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: JCB Laboratories, LLC

Physical Address: 7335 W. 33rd St. N.

City: Wichita State: KS Zip Code: 67205

Telephone: (316) 773-0405 Fax: (316) 773-0406

Toll Free Number: (877) 405-8066 (Required per NAC 639.708)

E-mail: licensing@jcblabs.com, tflinkman@jcblabs.com Website: www.jcblabs.com

Supervising Pharmacist: Tanis Flinkman Nevada License #: ~~64028~~ 19859 ✓

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

101347

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

FEI Number (From FDA application): 01-0744677

Please provide the name of the facility as registered with the FDA and the registration number:
JCB Laboratories; 177167470

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

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Tanis Flinkman Nevada License Number: 64028

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

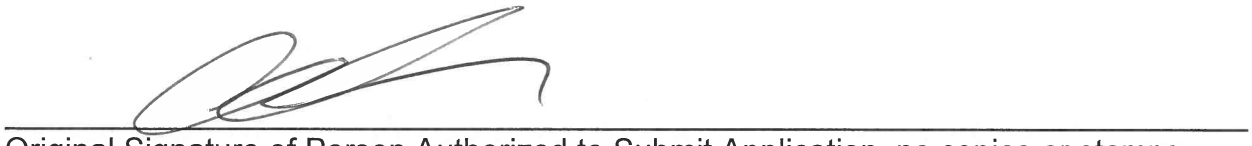
I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized Outsourcing Facility may be grounds for the revocation of this permit.

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

Alexander Govze

Print Name of Authorized Person

6/13/2018

Date

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

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Fagron Holding USA, LLC

Address: 2400 Pilot Knob Road

City: St. Paul State: MN Zip: 55120

Telephone: (651) 681-9517 Fax: (651) 681-9001

Contact Person: Dolly Bergan

For any corporation non publicly traded, disclose the following:

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

a) N/A. JCB Laboratories is an LLC. Please see attached.
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

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

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

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

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

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

GMP Fagron Sterile Services

NON-PUBLICLY TRADED LIMITED LIABILITY COMPANY INFORMATION

OWNER: FAGRON HOLDING USA, LLC
BUSINESS ADDRESS: 2400 PILOT KNOB RD., #200, ST. PAUL, MN 55120
TELEPHONE NUMBER: 651-681-9517
FORMED IN THE STATE OF: DELAWARE
INCORPORATION DATE: MAY 10, 2010
FEIN: 42-1771479
Please note that Fagron Holding USA, LLC is a holding company and that JCB Laboratories LLC has its own officers as indicated to run the business with a FEIN of 01-0744677 and was formed in Kansas on 09/24/2002.

JCB Laboratories

FULL NAME/TITLE: Alexander Govze, Officer
BUSINESS ADDRESS: 2400 Pilot Knob Road, St. Paul, MN 55120
TELEPHONE NUMBER: (612) 810-8388

FULL NAME/TITLE: Jason McGuire, Officer
BUSINESS ADDRESS: 8710 E 34th St N, Wichita, KS 67226
TELEPHONE NUMBER: (316) 773-0405

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

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

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

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

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 Eis (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

VERIFACLTY

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
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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.

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.

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

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.

WELLS PHARMACY

DATED: 10/24/14

BY: CEO
Authorized Representative

BEN DAVID - CEO
Printed Name

DATED: 11/6/2014

JOSEPH BRUNO, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: November 4, 2014

MICHAEL MILLER
Assistant Attorney General

JANET T. MILLS
ATTORNEY GENERAL

TEL: (207) 626-8800
TTY USERS CALL MAINE RELAY 711

STATE OF MAINE
OFFICE OF THE ATTORNEY GENERAL
6 STATE HOUSE STATION
AUGUSTA, MAINE 04333-0006

REGIONAL OFFICES
84 HARLOW ST. 2ND FLOOR
BANGOR, MAINE 04401
TEL: (207) 941-3070
FAX: (207) 941-3075

415 CONGRESS ST., STE. 301
PORTLAND, MAINE 04101
TEL: (207) 822-0260
FAX: (207) 822-0259

14 ACCESS HIGHWAY, STE. 1
CARIBOU, MAINE 04736
TEL: (207) 496-3792
FAX: (207) 496-3291

September 18, 2014

Susan B. Morrison, Esq.
Law Offices of Susan B. Morrison, P.A.
1200 W. Platt St., Suite 100
Tampa, FL 33606

