concerning a 2014 disciplinary action by the Maine Board of Pharmacy for failure to notify the Board of the Pharmacist-In-Charge change as required. Wells Pharmacy also failed to disclose criminal convictions of employees.
5. Wells Pharmacy Network admitted an error in failing to disclose criminal convictions and disciplinary actions of the pharmacy and employees.

Wells Pharmacy Network admits that as a result of these facts, grounds exist for possible denial of licensure or other disciplinary sanctions of their license pursuant to AS 08.01.075, AS 08.80.260(a)(1), and 12 AAC 52.920(a)(13). Wells Pharmacy Network is agreeing to this Imposition of a Civil Fine of one thousand dollars ($1,000) in cash, certified check, or money order payable to the "**State of Alaska**" within ninety (90) days after this Imposition of Civil Fine is accepted by the Board.

Wells Pharmacy Network has the right to consult with an attorney and a right to an administrative hearing on the facts in this case. Wells Pharmacy Network understands and agrees by voluntarily signing this Imposition of Civil Fine, Wells Pharmacy Network is waiving their rights to counsel and to a hearing on this matter.



For Wells Pharmacy Network, LLC

12/28/16
Date

Colleen S. Shapiro, Secretary
Authorized Representative Name / Title

ORDER

The Alaska Board of Pharmacy hereby adopts the Imposition of Civil Fine in this matter. The Board has determined that this is a technical violation of professional licensing statutes and regulations not related to the delivery of patient care and, therefore, this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 4th day of May, ~~2016~~ 2017, at Anchorage, Alaska.

BOARD OF PHARMACY

By: _____
Board Chair

AMK

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2015-2415

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION IN THE STATE OF COLORADO OF WELLS PHARMACY NETWORK, REGISTRATION NO. OSP 6079,

Respondent Pharmacy.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Wells Pharmacy Network, LLC ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Number 2015-2415, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2016).

2. Respondent Pharmacy was originally registered in the State of Colorado on or about August 8, 2012, being issued registration number OSP 6079, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Pharmacy's address of record with the Board and current location is 1210 SW 33rd Ave., Ocala, Florida 34474-2853.

4. Respondent Pharmacy admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. On June 9, 2015, Respondent Pharmacy entered into a Consent Order with the Arizona Board of Pharmacy due to deficiencies found during the course of an October 2014 inspection conducted by the Arizona Board.

6. Some of the deficiencies outlined in the October 2014 inspection, as detailed below, would be grounds for discipline in Colorado under Board Rule 21.00.00:

acts in any other state that would subject him or her to disciplinary action in this state.

12-42.5-124. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that the applicant licensee, or registrant has engaged in activities that are grounds for discipline.

TERMS OF DISCIPLINE

8. **Letter of Admonition.** This provision shall constitute a Letter of Admonition as set forth in Sections 12-42.5-124(6)(a), C.R.S. Respondent is hereby admonished for the acts and omissions described in the factual basis above. By entering this Order, Respondent agrees to waive the rights provided by Section 12-42.5-124(6)(b), C.R.S., to contest this Letter of Admonition.

9. **Other Requirements.** Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Pharmacy shall:

   a. promptly pay all Respondent Pharmacy's own fees and costs associated with this Final Agency Order;

   b. comply fully with this Final Agency Order; and

   c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

10. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. to appeal this Final Agency Order.

ACCEPTED AND AGREED BY

Respondent Pharmacy

Kristopher Fishman / Sr. VP of operations Dated: 03/31/2017
Authorized Representative / Title

Subscribed and sworn to before me in the County of Palm Beach, State of Florida, this 31st day of March, 2017, by Kristopher Fishman, authorized representative of Wells Pharmacy Network, LLC.

BRET JONATHAN PHILLIPS
NOTARY PUBLIC
STATE OF FLORIDA
Comm# FF173681
Expires 11/4/2018

My commission expires: 11/4/2018 Notary Public

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 18th day of May, 2017.

State Board of Pharmacy

BY: Wendy Anderson
~~Chris Gassen~~ Wendy Anderson
~~Acting~~ Program Director

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 17-0171

IN RE: PERMIT NO. FL1685 HELD BY WELLS PHARMACY NETWORK LLC

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("the Board"), and Wells Pharmacy Network LLC ("Respondent"), and the parties having been fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacists and pharmacies not delegated to another agency of the Commonwealth. The matter herein has not been delegated to another agency of the Commonwealth.

(2) Respondent is an out-of-state pharmacy licensed pursuant to KRS 315.0351, having been assigned permit no. FL1685.

(3) (a) On or about June 21, 2016, Respondent submitted documentation that it had entered into a Consent Order with the Arizona Board of Pharmacy on June 9, 2015; Respondent submitted the corrective action it took as a result of the order. The Consent Order arose from a sterile compounding inspection conducted by the Arizona Board of Pharmacy on or about October 7 and 9, 2014, and the following violations were noted:

- Compounding technician exited and re-entered the ante room without regarbing; same technician later observed in ante room without gloves or mask.
- Pharmacist failed to perform or document verification of components or weights prior to completion of finished preparation.
- Discrepancies in compliance with sterility, endotoxin, and sterile filtration testing results records.
- Standard operating procedures were not observed for: patient counseling, sterilization, depyrogenation, and pharmacist preparation of the first formulation of a complex preparation which is subsequently verified and approved by a pharmacist.
- Random review of prescriptions revealed failure to: maintain proper compounding records or quality assurance verification; document procedures for obtaining testing samples; document filter lot number/expiration date and bubble point testing in the compounding record; document the sampling plan for sterility/ endotoxin testing; and follow procedures/protocols for sterility and endotoxin testing sampling.
- Records and documentation discrepancies, SOP compliance, and problems with testing/sampling/shipping procedures.

(b) On or about September 22, 2016, and pursuant to a joint investigation by the FDA and Florida Board of Pharmacy, Respondent, "out of an abundance of caution," issued a voluntary nationwide recall of all compounded sterile preparations between February 22 – September 14, 2016; 220 of 25,543 patients involved in the voluntary recall were from Kentucky.

(c) Respondent failed to disclose its Arizona discipline within thirty (30) days as required by KRS 315.121(3) and could be subject to suspension or revocation of its Kentucky permit.

(4) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $11,000.00 payable by June 12, 2016. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that the

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
WELLS PHARMACY NETWORK, LLC	)	**BOARD OF PHARMACY**
	)	
Permit No. 113948	)	**CASE NO: 16-L-0120**
	)	
and	)	
	)	
WELLS PHARMACY NETWORK, LLC	)	
	)	**CASE NO: 16-L-0156**
Permit No. 113982	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a pending Statement of Charges and Notice of Hearing ("Statement") involving Wells Pharmacy Network, LLC (Wells), Permit No. 113948 located in Ocala, Florida and Permit No. 113982 located in Dyersburg, Tennessee.

Prior to the scheduled hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the parties through counsel have entered into an agreement the terms of which are set forth in this Consent Order as follows:

1. Wells agrees to voluntarily surrender Permit No. 113948 and Permit No. 113982.

2. Wells agrees to never apply for or seek any type, kind or description of any permit, license, registration or required authorization from the Board and further agrees that it shall never conduct or engage in any activities in the State of Alabama which the Board now or may in the future regulate.

3. The owners of Wells are correctly identified in the initial applications for the above identified permits or any renewals thereto and said owners agree and acknowledge they will not own in whole or part any entity which seeks any permit, license,

any judicial review. Wells 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.

9. By execution of this Consent Order, Wells 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.

10. Wells acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Wells 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 17th of May, 2017.

WELLS PHARMACY NETWORK, LLC
PERMIT NO: 113948

BY: [signature]

ITS: member/ secretary

[signature]

Carey McRae, attorney for Wells Pharmacy Network, LLC

WELLS PHARMACY NETWORK, LLC
PERMIT NO: 113982

BY: [signature]

ITS: member/ secretary

Before the New Hampshire
Board of Pharmacy
Concord, NH 03301

In the Matter of:
Wells Pharmacy, NR0198
(Show Cause Hearing for renewal of NRMO Pharmacy Application)

Docket No: 2017-01

ORDER OF DENIAL

A show cause hearing commenced on April 19, 2017 to determine whether the Board properly denied the Renewal Application of Wells Pharmacy ("Wells") NR 0198, of Ocala, Florida. For the following reasons, the Board has voted to DENY Wells' application.