Re: Maine Board of Pharmacy Complaint No. 2013 PHA 9589
Wells Pharmacy Network LLC

Dear Attorney Morrison:

As you know, at its June 5, 2014 meeting, the Maine Board of Pharmacy voted to offer Wells Pharmacy Network LLC ("Wells Pharmacy") a Consent Agreement in order to resolve the above referenced complaint filed against its license, and set the matter for an adjudicatory hearing in the event that Wells Pharmacy does not accept the Consent Agreement. Enclosed please find the Consent Agreement proposed by the Board to resolve this complaint. Pursuant to a request to change the deadline for acceptance, please note that the Consent Agreement must now be accepted by October 3, 2014.

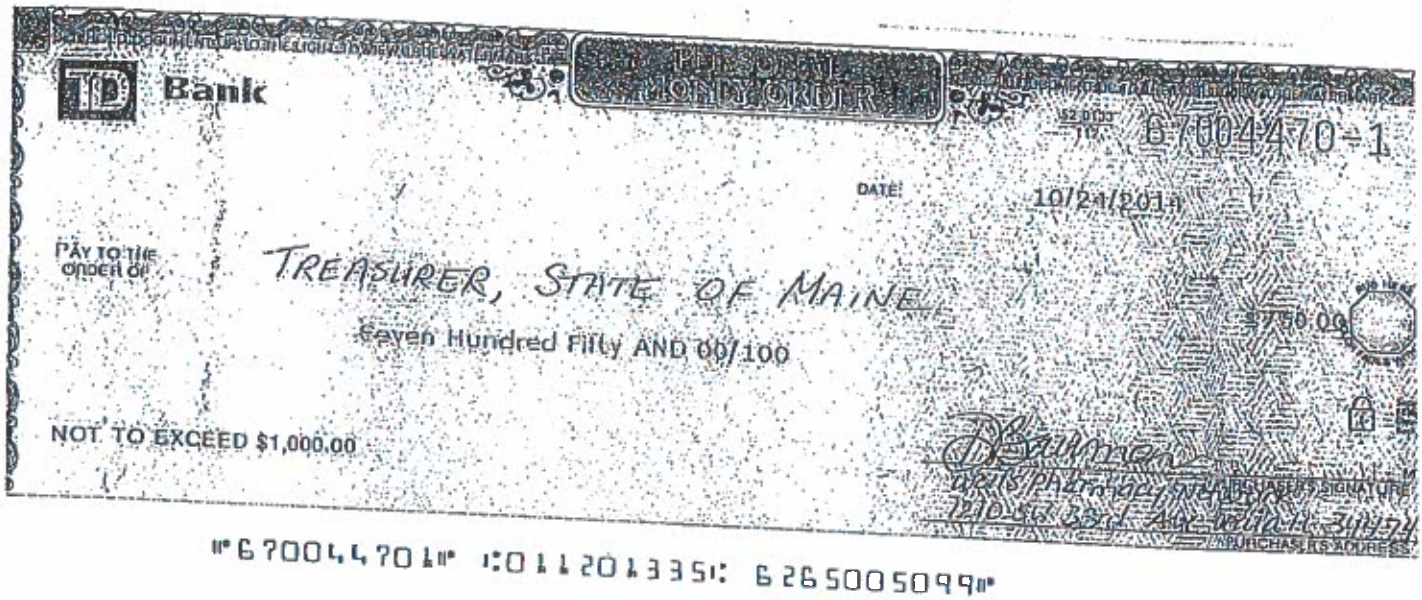
If Wells Pharmacy decides to accept the Consent Agreement, please have an authorized representative sign and date it and return it to Kelly McLaughlin, Senior Consumer Assistance Specialist, Maine Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333. Ms. McLaughlin will see that an authorized Board representative and I sign the document. You will then receive a copy of the fully-executed Consent Agreement. If you have any questions about this matter, please call me at 626-8891.

Sincerely,

MICHAEL MILLER
Assistant Attorney General

Enclosure

cc: Kelly McLaughlin, Senior Consumer Assistant Specialist (w/ enc.)


TD Bank

THE ORIGINAL MONEY ORDER

62-0000
710

6700447041

DATE 10/21/2011

PAY TO THE ORDER OF TREASURER, STATE OF MAINE

$750.00

Seven Hundred Fifty AND 00/100

NOT TO EXCEED $1,000.00

PURCHASER'S SIGNATURE

PURCHASER'S ADDRESS

⑈6700447041⑈ ⑆011201335⑆ 6265005099⑈

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, LLC. ("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.

Wells regrets that it was unable to satisfy the seven (7) day Notice requirement set forth in Maine Board of Pharmacy Rules Chapter 11, Section 3. However, it was unable to do so because of Mr. Pruneau's two week absence. The violation was certainly not intentional. In hind sight, it might have been more prudent to merely change the effective date of the PIC change to October 22, 2013, since Wells' prior PIC continued to serve in that role until Mr. Pruneau's return.

Wells understands the importance of fully complying with all statutes and rules applicable to its pharmacy practice and licensure status. It also recognizes the importance of your Department's role in ensuring public health, safety and welfare. We assure you that despite the late timing of the Change Application, Wells' pharmacy professionals have at all times conducted their pharmacy practices professionally and with the utmost care and consideration for the safety of the patients it serves.

We therefore respectfully request that the Complaint be dismissed or closed, without any further action. Mr. Pruneau advised that he just received a call from you inquiring about Wells' response and advising him that this matter is on the Board of Pharmacy Agenda for Tuesday's Board Meeting. Because Wells' pharmacy and officers are located in Florida, Wells would like to request permission to call-in to the meeting at such time that this matter is called up for discussion in order to further respond to any questions or concerns that the Board might have.

We thank you in advance for your prompt reply to the call-in request, and further request that you provide an appropriate call-in number.

Very truly yours,

Susan B. Morrison

cc: Ben David, President and CEO
Robert Pruneau, Vice President of Pharmacy

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

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www.maine.gov/professionallicensing

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

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

Maine Department of Professional and Occupational Regulation
Office of Licensing and Registration
Board of Pharmacy
Complaints & Investigations
35 State House Station Augusta Me 04333
(207)624-8621

PROFESSIONAL LICENSURE COMPLAINT

PRINT YOUR NAME (COMPLAINANT):	LICENSEE COMPLAINED ABOUT:
Thomas E. Avery Investigator Board of Pharmacy	Wells Pharmacy Network L.L.C..
TODAY'S DATE: October 29, 2013	LICENSEE'S ADDRESS: P1210 Southwest 33rd Ave., Ocala FL. 34474
YOUR SIGNATURE: Thomas E Avery	TYPE OF LICENSE HELD: Mailorder. Pharmacy MO40001342

PLEASE BE ADVISED THAT A COPY OF YOUR COMPLAINT WILL BE SENT TO THE LICENSEE FOR A RESPONSE.
Clearly explain your complaint. It is important to list the facts and details in the order they occurred, including names, dates, places and times. Include copies of any documents which support your complaint. If you require more space, include extra sheets. Return this form with any documentation to the address at the top of this form.

The Maine Board of Pharmacy received a Change of Pharmacist in Charge application on October 23, 2013 for the Wells Pharmacy Network located in Ocala Florida. According to the document Robert Pruneau took over as Pharmacist in Charge on October 3, 2013.

Allegation: Failure to notify Board of Pharmacy within 7 days of change of P.I.C..

Violation: Maine Board of Pharmacy Rules Chapter 11, Section 3

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

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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 # 991143
Lic. #
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

SECTION 1: COMPANY INFORMATION

Name of Mail Order Pharmacy	
Wells Pharmacy Network, LLC	
Mail Order Pharmacy Telephone Number	**Mail Order Pharmacy Fax Number**
(352) 622-2913	(352) 401-5650
Toll-Free Telephone Number	**E-mail Address**
(800) 622-4570	regulatoryaffairs@wellsrx.com
Web Address	**DEA**
www.wellsrx.com	FW3512515
All Trade Names or Business Names of the Mail Order Pharmacy	
Wells Pharmacy Network, LLC	

SECTION 2: PHARMACIST IN CHARGE INFORMATION *(32 MRSA §13702-A (23) "Pharmacist in charge means the pharmacist who is responsible for the licensing of the pharmacy," and the contact person for this office for licensing the mail order pharmacy.)*