Background

Wells filed an application for renewal for a Non-Resident Pharmacy Permit which was accepted for filing on December 13, 2016. On or about February 15th , 2017, the Board issued an Order denying Wells' application but giving Wells the opportunity to request a hearing on the denial and show cause why it should be licensed. The Board's reason for the denial was twofold. First, the Board found that Wells' application packet documented recent disciplinary action taken by at least four different states. On that basis, the Board denied Wells' application pursuant to Ph 905.01(a)(6). Additionally, the Board stated that through Wells' application, the Board first became aware that Wells engages in the process of lyophilization and the process of producing pellets; the Board stated that if Wells wishes to continue doing so it must obtain a manufacturing or 503-B permit from the Board.

On or about March 15th, 2017, Wells requested a hearing on its denial, and on April 19, 2017, the Board held a show cause hearing on Wells' application. Kristopher Fishman, Senior Vice President of Operations, appeared on behalf of Wells.

Mr. Fishman explained that after the remodel, the National Association of Boards of Pharmacy ("NABP") inspected the facilities. Mr. Fishman explained that Wells passed the NABP inspection. Shortly thereafter, NABP called the Texas Board of Pharmacy, and that board lifted the restrictions it had put on Wells' license. Shortly thereafter, the boards in both South Carolina and Arizona lifted the restrictions from Wells' license, as well.

With regard to lyophilization and pellets, Mr. Fishman stated that he is not a pharmacist so is not an expert, but told the Board that Wells uses the lyophilization process in order to keep the correct potency of the drugs. He stated that he understands that lyophilization can be difficult, particularly if a pharmacist does not have the correct equipment. Mr. Fishman stated that Wells will not lyophilize more than 250-500 vials at a time. Mr. Fishman explained that Wells does not produce pellets on site; the pellets are transferred from a 503(b) facility.

In response to Board questioning, Mr. Fishman admitted that once the mold was discovered, Wells failed to re-test frequently enough. Mr. Fishman stated that the individual who was responsible for overseeing quality at Wells is no longer with the company due to the unacceptable response to this incident.

Commissioner Stout stated that the standard operating procedures that Wells had provided in its packet to the Board were satisfactory. However, Commissioner Stout stated that the 2012 USP 797s, Compounding Standards, had wonderful guidance for operating procedures, and he asked why Wells failed to implement those. For instance, Commissioner Stout stated Wells had documented training deficiencies and cleaning deficiencies, and used to allow technicians to verify products for the final visual check. Commissioner Stout thus asked Mr. Fishman why the Board should be confident that Wells would comply with the satisfactory standard operating procedures it provided last week when it did not have sufficient procedures in

but shall not be resold or dispensed. Nonprescription items may be compounded upon order by a practitioner for sale as long as the labeling complies with RSA 318:47-a and the product is not a copy of, or similar to, prescription or nonprescription products. All compounding shall be done in compliance with the United States Pharmacopeia as defined by board of pharmacy rules.

II. The compound drug product shall bear the label of the pharmacy responsible for compounding and dispensing the product directly to the patient for administration, and the prescription shall be filed at that pharmacy. Compounded prescription labels shall include the phrase "compounded per subscriber request" or a similar statement on the prescription label or through the use of an auxiliary label attached to the prescription container.

III. A pharmacist shall offer a compounded drug product to a practitioner for administration to an individual patient, in limited quantities. The compounded drug products are for practitioner administration only and shall not be re-dispensed. The pharmacist shall maintain records to indicate what compounded drug products were provided to the medical office or practice. Compounding pharmacies may advertise or otherwise promote the fact that they provide prescription compounding services, in accordance with state law and rules of the board, as well as applicable federal laws.

IV. Where a commercial drug shortage exists because a manufacturer is the only entity currently manufacturing a drug product of a specific strength, dosage form, or route of administration for sale in the United States, and the manufacturer cannot supply the drug product to the public or to practitioners for use, a pharmacist may compound a limited quantity using the active pharmaceutical ingredient and sell to a patient with a valid prescription from a valid prescriber. When the compounded drug product is sold to a medical office or practice it is for the practitioner to administer to patients, and shall not be for resale.

V. The board shall adopt rules under RSA 541-A concerning the regulation of compounding.

VI. Labeling requirements pursuant to paragraph II shall not apply when medication is dispensed to institutionalized patients as provided under RSA 318:47-b.

Ph 905.01 Effect of Revocation and Denial.

(a) The board shall refuse to issue a registration or shall revoke a registration whenever the board determines that a mail-order pharmacy, its pharmacist-in-charge, owner(s) or corporate officer(s) has, after notice and opportunity for a hearing, except pursuant to (c) below, committed an act such as but not limited to:

. . .

(4) Failed to comply with RSA 318:37, II, the provisions of Ph 900, or both;

. . .

(6) Been found guilty of any violation of federal, state or local drug law or have entered into any agreement to resolve violations of such.

. . .

(c) Notwithstanding the above the board shall issue a registration or not revoke if:
(1) No harm resulted from the actions of the applicant or registrant;
(2) There was no intent to violate any provisions of RSA 318;
(3) Corrective action has been taken by the registrant;
(4) Remunerations have been made to the affected party(s); and
(5) The board determines the action is unlikely to occur again.

Mr. Fishman's testimony, then, the Board determines that the mitigating factor in Ph 905.01(c)(1) has been met.

The Board questions whether, under Ph 905.01(c)(2), there was no intent to violate any provisions of RSA 318. The Board does find that Wells did not intend to violate RSA 318 with its past contamination problems, as the Board is satisfied that the airborne mold was caused by a leaky pipe that remained undiscovered. However, as the Board noted at the hearing, Wells' practice of distributing directly to veterinary practices is not in compliance with RSA 318:14-a, III and Ph 404.02. The Board understands from Mr. Fishman's testimony that Wells was unaware of this regulation in New Hampshire, but the Board notes that it is the responsibility all licensees and registrants to comply with the relevant laws.

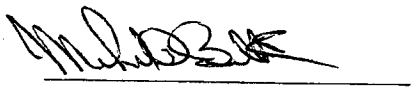
The Board next finds that under Ph 905.01(c)(3), Wells has taken corrective action. Mr. Fishman testified that Wells has since demolished the contaminated compounding room, fixed the leak, and rebuilt the room to 800 standards. In addition, Wells recalled all the affected products and it now does daily testing for viables. The Board does note that Wells did not test frequently enough after first discovering the contamination. Mr. Fishman, however, admitted this and stated the individual responsible for overseeing quality during that time was no longer with the company due to the unacceptable response to this incident.

The Board finds that under Ph 905.01(c)(4), Wells made remunerations to the affected parties. As stated above, Wells recalled all affected products and no adverse effects were reported.

The Board finds, however, that under Ph 905.01(c)(5), it does not have confidence yet that the action is unlikely to occur again. The Board is concerned that Wells in the past failed to follow the guidance of the 2012 USP 797 Compounding Standards. The Board specifically notes

BY ORDER OF THE BOARD_*/

Dated: July 18th, 2017



Michael D. Bullek, BSP, R.Ph.
Authorized Representative of the
New Hampshire Board of Pharmacy

_*/ Board Member recused

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Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of **Wells Pharmacy Network,** Holder of Pharmacy Permit No. Y005709 in the State of Arizona.	Board Case No. 14-0019-PHR **CONSENT AGREEMENT FOR PROBATION, CIVIL PENALTY, COSTS AND INSPECTION**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.*, Wells Pharmacy Network, holder of Pharmacy Permit Number Y005709 in the State of Arizona ("Respondent"), and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

8. Respondent acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, it may not revoke its acceptance of the Consent Agreement or make any modifications to the document regardless of whether the Consent Agreement has been signed by the Executive Director. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

9. This Consent Agreement is subject to the approval of the Board and is effective only when accepted by the Board and signed by the Board's Executive Director. In the event that the Board does not approve this Consent Agreement, it is withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that should the Board reject this Consent Agreement and this case proceeds to hearing, Respondent shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

10. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

11. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

12. Respondent understands that any violation of this Consent Agreement constitutes unethical conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(A) and A.R.S. § 32-1927.02(A).

13. Respondent agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

October 10, 2014 requested additional documents which were provided by Respondent on October 15, 2014.

5. At the October 7 and 8, 2014 inspection Board compliance officers observed a technician working at Respondent's facility exiting and re-entering the ante room without re-garbing and later observed the same technician working in the ante room without gloves or a mask both activities were not in compliance with Respondent's standard operating procedures.

6. At the October 7 and 8, 2014 inspection Board compliance officers noted that the pharmacist in the general compounding area was not performing or documenting a verification of the components or weights prior to the completion of the finished product.

7. At the October 7 and 8, 2014 inspection Board compliance officers conducted a random sampling of the compounding records regarding the "Beyond Use Date" (BUD) for several lots of Trimix injectable.

8. At the October 7 and 8, 2014 inspection Board compliance officers observed discrepancies in Respondent's compliance with sterility, endotoxin and sterile filtration testing results records.

9. At the October 7 and 8, 2014 inspection Board compliance officers observed that Respondent's employees were not following Respondent's standard operating procedures regarding patient counseling of compounded preparations, sterilization and depyrogenation and pharmacist preparation of the first formulation of a

3. The conduct and circumstances described above constitute unethical conduct pursuant in violation of A.R.S. § 32-1901.01(A) (5) (Violating a federal or state law or administrative rule relating to the manufacture, sale or distribution of drugs. devices, poisons, hazardous substances or precursor chemicals).

4. The conduct and circumstances described above constitute unethical conduct pursuant to A.R.S. § 32-1901.01 (A) (5) by violating A.A.C. R4-23-402 (I), R4-23- 410 (I) (2) (a) and (b), A.A.C. R4-23-410 (I) (5), A.A.C. R4-23-410 (J) (1) (d) and A.A.C. R4-23-670 (C) (1).

ORDER

Based upon the above Findings of Fact and Conclusions of Law, the Board issues the following Order:

1. Respondent's permit no. Y005709 is placed on probation for a period of one (1) year.

2. Respondent shall pay a civil penalty of $9,000.00 within 90 days of the effective date of this Order.

3. Respondent shall pay for the costs of the inspection conducted by Board compliance officers in October 2014 in the amount of $2,345.37 within 90 day of the effective date of this Order.

4. Respondent shall to submit to and pass one (1) unannounced random inspection by Board compliance officers within one (1) year of the effective date of this Order and shall pay for the costs of this inspection in an amount not to exceed $3,000.00. Respondent shall pay for the costs of this inspection within 90 days of receiving written notification from Board staff of the incurred costs.

5. If Respondent pays the civil penalty in paragraph 2 of this Order, pays the costs of the October 2014 inspection in paragraph 3 of this Order, submits to and passes the unannounced random inspection in paragraph 4 of this Order and pays the costs of the

COPY OF THE FOREGOING MAILED
this 9 day of June, 2014 to: 2015

Montgomery Lee
Assistant Attorney General
1275 W. Washington Street, CIV/LES
Phoenix, Arizona 85007
Attorney for the State of Arizona

Doc #4200554

were no findings of "Substantially Non-Compliant"). A copy of the NABP inspection report and cover letter are enclosed as Exhibit A. Wells has made a few adjustments in response to the NABP findings, which are explained in Wells' January 14, 2015 response to the NABP. Wells' response is enclosed as Exhibit B.

Wells understands that it is easy to say it is committed to compliance, but hard to prove it. For that reason, we hope the Board will note that the few items of concern identified by the NABP inspection were unrelated to the items identified by the Board's Compliance Officers. Wells believes this is due to the compliance efforts Wells was implementing prior to and at the time of the Board's inspection and that Wells has implemented as a result of the Board's inspection. Wells understands that compliance is a journey, not a destination, and it will continue to review and improve its operations to ensure and maintain compliance.

The following responds to the "potential concerns/violations" in the Compliance Officers' October 15, 2014 report and the Board's proposed Consent Agreements.

I. **"Breach of sterile garbing SOP by technician in ante room."**

The Compliance Officers observed a technician exiting and re-entering the ante room without re-garbing and later observed the same technician working in the ante room without gloves or a mask.

As the Compliance Officers' noted, the technician's conduct violated Wells' standard operating procedure (SOP). Wells counseled the technician regarding the violations and the SOP on the same day the violations occurred and cautioned her that future violations could result in termination. Wells also retrained all sterile personnel regarding the SOP, which requires a sterile gown change before going into the clean room and working on preparations. No further violations have been noted. Enclosed as Exhibit C are Wells' training records for the technician at issue and other sterile personnel.

II. **"SOPs – may not be indicative of current practices", "Provision of patient written information not consistent" and "Position of Quality Manager currently filled by a technician when pharmacist required by SOP."**

The Compliance Officers observed that Wells' employees were not following Wells' SOPs regarding patient counseling of compounded preparations, sterilization and depyrogenation and pharmacist preparation of the first formulation of complex preparations, which is then verified and approved by the Quality Manager who was supposed to be a pharmacist.

Wells has permits in multiple states and, therefore, its operations must comply with multiple states' regulations. Compliance with these regulations requires continuous review and updating of Wells' current procedures and SOPs. In addition, at the time of the inspection, Wells

document verification of the components or weights before the finished product is completed – the pharmacist may assume responsibility for these items, which is what is assumed by Wells' pharmacists performing the final check.

However, in an effort to ensure compliance with the Board's interpretation, Wells has increased pharmacist activity in the non-sterile compounding area. For example, Wells has reduced some of the lab pharmacists' duties and increased their time monitoring and mentoring technicians. The pharmacists also have taken a more active role in compounding, to get hands on experience with manipulating the powders. We would appreciate the Board's clarification of its interpretation and confirmation that Wells' current practices are compliant.

IV. **"Multiple inconsistencies in documentation practices of [Logged Formula Worksheets] and [Formula Worksheets] including:" Beyond Use Date, sterile filtration, sterility sampling, and quality assurance verification.**

The Compliance Officers reviewed ten (10) random prescriptions/orders from the Arizona report which revealed that Wells failed to maintain proper compounding records of quality assurance verification, documentation of procedures for obtaining samples for testing, documentation of filter lot number/expiration date and bubble point testing in the compounding record, documentation of the sampling plan for sterility/endotoxin testing and failure to follow proper procedures/protocols for sterility and endotoxin testing sampling. On or about October 15, 2014, the Compliance Officers reviewed additional documents and identified additional discrepancies regarding the records, documentation, compliance with SOPs, testing procedures, sampling procedures and shipping procedures involving additional prescriptions/orders from the Arizona report.

While it is certainly no excuse, Wells recognized inconsistencies in and the need to improve its documentation practices and, in fact, it had reorganized its quality unit prior to the inspection. Unfortunately, the majority of issues noted by the Compliance Officers were in documents that were created prior to the reorganization.

Wells has consistently practiced Continuous Quality Improvement (CQI) and it continues to make strides to be USP <797> compliant.[2] At the heart of CQI is serial experimentation applied to everyday practices. For example, Wells retrains the applicable staff in the event of a breach of aseptic technique and it continually reviews and refines its processes, including documentation, gowns, storage, mixture and so forth. In addition, Wells is in the process of implementing many cGMP best practices on top of USP standards. For example, Wells' compounding staff wears sterile gowns, booties and face masks, Wells analyzes the efficacy of its cleaning agents and make changes to exceed required standards and Wells utilizes equipment validation studies.

[2] Enclosed as Exhibit F is Wells' recently updated SOP 9.161 regarding its CQI program.

Wells' pharmacists have decades of experience and they determined that, with respect to the Trimix injectables reviewed by the Compliance Officers, it was appropriate to have a BUD that was later than certain components of the injectables. However, since the Compliance Officers' inspection, Wells has updated and reduced the BUD for Trimix injectables.

Presently, Wells mixes its stock solutions, tests their sterility and assigns the following BUD:

Chemical	BUD	Condition	Documentation
Papaverine	90	Refrigerated	PCCA/Eagle BUD study[3]
Phentolamine	90	Refrigerated	PCCA/Eagle BUD study
Alprostadil	60	Refrigerated	PCCA/Eagle BUD study

After the solutions are mixed together, Wells' assigns a BUD based on the earlier of the product's storage method (i.e., 14-day BUD if refrigerated and 45-day BUD if frozen) or the earliest expiration date of any component. We believe this updated process for determining BUDs is consistent with both A.A.C. R-4-23-410(B)(3)(d) and USP <797> and the Compliance Officers' interpretation. However, if the Board believes additional revision is necessary, we respectfully request that the Board clarify how Wells should determine the BUD, so as to ensure future compliance.

VII. Clarification of Consent Agreement Terms.

With respect to the Board's proposed Consent Agreement requiring probation, Paragraph 6 on page 2 states that the Consent Agreement "does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any." Wells is not aware of any other pending matters before the Board. However, since the Consent Agreement "may be considered in any future disciplinary action by the Board", we would appreciate it if the Board would clarify whether any other matters are currently pending.