Last Name	First Name	Middle
Pruneau	Robert	J
Contact Address		
1210 SW 33rd Ave		
City	**State**	**Zip Code**
Ocala	FL	34474
Telephone Number	**E-mail Address**	
352-622-2913	regulatoryaffairs@wellsrx.com	
License Number	**State Issued**	**License Expiration Date**
PS18878	Florida	9/30/15

EFFECTIVE DATE OF CHANGE

Effective date you, the pharmacist in charge, will take over as PIC
10/3/13

RJP INITIALS OF APPLICANT

Published under appropriation 01402A4380012
35 State House Station, Augusta ME 04333 Revised 08/2012
Website: www.maine.gov/professionallicensing

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OCT 23 2013

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

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SECTION 3: NOTICES

10 Day Notification Requirement

This applicant/licensee must report in writing to the Board the following information no later than 10 days after the change or event, as the case may be:

a. Change of name or address of the licensee;

b. A criminal conviction of the licensee or anyone listed on this application as having an ownership interest in the licensee;

c. A revocation, suspension, or other disciplinary action taken in this or any other jurisdiction against any occupational or professional license held by the applicant/licensee or anyone listed on this application as having an ownership interest in the licensee; or

d. Any material change in the conditions or qualifications set forth in the original application for licensure submitted to the Board.

Notice to Consumers (Board Rule Chapter 11, Section 5)

A mail order prescription pharmacy and mail order contact lens supplier shall include with each prescription filled prominent notice that complaints against the mail order prescription pharmacy may be filed with the Complaint Coordinator, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME 04333.

EL INITIALS OF APPLICANT

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.

- ☒ Each section of the application has been completed.
- ☒ Each page of the application, where noted, has been initialed.
- ☒ Signature present where noted.
- ☒ 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
	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
	10/22/13

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Respondent, neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that Respondent's license is reprimanded.

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

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.

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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.

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Completion of Observation 1
Corrective actions completed in full at time the September 20, 2016 response was submitted.

Observation 2:

A fungal contamination in the cleanroom starting in January was not identified until May.

Response to Observation 2:

Fungal recoveries were observed in the environmental monitoring results in the positive cleanroom beginning 22 February 2016 (no excursions were noted in January) and included corrective actions by the onsite Microbiologist to address accordingly as listed in each respective investigation. However, in June and July 2016 respectively it was noted that sterility results of four (4) products were suspect. Upon further investigation, it was determined that the annex room that is adjacent to the compounding room contained fungal growth that began to show a drift of environmental contamination into the adjacent compounding cleanroom. The root cause of the issue was determined to be caused by a leaking pipe above the cleanroom which has since been resolved.

The laminar flow hood used to test the products for sterility indicated similar fungal recovery as seen in the annex room. The suspect sterility products were sent to a third party testing laboratory and was determined that product was not compromised by the environmental conditions at the time (Attachment 5 – Mold Remediation Plan). No adverse reactions have been reported by customers or physicians regarding the sterile lots listed in the recall.

Although no sterility failures or adverse events have been noted to date at Wells Pharmacy Network, as a precautionary measure, Wells Pharmacy Network ceased all sterile compounding on September 14, 2016 and a patient level voluntary recall was issued for all sterile products compounded between 22 February 2016 and 14 September 2016.

On 02 September 2016, the remaining lots prepared between 20 June 2016 and 15 July 2016 in the positive cleanroom were pulled from the shelves internally and sent for testing with a third party laboratory (Attachment 6 – Sterile product removed from inventory). An aliquot sample from each vial is being tested for sterility and endotoxin. Interim results indicate no suspect sterility or endotoxin results. The results for all vials sent for testing will be available starting 27 September 2016 for some lots and with all lots off test by 07 October 2016.

Additionally, a robust cleaning program was implemented on 02 August 2016 to include new cleaning agents (Attachment 7 – Cleaning and Disinfection of Classified Areas (the cleaning program has since been revised and enhanced)).

A robust environmental monitoring procedure (Attachment 8 – Environmental Monitoring of the Cleanroom) was implemented on 16 September 2016 to include dynamic monitoring of contact sites and personnel contact plates for each lot compounded to provide visibility into the environmental conditions during each lot compounded. No compounded sterile batch will be released until environmental monitoring data for that lot is completed and reviewed by the Quality Assurance department.