In addition, Paragraph 4 on page 7 of the Consent Agreement states that Wells must "pass one (1) unannounced random inspection by Board compliance officers...." However, the Consent Agreement does not clarify what constitutes a "pass[ing]" inspection. For example, are no deficiencies required to pass? What if there are minor deficiencies? If so, what would constitute a "minor" deficiency and how many would be permitted? Obviously Wells intends to be in complete compliance; however, considering the size and complexity of Wells' pharmacy and human error, and the potential consequences of not passing an inspection (see next

[3] Enclosed as Exhibit H are the results of the PCCA/Eagle study

Arizona State Board of Pharmacy

To : Hal Wand, Executive Director, ASBP
Cheryl Frush, Deputy Director, ASBP

Date: 10/15/2014

From: Sandra Sutcliffe, CO ASBP
Dennis Waggoner, CO ASBP

Subject: Wells Pharmacy Network

As directed by the Board, CO Sandra Sutcliffe and CO Dennis Waggoner visited Wells Pharmacy Network (Y005709) located at 1210 SW 33rd Avenue, Ocala, FL 34474 on October 7-8, 2014 to conduct an inspection and provide feedback related to the observations noted on FDA Form 483 issued 3-7-2014. The Notice of Inspection Rights was reviewed with Kris Fishman, Vice President of Pharmacy Operations, and Rita Weiss, RPh, Esq, Pharmacy Manager (as of 8-1-2014).

The purpose of the visit was discussed with Mr. Fishman and Ms. Weiss as well as Travis Wood, CPhT, Quality Manager. Ms. Sutcliffe stated that the inspection was to determine compliance with Arizona regulations as well as to discuss the observations of the FDA Form 483. Wells Pharmacy Network (WPN) is primarily a compounding pharmacy (>95%) providing both patient-specific prescriptions and office-use compounded products to practitioners. Sterile and non-sterile low, medium and high risk compounds are produced. Weekly volume was provided as 3200 orders with 240 pharmacist hours utilized. Both Arizona and DEA licenses were produced and are current. A roster of pharmacists and technicians was provided including Florida license number and expiration date. WPN is licensed in all states where non-resident licensure is required. A copy of the most recent Florida inspection report was provided with no observations noted.

- WPN stated that they would be requesting an NABP inspection within the next few weeks as Texas is requiring a report prior to renewing that license. WPN will provide a copy of the NABP report to Arizona when completed.

The following records were requested initially:

- A report of all prescriptions/orders sent to Arizona for the past 12 months
- Training records for technicians
- Media fill and environmental testing results for the past 12 months
- Clean room and hood certifications
- SOP index
- Equipment calibration/maintenance records
- Cleaning documentation

A tour of the facility was requested. Receipt of prescriptions/orders are processed in a cubicle environment with both technicians and pharmacists present. The pharmacy area consists of several small suites for non-sterile compounding segregated primarily by dosage form, a storage room where components are stored, an ante room leading to a positive pressure clean room for sterile compounding, a pharmacist final-check room, a second ante room leading to a negative pressure clean room and a large central area where staging and quality assurance testing is conducted. Refrigerators are electronically monitored with alarms and emails for excursions. During the tour, Anthony Campbell, PharmD, was

- WPN explained that when the above orders were dispensed, the BUD was revised to 14 days. This is not documented in the compounding record.

Each of the above items were compounded from the following compounded bulk ingredients:
Lot 08142014@17 Papaverine HCL 40mg/mL (BUD 2/10/15)
Lot 08142014@19 Phentolamine 20mg/mL (BUD 2/10/15)
Lot 08142014@20 Alprostodil (M) 500mcg/mL (BUD 2/10/15)

- Inconsistencies were observed regarding BUD dating by edits in the Log instructions and notes area.

Sterility and endotoxin testing results were provided. Most sterility testing is performed inhouse utilizing ScanRDI technology. Testing and control protocols were provided as well as an article comparing ScanRDI reliability to USP<71>.

- A review of the article describes a favorable comparison of results; however, the article states that the sampling plan of USP<71> regarding number of containers and total volume tested should be followed. WPN pulled 2 X 5mL samples from each of the above bulks, regardless of the number of containers/volume compounded. While this is current practice at WPN, this is not in compliance with USP<71> requirements.

- Additionally, WPN explained that sampling/testing is not formalized in WPN SOPs but was in development. However, a review of SOP 9.120 STERILE COMPOUNDING FINISHED PREPARATION TESTING found reference to USP<71> requirements to be followed in section 9.1.4.

- An article was provided to justify the 180 day BUD for the bulk compounds. A review of the article stated that a 6 month BUD was appropriate for a Trimix compound when frozen, but 1 month when refrigerated. There was no indication of a BUD recommendation for the individual components prior to compounding as Trimix. Also, the compounding records are unclear as to storage of the bulk prior to use in a final compound.

Lot 09022014@53 Hyaluronidase – Preservative Free 150 U/mL Injectable
Logged Formula Worksheet (LFW) not documented by a pharmacist, but a Formula Worksheet (FW) stapled to LFW was initialed by a pharmacist; however, WPN explained that the LFW is the compounding record.

- Sterile filtration indicated in the procedure, but no documentation of filter testing results.

Lot 09022014@35 Bevacizumab Tesi – (0.05mL Syringe, 31G, 5/16") 25mg/mL Injectable
The LFW has "20 labels" written over the record. WPN explained that 20 previously prepared syringes were placed in individual sleeves per prescriber request.

- A new lot number was assigned to this order. The record is confusing in that it reads as if the syringes were prepared and packaged, not just packaged. The BUD is manually struck through and edited with the BUD of the previously prepared syringes. An article was provided to justify the 90 day BUD.

- Rx [redacted] (office use)-compounding record indicates that 2 vials were tested for sterility and endotoxins from a batch size of 50 vials.

For office use orders, current license numbers/expirations dates of practitioners are maintained electronically.

Review of FDA Form 483 observations dated 3-7-2014:

Observation 1-media fill testing results/SOPs were reviewed.
Observation 2-most recent clean room/hood certifications were conducted under operational conditions by new vendor.
Observation 3-SOPs/results were reviewed for routine air/surface and fingertip testing.
Observation 4-agents for disinfection/cleaning in SOP were present on USP<797> list.
Observation 5-Avastin syringes are tested for endotoxins and sterility (via Scan RDI); however, sampling plan is not compliant with USP<71> requirements.
Observation 6-current BUD meets requirements of R4-23-410(B)(3)(d).
Observation 7-sterile gowns not required for USP<797> compliance; however, observed breach of ante room protocol was described above.
Observation 8-ScanRDI qualification was presented to FDA by WPN during exit interview.
Observation 9- not required in Arizona for pharmacy permitees.
Observation 10- not required in Arizona for pharmacy permitees.
Observation 11-calibration/maintenance of gauges performed by new environmental certification vendor.

Additional observations:

Distribution of Avastin was discussed in relation to compounding versus repackaging.

A copy of a prescription label was provided and found to be in substantial compliance with Arizona requirements.

Additional records were requested on October 10, 2014 and received on October 15, 2014:

Of note:

Rx [redacted] compounding record indicates a kit lot number of 01062014@15 with BUD 6-30-2014. The kit includes Chorionic Gonadotropin + B12, Lyophylized 10,000 Unit vial lot 12202013@2 with BUD 6-30-2014. The compounding record for lot 12202013@2 includes the following components:
Cyanobobalamin (Vit B12)-Dextrose Lot 10142013@66, BUD 4-12-2014
Sodium Phosphate, Monobasic, USP Anhydrous Lot C152858, expiration date 5-1-2014
Sodium Phosphate Dried Dibasic Powder Lot WWC150510, expiration date 5-30-2014

- <u>As indicated, these three components have BUD/expiration dates that occur prior to the BUD stated for the compounded item as well as the kit. Also, the amount of B12 in not stated in the drug name of the compound record. It is unknown if the amount in included on the final container label. Sterility testing results do not include the number of samples tested.</u>

Documents received/reviewed:

SOP Index
Pharmacist/Technician roster
Florida Community Pharmacy Inspection report
Florida Standards of Practice for Compounding Sterile Preparations (CSPs) report
Arizona prescriptions/orders report (sorted by date)
Arizona prescriptions/orders report (sorted by name)
Filling/compounding records for:
Rx [redacted]
Compounding records for:
Lot 09022014@1, 09022014@2, 08142014@17, 08142014@20, 08142014@19
Article: Long-Term Stability of Trimix: A Three-Drug Injection Used to Treat Erectile Dysfunction
Compounding record for:
Lot 09022014@35
Article: Six-month Stability of Bevacizumab (Avastin) Binding to Vascular Endothelial Growth Factor after Withdrawal into a Syringe and Refrigeration or Freezing
Lab report for Lot 08252014@48
Reprint of office-use label
Use log for Flumethasone Pivalate Powder
Compounding record for:
Lot 09022014@53, 09022014@54
ScanRDI documentation:
Scan Bio II protocol using FIFU, Daily Control (FIFU/CB04)
Article: The ScanRDI Sterility Test Protocol as an Effective and Reliable Test for Sterile Compounded Preparations
Certificates of Compliance from Medrep Technologies for clean room and chemo room
Practitioner license verification screenprint
SOPs:
1.010, 1.030, 2.020, 2.030, 2.040, 3.010, 3.020, 3.030, 3.040, 3.050, 4.030, 4.070, 4.090, 4.110, 4.130, 4.200, 4.210, 5.010, 5.011, 5.040, 5.050, 5.070, 6.010, 6.020, 8.010, 9.010, 9.020, 9.040, 9.050, 9.060, 9.080, 9.090, 9.100, 9.110, 9.120, 9.140, 9.150, 9.161
Filling/compounding records for:
Rx [redacted]
Copy of letter from WPN dated October 14, 2014

Steven L. Simas
Justin D. Hein
Lindsay H. Yoshitomi
Daniel J. Tatick

SIMAS & ASSOCIATES
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SACRAMENTO
SAN DIEGO
SAN LUIS OBISPO
SANTA ROSA

May 26, 2017

Re: ***In the Matter of the Accusation Against Wells Pharmacy Network, LLC***
Case No.: 5887; OAH Case No.: 2017011087

To Whom It May Concern:

Our office represented Wells Pharmacy Network ("WPN") in the above-referenced matter against the California Board of Pharmacy ("Board"), which has since been resolved. Because WPN has active licenses in several other states, we wanted to explain the Accusation, the resolution reached, WPN's reasoning for agreeing to settle, the steps taken by WPN to remedy the situation, and the changing regulations. Each is discussed in further detail below.

Accusation

On March 4, 2016, WPN's Tennessee facility was inspected by a Board inspector. The inspector determined WPN was using the improper cleanroom environment when compounding non-sterile to sterile drugs. WPN utilized an ISO 7 cleanroom when California Business and Professions Code § 4127.7 (at the time) required an ISO 5 cleanroom. Additionally, the Board inspector determined the sterile injectable drug products WPN was manufacturing were not adequately subjected to documented end product testing for sterility and pyrogens pursuant to Title 16 of California Code of Regulations § 1751.7.

After this inspection visit, on March 11, 2016, WPN immediately resolved all issues addressed in the report and reported same to the Board.

In spite of WPN's immediate efforts to comply with this unique California provision and the report of the Board inspector, on October 14, 2016, the Board still issued an Accusation regarding these former violations. The Accusation alleged two (2) causes for discipline. WPN timely filed its Notice of Defense denying the charges in the Accusation and requesting a

Nutek Corporation ("Nutek") and Steri-Tek, both California companies. Nutek/Steri-Tek use E-Beam sterilization which is approved by the Food and Drug Administration ("FDA"). Prior to the inspection, WPN utilized Eagle Laboratories and Dynalabs, both of which tested potency/purity and Endotoxins.

These facilities and their equipment met the stringent American National Standard ISO 11137 requirements for sterilization of health care products. Sterilization utilizing E-Beam technology at an FDA approved facility eliminated the need for the usual sterility, Endotoxin, and pyrogen testing. This form of terminal sterilization eliminates the requirement for employee media fill validation. Moreover, WPN demonstrated its dedication to the highest standards of continued education and training for its manufacturing employees by ensuring its employees completed requisite on-line courses in its on-line database. The database ensured prompt and timely completion of each required course and immediately records the date of each completed training and the recurring deadline for taking each course. Lastly, WPN revamped its Simplifi 797: Task Scheduler to ensure all cleaning steps and activities were listed and logged. As you can see, WPN took the necessary steps to address the Board's concerns.

Changes in Regulations

We also believe that significant changes in California law have contributed to the Board's willingness to settle our client's case. California regulations are some of the strictest in the country. WPN had been operating its Tennessee facility in compliance with FDA regulations which mirrored the requirements of other jurisdictions. Unfortunately, California had changed the requirements in 2005 and no longer allowed for an ISO 7 cleanroom when compounding non-sterile to sterile drugs. This change required an ISO 5 cleanroom which created confusion and issues across the state.

Because of this confusion, the California Legislature has introduced a bill in January 2017, to change this law back to the prior version eliminating the need for an ISO 5 cleanroom. Senate Bill 510 addresses this change which was passed unanimously by the Senate on March 27, 2017, with the Board's support.[1] SB 510 is currently awaiting a vote in the California State Assembly which is expected to occur sometime in June, and is, likewise, expected to pass. The Board continues to support SB 510.

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[1] https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180SB510

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **WELLS PHARMACY NETWORK LLC** **450 US Hwy 51, Bypass N** **Dyersburg, TN 38024** **Non-Resident Pharmacy Permit No. NRP 1325** **Non-Resident Sterile Compounding Permit No. NSC 99824** Respondent.	Case No. 5887 OAH No. 2017011087 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL**

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 26, 2017.

It is so ORDERED on June 26, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

JURISDICTION

3. On or about May 28, 2013, the Board issued Original Non-Resident Pharmacy Permit No. NRP 1325 to Respondent. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5887, expired on May 1, 2017, and has not been renewed.

4. On or about July 1, 2013, the Board issued Original Non-Resident Sterile Compounding Permit Number NSC 99824 to Respondent to compound injectable sterile drug products. The Non-Resident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5887, expired on May 1, 2017, and has not been renewed.

5. Accusation No. 5887 was filed before the Board and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on October 21, 2016. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 5887 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5887. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

///

14. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that both Non-Resident Pharmacy Permit No. NRP 1325 and Non-Resident Sterile Compounding Permit No. NSC 99824 issued to Respondent Wells Pharmacy Network LLC shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 5887, attached as exhibit A.

Cost Recovery. Respondent shall pay $6,155.25 to the Board for its costs associated with the investigation and enforcement of this matter. Respondent shall be permitted to pay these costs in a payment plan approved by the Board. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew its Non-Resident Pharmacy Permit or its Non-Resident Sterile Compounding Permit until Respondent pays costs in full.

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 5/23/2017

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General

DAVID E. BRICE
Deputy Attorney General
Attorneys for Complainant

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KENT D. HARRIS
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Sacramento, CA 94244-2550
Telephone: (916) 324-8010
Facsimile: (916) 327-8643
E-mail: David.Brice@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **WELLS PHARMACY NETWORK LLC** **450 US Hwy 51 Bypass N** **Dyersburg, TN 38024** **Non-Resident Pharmacy Permit No. NRP 1325** **Non-Resident Pharmacy Permit No. NSC 99824** Respondent.	Case No. 5887 **ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about May 28, 2013, the Board of Pharmacy issued Original Non-Resident Pharmacy Permit Number NRP 1325 to Wells Pharmacy Network LLC (Respondent). The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2017, unless renewed.

3. On or about July 1, 2013, the Board of Pharmacy issued Original Non-Resident Pharmacy Permit Number NSC 99824 to Respondent to compound injectable sterile drug

REGULATIONS

8. Section 1751 of title 16 of the California Code of Regulations (16 CCR 1751) states, in pertinent part: "(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7."

9. 16 CCR 1751.7 states, in pertinent part:

> (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

COST RECOVERY

10. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FIRST CAUSE FOR DISCIPLINE

(Compounding Sterile from Non-Sterile Drugs in Improper Environment)

11. Respondent is subject to disciplinary action under Code section 4127.7 and 16 CCR 1751(c), by and through Code section 4301(o), in that Respondent compounded sterile injectable drugs from non-sterile ingredients in an improper environment. The circumstances are as follows:

12. On or about March 4, 2016, during an inspection of Respondent's premises, a Board inspector found that Respondent compounded non-sterile to sterile drugs in a clean room that was certified only as an ISO 7 environment, instead of the required ISO 5 environment.[1]

SECOND CAUSE FOR DISCIPLINE

(Failure to Document Quality Assurance)

13. Respondent is subject to disciplinary action under 16 CCR 1751.7(c), by and through Code section 4301(o), in that Respondent failed to document end product testing for sterility and

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[1] Clean rooms are classified by the International Organization for Standardization (ISO) according to the size of particles permitted in the air, from ISO 1 (smallest) to ISO 9 (largest).

DARIA A. LOY-GOTO 6175
JOHN T. HASSLER 5311
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of)	PHA 2016-30-L
)	
WELLS PHARMACY NETWORK, LLC,)	SETTLEMENT AGREEMENT PRIOR TO
)	FILING OF PETITION FOR DISCIPLINARY
Respondent.)	ACTION AND BOARD'S FINAL ORDER;
)	EXHIBITS "1" THROUGH "3"
)	

241042211

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS, REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent WELLS PHARMACY NETWORK, LLC (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was the holder of miscellaneous permit number PMP 797, issued by the Board of Pharmacy (hereinafter the "Board"). The miscellaneous permit was issued on or about August 2, 2012. The miscellaneous permit will expire or forfeit on or about December 31, 2017.