Tracking and trending of the environmental monitoring data was implemented on 16 September 2016 with management review (Attachment 9 – EM Tracking and Trending Spreadsheet). A procedure was developed and implemented on 30 September 2016 (Attachment 10 – Tracking and Trending Program). In the event an actionable environmental monitoring excursion is noted, Wells Pharmacy Network will open an investigation and determine the root cause and discard the batch associated with the EM.

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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.

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Completion of Observation 3
Corrective actions completed in full at time the September 20, 2016 response was submitted. Environmental Monitoring to qualify the fitness of the cleanrooms began on October 28, 2016. Routine Environmental Monitoring per batch is scheduled to begin on November 04, 2016, upon resuming sterile compounding.

Observation 4:

Certification does not document the use of the fume hood and that weighing and mixing in the ISO 7 was conducted during the certification.

Response to Observation 4:

The certification of the fume hoods were not performed during dynamic conditions that mimic normal operating conditions. Wells Pharmacy Network states the certification of the hood is within specification for static conditions. Wells Pharmacy Network understands dynamic conditions will portray realistic conditions as to the functionality of the equipment during compounding. The dynamic certification of the fume hoods was performed on 29 and 30 September 2016. In addition to the certification, a smoke study was performed and video recorded on 29 September 2016 to ensure the designed function of the fume hood was not compromised by the compounding activities taking place in the hood during dynamic conditions.

Completion of Observation 4
Certification of the cleanrooms under static conditions was performed October 17 and continued through October 27 in the cleanroom spaces respectively. The certification included, but is not limited to, video recorded static smoke studies, performance testing of the HEPA filters, particle testing, etc. Dynamic smoke studies are scheduled to be performed on November 02, 2016 per Wells Pharmacy Network Smoke Study procedure (Attachment 1).

Observation 5:

Documentation of validation is not available. Depyrogenated glassware is held in an area that is not certified for up to 30 days.

Response to Observation 5:

The oven validation documentation was filed at Wells Pharmacy Network's offsite warehouse; however, the documentation was unable to be located at the time of the inspection. The 2014 validation documents were reviewed by the inspector during the inspection. The 2015 oven validations were completed in January and June of 2015 (Attachment 23 – Oven Validation 2015). Wells Pharmacy Network agrees that an oven validation is vital to ensuring the sterility of our products and is in the process of developing a robust oven validation program that includes equipment and cycle validation with an expected completion date of November 2016.

In addition, the depyrogenated glassware that was held in a controlled not classified area for up to 30 days was moved into classified glassware environment (ISO 8) on 30 September 2016 to assure sterility. A study is currently being developed to test the glassware to validate an appropriate hold time to ensure sterility assurance and shall be completed by November 2016. As indicated by the sterility testing reports of all sterile products to date, the sterility of Wells Pharmacy Network's product has not been impacted by the depyrogenated glassware.

Completion of Observation 5
Glassware hold time study was completed with negative sterility results (Attachment 6). The glassware stored in the unclassified area was removed, recleaned, rewrapped, and depyrogenated. The glassware hold study shall

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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

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sterile garments. However, due to the design of the chemotherapy cleanroom, the current practice is to wash hands in the controlled not classified area, don facemask, don sterile booties, and sanitize hands prior to adding sterile gloves.

Wells Pharmacy Network agrees with the observation of the Florida Department of Health and has updated their gowning practice in the chemotherapy area as follows (Attachment 13 - Gowning Procedure and Requirements for Entry into Classified Areas for Ocala, Florida – Effective 30 September 2016):

Upon entry into the controlled not classified area, thoroughly wash hands with Antimicrobial Soap for approximately 60 seconds up to the elbow if in short sleeve gown and hands only if in long sleeve gown, focusing under the nails with a sterile nail pick and in skin creases.
Rinse up towards elbow, not down towards fingertips.
Dry hands with a low linting disposable wipe, wiping towards elbow not fingertips if in short sleeve gowning.
Don sterile gloves.
Apply facemask.
Apply sterile booties.
Remove sterile gloves and sanitize hands with Sterillium.
Don sterile gloves.
Continue with donning sterile garments.

Training on the updated gowning procedure was provided to the sterile technicians on 28 September 2016.

Completion of Observation 8
Corrective actions completed in full at time the September 20, 2016 response was submitted.

Observation 9:

Didactic training is delinquent.