2. Respondent's mailing address for purposes of this action is 1210 S.W. 33rd Avenue, Ocala, Florida 34474.

3. RICO received a request for investigation from the Board after Respondent reported disciplinary actions taken by the states of Maine and Arizona on a December 14, 2015 renewal application. Respondent later reported disciplinary action by the State of Florida.

4. Respondent being at all times relevant herein the holder of a miscellaneous permit acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent represents Exhibit "1" is a true and correct copy of the Maine Agreement.

6. Respondent represents Exhibit "2" is a true and correct copy of the Florida Agreement.

7. Respondent represents Exhibit "3" is a true and correct copy of the Arizona Agreement.

8. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this settlement agreement may be grounds for further disciplinary action under HRS chapters 436B and 461.

9. Respondent further understands that RICO enters into this settlement agreement, and agrees to the specific terms contained in this settlement agreement, based upon Respondent's representations made herein.

10. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's miscellaneous permit. Respondent states it does not compound drugs in the State of Hawaii.

11. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

12. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2016-30-L.

13. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

14. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative costs. Respondent agrees to pay costs in the amount of TEN THOUSAND AND NO/100 DOLLARS ($10,000.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn.: John T. Hassler, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment shall be due at the time this Settlement Agreement is returned to RICO.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Winter Park (City), Florida (State), April 26, 2017 (Date).

WELLS PHARMACY NETWORK, LLC
Respondent

By: Colleen S Shapiro (Signature)
Colleen Stacy Shapiro (print name)
Its member/Secretary

DATED: Honolulu, Hawaii, MAY 16 2017.

John T. Hassler

DARIA A. LOY-GOTO
JOHN T. HASSLER
Attorneys for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF WELLS PHARMACY NETWORK, LLC; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" THROUGH "3"; RICO CASE NO. PHA 2016-30-L

STATE OF Florida)
) SS.
COUNTY OF Seminole)

On this 26th day of April, 2017, before me personally appeared Colleen Stacy Shapiro, to me known to be the person described, and who executed the foregoing instrument on behalf of WELLS PHARMACY NETWORK, LLC as its Member/Secretary, and acknowledged that he/she executed the same as his/her free act and deed.

This 7-page SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER document dated April 26, 2017 was acknowledged before me by
[Date Document Signed by Respondent]
Colleen Stacy Shapiro this 26 day of April, 2017,
[Name of Person Signing Document]
in the City of Winter Park, in the County of Seminole, in the State of Florida. Colleen S Shapiro

Name: [illegible]
Notary Public, State of Florida

Nancy Lyn Velasquez
NOTARY PUBLIC
STATE OF FLORIDA
Comm# FF978178
Expires 7/5/2020

My Commission expires: 7/5/20

4. Title 32 M.R.S. § 13753(1)(C) requires that change of a Pharmacist in Charge requires notice to the Board no later than seven (7) days after the change. In addition, upon a change in Pharmacist in Charge, a mail order pharmacy shall file a new application with the Board no later than seven (7) days after the change. Board Rule Chapter 11, § 3.

5. Wells Pharmacy was required to file an application and notify the Board of the change in the Pharmacist in Charge no later than October 10, 2013, but failed to do so until October 23, 2013.

6. On June 5, 2014, following a presentation of the complaint, the Board voted to offer Wells Pharmacy this Consent Agreement in order to finally resolve Complaint No. 2013 PHA 9589.

7. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Kelly McLaughlin, Senior Consumer Assistance Specialist, 35 State House Station, Augusta, Maine 04333-0035 by October 3, 2014, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

8. Wells Pharmacy admits the facts stated above and that such conduct constitutes grounds for discipline pursuant to 10 M.R.S. §§ 8003(5-A)(A)(4),(5), 32 M.R.S. § 13753(1)(C), and Board Rule Chapter 11, § 3, for its failure to notify the Board of the change in Pharmacist in Charge and file the required application within seven (7) days of the change.

9. Wells Pharmacy agrees to accept the following discipline:

   a. A WARNING; and

WELLS PHARMACY

DATED: 10/24/14

BY: [signature] CEO
Authorized Representative

BEN DAVID - CEO
Printed Name

DATED: 11/6/2014

[signature]
JOSEPH BRUNO, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: November 4, 2014

[signature]
MICHAEL MILLER
Assistant Attorney General

RECEIVED
PROF & OCCUPATIONAL
LICENSING DIVISION
'15 DEC 18 P4:16
DEPARTMENT OF
PROFESSIONAL
REGULATION

2. Petitioner has received a complaint in this matter containing allegations that Respondent may have compounded sterile products without being in compliance with Rule 64B16-27.797, Florida Administrative Code.

3. So as to avoid the necessity of an order restricting or suspending its license to practice as a Special Sterile Compounding Pharmacy in the State of Florida, Respondent has agreed to voluntarily restrict its practice in the State of Florida. Respondent ceased sterile compounding on September 14, 2016.

Immediately upon executing this Agreement, Respondent shall cease compounding sterile products and shall cease dispensing or shipping sterile products it has previously compounded.

4. Respondent has agreed with the United States Food and Drug Administration ("FDA") to cease sterile compounding until the necessary corrective actions can be implemented to address the FDA's alleged concerns. Respondent shall, under separate cover, submit to the Department of Health each of the corrective actions taken as well as any subsequent testing confirming the corrective actions to successfully resolve

EXECUTED this 27th day of September, 2016.

Institutional Representative for
Wells Pharmacy Network, LLC
License No. PH27462

STATE OF Florida
COUNTY OF Palm Beach

Before me, personally appeared Ben David, whose identity is known to me by Professional relationship (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 27th day of September, 2016.

NOTARY PUBLIC

My Commission Expires: 11/4/2018

BRET JONATHAN PHILLIPS
NOTARY PUBLIC
STATE OF FLORIDA
Comm# FF173881
Expires 11/4/2018

RECITALS

1. Respondent has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Respondent understands that it has a right to a public administrative hearing concerning the above-captioned matter, at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Respondent knowingly and voluntarily relinquishes all right to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Respondent affirmatively agrees that this Consent Agreement shall be irrevocable.

4. Respondent understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board.

5. Respondent understands this Consent Agreement deals with Board Complaint No. 4338 involving allegations of unethical conduct against Respondent. The investigation into these allegations against Respondent shall be concluded upon the Board's adoption of this Consent Agreement.

6. Respondent understands that this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

7. Respondent also understands that acceptance of this Consent Agreement does not preclude any other agency, subdivision, or officer of this State from instituting any other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.

ACCEPTED AND AGREED BY RESPONDENT

Wells Pharmacy Network Dated: 3-31-14

by Ben David, CEO on behalf of Wells Pharmacy Network

Subscribed and sworn to before me in the County of Palm Beach, State of Florida, this 31st day of March, 2014, by Ben David, on behalf of Wells Pharmacy Network.

BRET JONATHAN PHILLIPS
NOTARY PUBLIC
STATE OF FLORIDA
Comm# FF173681
Expires 11/4/2018

NOTARY PUBLIC

My Commission expires: 11/4/2018

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Respondent is the holder of Pharmacy Permit Number Y005709.

3. From February 21, 2014 through March 7, 2014 representatives of the United States Food and Drug Administration ("FDA") conducted an inspection of Respondent's facility located at 1210 SW 33rd Ave., Ocala, Florida. As a result of that inspection, the FDA issued a report on March 7, 2014 which contained eleven (11) observations detailing potential violations. Based upon its concerns regarding the observations identified in the FDA report the Board directed its staff to conduct an inspection of Respondent's facility in Ocala, Florida.

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PROF & VOCATIONAL
LICENSING DIVISION

4. On or about October 7 and 8, 2014 Board compliance officers conducted an inspection of Respondent's facility located at 1210 SW 33rd Ave., Ocala Florida and on

required unannounced random inspection in paragraph 4 of this Order prior to the expiration of the one (1) year probationary period, Respondent may petition the Board for early termination of the probation by submitting such a request in writing and appearing before the Board at a regularly scheduled meeting.

6. If Respondent violates this Order in any way or fails to fulfill the requirements of this Order, the Board, after giving the Respondent notice and the opportunity to be heard, make take disciplinary action against Respondent's permit. The issue at such a hearing will be limited solely to whether this Order has been violated.

DATED this 09 day of June, ~~2014~~. 2015

ARIZONA STATE BOARD OF PHARMACY

(Seal)

By: _____
KAMLESH GANDHI
EXECUTIVE DIRECTOR

ORIGINAL OF THE FOREGOING FILED
this 09 day of June, ~~2014~~ 2015 with:

Arizona State Board of Pharmacy
1616 W. Adams St.
Phoenix, Arizona 85007

COPY OF THE FOREGOING MAILED
BY CERTIFIED MAIL
this 09 day of June, ~~2014~~ 2015

Wells Pharmacy Network
1210 SW 33rd Ave.
Ocala, Florida 34474
Respondent

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PROF & VOCATIONAL
LICENSING DIVISION
'15 DEC 18 P4:15

Grossman, Furlow
& Bayó, LLC
ATTORNEYS AT LAW

State Board of Pharmacy

Re: Wells Pharmacy Network, LLC (NABP # 1002752)

To Whom It May Concern:

This firm serves as Regulatory Counsel for Wells Pharmacy Network, LLC ("Wells"). We would like to notify you of our client's current regulatory situation with the Florida Department of Health ("DOH") and the Food and Drug Administration ("FDA").

Our client was recently inspected by the FDA and DOH. As a result of that inspection, and effective September 14, 2016, our client has voluntarily ceased its sterile compounding operations until such time as necessary corrective actions can be implemented to address the FDA and DOH's alleged concerns. Wells has agreed with the FDA and the DOH to submit evidence of each corrective action taken as well as any subsequent testing confirming/validating the corrective measures implemented to successfully resolve all stated concerns. Once all of these corrective measures have been successfully resolved and documented to the FDA and DOH, Wells is permitted to resume sterile compounding. Enclosed is a copy of the Voluntary Agreement to Restrict Practice of Sterile Compounding accepted by the DOH.

Wells takes its legal and ethical responsibilities very seriously. Our client understands that the FDA and various states have been responding to and increasing the legal oversight and safety of compounded medications. The oversight of compounding facilities—as well as the various compounding facilities' response to the updated laws and potential regulations—has presented challenges during what has been a multiyear transition period. Wells has responded to these challenges by investing in the upgrade of its facility to meet the upcoming USP 800 regulation and firmly believes it operates a high quality facility with the resolution of the aforementioned appropriate procedures.

When issues have arisen, such as from the FDA, Wells has worked with the FDA to clarify and respond to those concerns. In fact, the FDA acknowledged at this recent inspection the previous 483 observations had been corrected by Wells. Even when the FDA has taken positions that might push the limits of existing laws—such as in 2013 when the FDA's authority was questioned by the U.S. GAO—Wells' goal has been to focus on safe practices and future upgrades. (See "Drug Compounding: Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight," U.S. Government Accountability Office, 7/31/13,

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2016-23508**

WELLS PHARMACY NETWORK, LLC,

Respondent.

_____/

VOLUNTARY AGREEMENT TO RESTRICT PRACTICE OF STERILE COMPOUNDING

Ben David, CFO, as owner and/or institutional representative of **Wells Pharmacy Network, LLC,** permit number **PH27462,** hereby agrees to restrict practice of **Wells Pharmacy Network, LLC,** as a Special Sterile Compounding Pharmacy in the State of Florida and states as follows:

1. Respondent understands that this Agreement constitutes a legal obligation within the meaning of Section 456.072(1)(k), Florida Statutes. Respondent further understands that any violation of the terms of this Agreement by Respondent shall constitute sufficient probable cause for the issuance by Petitioner of an Emergency Suspension of Respondent's license to practice pharmacy in the State of Florida.

and address the FDA's alleged concerns and demonstrate compliance with Rule 64B16-27.797, Florida Administrative Code. Upon successful completion of the stated corrective actions, Respondent shall give the Department of Health 72-hour advance notice of its intent to resume sterile compounding.

5. Respondent understands that this Agreement in no way precludes additional proceedings by Petitioner for any acts or omissions by Respondent not referenced in this matter.

6. Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action.

7. Respondent, being fully advised of the consequences of so doing and having the opportunity to consult with counsel of his/her choosing, hereby agrees that upon his/her execution of this Agreement, it shall immediately be made accessible to the public. In addition, Respondent's licensure status and profile with the Board of Pharmacy will reflect the restriction stated herein.

wells pharmacy network
superior science & service

1210 SW 33rd Avenue | Ocala, FL 34474 | 800.622.4510

November 4, 2016

Edwin A. Bayo, Esq.
Grossman, Furlow & Bayo, LLC
2022-2 Raymond Diehl Road
Tallahassee, FL 32308

Dear Mr. Bayo,

Per Florida Department of Health's request, Wells Pharmacy Network is notifying you of our completed corrective actions as stated from our September 20, 2016 response letter and the Company's intent to resume sterile compounding at 9 am on November 09, 2016 for the purpose of dispensing and shipping.

Observation 1:

The cleanrooms are negative pressure and are used for both hazardous and non-hazardous drugs. Compounding records document that hazardous drugs (HD) and chemotherapy and non HD drugs were compounded in the same room and PEC on the same day. Non-hazardous drugs must be compounded in a positive pressure room and not exposed to contamination with HD.

Response to Observation 1:

The negative pressure cleanrooms were used to compound hazardous drugs and non-hazardous drugs between the dates of 19 July 2016 and 14 September 2016. Between each lot compounded during this timeframe, a chemical deactivating cleaning agent (CIP 100) was used to ensure cross contamination between batches did not occur. However, this chemical clean was not documented as an additional clean in our normal process. The current cleaning documentation practice was driven by tasks created in Simplifi<797> software system. The software was not updated to include chemical cleans during this time frame. Prior to 19 July 2016, all non-hazardous drugs were only compounded within the positive pressure cleanroom.

As a precautionary measure, a voluntary recall has been issued for all products compounded in the negative pressure cleanroom during the timeframe of 19 July 2016 and 14 September 2016 (Attachment 2 – Recall Spreadsheet). No adverse reactions have been reported by customers or physicians regarding the sterile lots listed in the recall.

In addition to the recall, Wells Pharmacy Network has tested several lots of non-hazardous products that were compounded during this timeframe in the negative pressure cleanroom for potency testing to confirm no trace hazardous drug exists within the non-hazardous products (Attachment 3 – Dyna Labs Reports).

The Cleaning of ISO 5 Enclosures procedure (Attachment 4 – Cleaning, Disinfection, Operation and Maintenance of ISO 5 Enclosures) was updated and effective on 16 September 2016 to include the use and documentation of use of the chemical deactivating cleaning agent to clean the compounding hood in-between lots of different products.

Furthermore, each class of product shall be compounded in their respective areas going forward. All non-hazardous medications shall be compounded in the positive pressure cleanroom, chemotherapy medications shall be compounded in the negative pressure chemotherapy cleanroom, and hazardous medications shall be compounded in the negative pressure hazardous compounding cleanroom. Under no circumstance will any of these products be produced in another cleanroom with a different class of products.

The environmental monitoring program now has oversight by the Senior Director of Quality Assurance. The affected cleanroom has since undergone planned renovation activities as well as a complete post construction clean and decontamination with Vaporized Hydrogen Peroxide by a third party company.

Completion of Observation 2

The lots prepared between June 20, 2016 and July 15, 2016 in the positive cleanroom that were pulled from the shelves internally and sent for testing with a third party laboratory have been completed and indicate no suspect sterility or endotoxin results.

Bioquell, a third party decontamination company, was on site October 26, 27 and 28 to fog the cleanrooms with vaporized hydrogen peroxide. The validated method provided by Bioquell has been shown to provide a $\log^6$ reduction in microorganisms within the cleanroom space. Biological indicators shall be used to confirm the efficacy of the fogging process and will be available for confirmation from the required incubation period along with a summary report expected on November 06, 2016.

Breach cleaning of the areas began October 24, 2016 consisting of full cleaning ceiling, walls, equipment, surfaces, and floors and was completed in all rooms on October 31, 2016.

Validation of the Lighthouse continuous monitoring system for pressure, temperature, humidity, viable and non-viable air samples has begun with an expected completion date of November 04. The continuous monitoring system shall begin routine monitoring on November 07. The continuous monitoring system will capture compounding conditions inside the cleanroom space as well as inside the biological safety cabinets and laminar flow hoods.

Environmental Monitoring Performance Qualification began October 28 and will continue through November 17 to validate the fitness of the cleanrooms. This monitoring shall include viable air samples, non-viable air samples, and contact plate samples during static and dynamic conditions.

Routine environmental monitoring shall commence following the environmental monitoring performance qualification on November 21. Routine environmental monitoring includes contact plates during dynamic conditions and cleanroom viable air samples and contact plates during static conditions.

Observation 3:

Surface sampling is done after cleaning.

Response to Observation 3:

Routine environmental monitoring was performed during the day after compounding activities prior to the evening clean; however, the surfaces of the tables, carts, and ISO 5 laminar flow hoods were wiped per procedure after the completion of compounding for the day. Environmental monitoring surface sampling was originally designed to evaluate the cleanliness of the room and not designed to determine the conditions during compounding.