Response to Observation 9:

Didactic training for the sterile compounding technicians and pharmacists are performed on an annual basis via Critical Point (an extension of Simplifi797) software system. However, in 2015 didactic training was performed through the freeCE program with a hardcopy filed in each employee's training binder (Attachment 14 – Didactic Training). Formal didactic training has been performed throughout the year (2016) with the expected completion of December 2016. In addition, several training sessions have been performed with the sterile compounding team with the new procedures that have been implemented. The following training procedures were completed at the time of the Florida Department of Health inspection:

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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).

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Observation 11:

BUD for some products lack justification. Potency and stability has not been conducted for HCG, Sermorelin, Cyclosporin, Mitomycin and Testosterone.

Response to Observation 11:

Potency has previously been conducted for various Testosterone injection products (Attachment 15 – Dyna Labs Potency Reports), and a stability study has been initiated. However potency and/or stability studies have not been performed for HCG, Sermorelin, Cyclosporin, and Mitomycin. The BUD for these products were previously determined based on based on the USP<797> and USP<795> recommendations of 180 days for non-aqueous formulations (Attachment 20 – USP <795> BUD).

No compendial method exists for testing of Sermorelin currently. Additionally, the USP assay for HCG is dated with the use of animals for testing. A confirmation of label claim for Sermorelin and HCG via ELISA is currently pending with a third party testing laboratory with an expected completion date of 18 November 2016 (Attachment 22 – Email from RayBiotech). In addition, Wells Pharmacy Network has developed a stability time study to include sterility and endotoxin testing of Sermorelin and HCG at multiple time points to confirm the assigned Beyond Use Date (BUD). Mitomycin and Cyclosporin have been sent to a third party testing laboratory for potency and stability testing to confirm the current assigned BUD and expect results by 14 October 2016.

Completion of Observation 11

Wells Pharmacy Network will compound HCG and Semorelin with an assigned BUD of 180 days per the USP<797> and <795> guidelines for non-aqueous products since there is no readily available compendia method. Wells Pharmacy Network begin a stability program on HCG and Semorelin consisting of endotoxin and sterility testing at multiple time points to confirm the container closure over time.

Wells Pharmacy Network will prepare a batch of Mitomycin to send to a third party laboratory for a time study to confirm assigned BUD.

Cyclosporin time study is currently underway to confirm the BUD. The first time point has past and testing confirmed the product was within specification at 30 days. The next time point to test is at day 60 on November 11, 2016.

Observation 12:

Does not have a formal training program for patients and caregivers in the proper storage, handling, use and disposal of compounded sterile products. There is no procedure for patients to ask questions and report concerns or adverse events.

Response to Observation 12:

As part of Wells Pharmacy Network's commitment to patient and caregiver safety, Wells has developed a formal program to distribute information pamphlet with each shipment on the proper storage, handling, use, and disposal of compounded sterile products (Attachment 16 – Patient and Caregiver Training Procedure). In addition, the information pamphlet includes the following:

Call your doctor for medical advice about side effects.
You may report effects to the FDA at 1-800-FDA-1088.
A Well Pharmacy Network pharmacist would like to answer any questions. For consultation please call 1-800-622-4510.

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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

wells pharmacy network
superior science & service

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Attachments
Attachment 1: Smoke Study Procedure
Attachment 2: Sterilized Glassware Hold Study
Attachment 3: Sterile Compounding Personnel Qualification - Draft
Attachment 4: Visual Inspection
Attachment 5: Generic Pamphlet for Sterile Medication handling, storage, and disposal
Attachment 6: Glassware study results

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,

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available at http://www.gao.gov/products/GAO-13-702 (noting the FDA's unclear authority at that time to oversee compounding pharmacies).)

Providing some context, the FDA's efforts in this area have resulted in a learning curve for a vast number of 503a compounding pharmacies. Since 2012, over 300 different 503a compounding pharmacies have been issued either a Warning Letter or an FDA Form 483. The total number of FDA Form 483s issued since 2012 is more than 350. According to the FDA website: "A Form FDA-483 is issued when investigators observe any significant objectionable conditions." (See "Compounding: Inspections, Recalls, and other Actions" (updated as of 9/27/2016), U.S. Food and Drug Administration website, available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm.