On 16 September 2016, the new Environmental Monitoring procedure became effective (Attachment 8 – Environmental Monitoring of the Cleanroom) that evaluates the cleanliness of the room on a routine basis as well as capturing the dynamic conditions of the surfaces and personnel during each compounding lot. Training for all technicians performing the environmental monitoring was completed on 16 September 2016.

be repeated as the glassware is now stored in a classified ISO 8 cleanroom space as indicated in the procedure (Attachment 2 – Sterilized Glassware Hold Study).

Observation 6:

The gloves and masks are not labeled for use with hazardous drugs.

Response to Observation 6:
Wells Pharmacy Network takes seriously the health and wellbeing of the compounding technicians. Upon discovery of the observation above, Wells Pharmacy Network immediately contacted multiple cleanroom suppliers to order the appropriate gloves and masks. After discussing with multiple vendors, there are no masks on the market that are labeled for chemotherapy use. Wells Pharmacy Network chose the most aggressive sterile mask on the market to provide the most protection against hazardous drugs. The glove and mask descriptions are as follows:

Gloves: Medline Nitrile Sterile Exam Gloves
Masks: Sterile pouch style facemask, head loop, gamma irradiated, low linting, latex free

The specification sheets for each are attached (Attachment 18).

Completion of Observation 6
Corrective actions completed in full at time the September 20, 2016 response was submitted.

Observation 7:

Documentation of training in safe handling of hazardous drugs was not provided.

Response to Observation 7:

Although hazardous drug handling training is provided to each pharmacy technician upon hire through on the job training as well as reading of the procedure, documentation of such training has not occurred. As a result, a more robust training program for handling of hazardous drugs was developed and implemented on 23 September 2016 (Attachment 11 – Handling of Cytotoxic or Hazardous Compounds). Formal refresher training was provided for all staff handling the hazardous drugs on 22 September 2016 and 23 September 2016 and documented (Attachment 12 – Training on Handling of Cytotoxic or Hazardous Compounds).

Completion of Observation 7
Corrective actions completed in full at time the September 20, 2016 response was submitted.

Observation 8:

Hands are washed in the unclassified area, then sterile shoe covers are donned over the booties worn in the unclassified space, masks are donned (technician placed the straps over ears and under the bouffant and instructed the inspector in the same method which required touching hair and skin with the cleansed hands). Hands are not rewashed, hand sanitizer is applied prior to gloving.

Response to Observation 8:

The normal process for gowning in the hazardous and positive cleanroom is to don the mask and first pair of sterile booties, wash hands in the sink located in the classified area and enter the ISO 7 ante room for donning

Procedure	Date Technicians and Pharmacists Trained					
	Harmony SanFillipo	Donna Mast	Paul Mast	Daniel Lakatos	Anthony Campbell, RPh	Michael Farfaglia, RPh
Gowning Validation	8/5/16	8/5/16	8/5/16	8/5/16	8/9/16	8/5/16
Cleaning and Disinfection of Classified Areas	8/5/16	8/5/16	8/5/16	8/5/16	8/9/16	8/5/16
Filter Integrity Testing	7/18/16	7/18/16	7/18/16	7/18/16	7/6/16	*
Good Documentation Practices	7/18/16	7/1816	7/18/16	7/18/16	7/18/16	*
Gowning Procedure and Requirements for entry into Classified Areas	7/18/16	7/18/16	7/18/16	7/18/16	7/5/16	*
Fingertip Monitoring	8/30/16	3/21/16	8/30/16	4/19/16	1/29/16	8/23/16

* These trainings were performed on 8/5/16; however, the training form has inadvertently been misplaced. A retraining of the procedures was performed and documented on 9/26/16.

Didactic training for Michael Farfaglia was completed in June 2016. Didactic training for all sterile technicians was completed 27 September 2016. Didactic training for Anthony Campbell will be completed by 07 October 2016.

Completion of Observation 9

Didactic training is current with all sterile technicians and sterile pharmacists as of October 03, 2016. A procedure is currently in the revision process to include didactic training requirements and ensure all didactic training is performed annually (Attachment 3: Sterile Compounding Personnel Qualification – Draft with an expected implementation date of November 04, 2016).

Observation 10:

Final visual inspection check of the product is conducted by technicians instead of the pharmacist 64B16-27.1001 FAC.

Response to Observation 10:

Visual inspection is currently performed informally during the labeling of vials by the sterile compounding technicians. The formal visual inspection is performed by the Quality Control personnel in a lightbox with a black and white background. 100% of the vials are visually inspected. Once completed, the pharmacist signing off on the batch views vials at random to confirm the visual inspection. 100% visual inspection is performed by a pharmacist once the vials are dispensed from inventory and brought to the second pharmacist verification station prior to shipment. At this checkpoint, pharmacists verify the product, label, crimp/seal, as well as visually inspecting the vials against a fluorescent light background for particulates or visual defects.

Wells Pharmacy Network has updated the process to include a pharmacist 100% visual inspection of all sterile products immediately after compounding and prior to being labeled. This visual inspection is performed against a black and white background in the lightbox. The procedure was updated with the final version expected to be effective on 07 October 2016 (Attachment 21 – Visual Inspection Program).

Completion of Observation 10

Visual inspection procedure has been finalized and all pharmacists have been trained. The procedure shall be implemented as the sterile compounding resumes within the facility (Attachment 4).

A generic pamphlet was developed to send to patients with each sterile hazardous product. Circulation of this pamphlet began on 30 September 2016.

Completion of Observation 12

Wells Pharmacy Network ceased sterile compounding activities on September 14, 2016. A Generic Pamphlet for Sterile Medication handling, storage, and disposal (Attachment 5) has been created however has not been circulated as sterile compounding has not occurred. When sterile compounding resumes, the pamphlet will be included with all sterile compounded drug shipments.

All renovation activities within the Wells Pharmacy Network facility are finalized as of October 24, 2016. All other corrective actions listed in our response letter dated September 20, 2016 have been completed in its entirety and successfully tested. Wells Pharmacy Network is providing the Florida Department of Health 72 hours notice of its plans to resume sterile compounding with the intent to dispense with this letter. Please do not hesitate to contact me should you have any questions.

Sincerely,

Melissa Stefko Digitally signed by Melissa Stefko Date: 2016.11.03 20:30:12 -04'00'

Melissa Stefko
Senior Director of Quality Assurance

Department of Health

License Number: PH27462

Data As Of 11/5/2016

Profession	Pharmacy
License	PH27462
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2017
License Original Issue Date	02/06/2014
Address of Record	1210 SW 33 AVE OCALA, FL 34474
Controlled Substance Prescriber	No
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.

AGREED BOARD ORDER #L-15-037

RE: IN THE MATTER OF
WELLS PHARMACY NETWORK LLC
(PHARMACY LICENSE #28293)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 28293 issued to Wells Pharmacy Network LLC (Respondent), 1210 Southwest 33rd Avenue, Ocala, Florida 34474.

By letter dated May 5, 2016, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Sections 565.002(a)(3) and (13); and 565.002(c) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2013), as alleged in the Count below.

The conduct described in the Arizona State Board of Pharmacy Consent Agreement is substantially similar to conduct described in:

> Section 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013); and
>
> Sections 291.133(d)(12)(C)(v); 291.133(d)(13); 291.133(d)(14);and 291.133(e) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014).

COUNT

On or about June 9, 2015, the Arizona State Board of Pharmacy entered a Consent Agreement against the Arizona pharmacy permit number Y005709 held by Wells Pharmacy Network. The Order was based on findings of fact regarding inspections by the United States Food and Drug Administration (FDA) conducted at the pharmacy's licensed location in Ocala, Florida, between February 21, 2014, and March 7, 2014. During the inspections, FDA identified violations of law concerning the pharmacy's sterile compounding operation. In addition, a compliance inspection by the Arizona State Board of Pharmacy on October 7 and 8, 2014, identified violations related to maintaining proper records of quality assurance of compounded preparations. The Agreement imposed a one year probation, $9,000 civil penalty and an unannounced random inspection by the Board within one year of the entry of the agreement.

By letter dated May 5, 2016, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Colleen Stacy Shapiro, Board Member of Wells Pharmacy Network, LLC, on behalf of Respondent; and Michael R. Sharp, Legal Counsel for

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 1st day of November, 2016.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Colleen Stacy Shapiro, Board Member, Wells Pharmacy Network, LLC
For and on behalf of Wells Pharmacy Network LLC

Michael R. Sharp, Legal Counsel for Wells Pharmacy Network, LLC
Law Firm of Sharp & Cobos
4705 Spicewood Springs Road, Suite 100
Austin, Texas 78759

APPROVED AS TO FORM:

Kelstin Arnold, General Counsel
Texas State Board of Pharmacy