Our reference to these enforcement statistics is not to take the position that objectionable conditions are acceptable. Instead, the reference concisely reveals the challenges almost all compounding pharmacies are experiencing in attaining full compliance with the new laws and standards. Moreover, the practices and safety standards of compounding pharmacies continue to develop.

It is important to note that there have been no adverse events reported to date from the FDA and DOH's alleged concerns.

Please let me know if you have any questions. Requests for additional information or copies of any relevant documents can be directed to me at (850) 385-1314 or at e.bayo@gfblawfirm.com.

Sincerely,

Edwin A. Bayó

cc: Wells Pharmacy Network

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, CEO, 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.

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

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.

EXECUTED this 27th day of September, 2016.

CEO

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# FF173681
Expires 11/4/2018

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK

STATE OF FLORIDA
DEPARTMENT OF HEALTH

CLERK: Linda Leonard
DATE 10·5·16

DEPARTMENT OF HEALTH,
Petitioner,

v.

WELLS PHARMACY NETWORK, LLC,
Respondent.
_____/

VOLUNTARY AGREEMENT TO RESTRICT PRACTICE OF STERILE COMPOUNDING

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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.

EXHIBIT "2"

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

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LICENSING DIVISION
'15 DEC 18 P4:16

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

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.

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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.

THOMAS C. HORNE
Attorney General
(Firm State Bar No. 14000)

MONTGOMERY LEE
Assistant Attorney General
State Bar No. 005658
1275 W. Washington, CIV/LES
Phoenix, Arizona 85007-2997
Tel: (602) 542-7980
Fax: (602) 364-3202

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.

EXHIBIT "3"

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# FF173661
Expires 11/4/2018

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.

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

STATE OF MAINE
BOARD OF PHARMACY

IN RE:

WELLS PHARMACY NETWORK LLC

Complaint No. 2013 PHA 9589

CONSENT AGREEMENT

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.

EXHIBIT "1"

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

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

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

KERRI OKAMURA
Chairperson

DATE 6/15/17

GARRETT A. LAU
Vice Chairperson

MARCELLA CHOCK

MARY JO KEEFE

CAROLYN S. J. MA

RONALD WEINBERG

JULIE YURIE TAKISHIMA-LACASA

PVL 05/26/16

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

DATED: Honolulu, Hawaii, MAY 16 2017.

_____
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

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous pharmacy permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., C.7., and C.8. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

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.

4. Respondent provided a copy of a Consent Agreement issued to Respondent by the Maine Board of Pharmacy in Complaint No. 2013 PHA 9589 (hereinafter "the Maine Agreement") (Exhibit "1"). The Maine Agreement was based on allegations Respondent failed to timely notify of changes to the required pharmacist in charge, issued a warning, and imposed a civil penalty of $750.00.

5. Respondent also provided a copy of a Voluntary Agreement to Restrict Practice of Sterile Compounding issued to Respondent by the Florida Department of Health filed on October 5, 2016 (hereinafter "the Florida Agreement") (Exhibit "2"). The Florida Agreement alleged 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 in Ocala, Florida. Thereafter, the FDA issued a report detailing potential violations. A subsequent investigation was conducted by the Florida Department of Health. Following that investigation, Respondent voluntarily agreed to restrict sterile compounding while it addressed Florida's concerns. The restriction was lifted by the Florida Department of Health on November 5, 2016.

6. Respondent also provided a copy of a Consent Agreement for Probation, Civil Penalty, Costs and Inspection issued to Respondent by the Arizona Board of Pharmacy in Board Case No. 14-0019-PHR (hereinafter "the Arizona Agreement") (Exhibit "3"). The Arizona Agreement was based on discrepancies observed during inspections by representatives of the United States Food and Drug Administration during inspections in Florida and imposed civil penalties and costs totaling $11,345.37.

7. RICO alleges that disciplinary action was taken against Respondent by the states of Maine, Florida, and Arizona.

8. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state or federal agency).

9. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

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 WELLS PHARMACY NETWORK, LLC, Respondent.	PHA 2016-30-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY 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.

pyrogens of batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients. The circumstances are as follows:

14. Between May 2015 and March 2016, Respondent shipped about 2,890 batch-produced non-sterile to sterile compounded injectable drug products into California without documentation of end product sterility or pyrogen testing.[2]

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 1325, issued to Wells Pharmacy Network LLC;

2. Revoking or suspending Non-Resident Pharmacy Permit Number NSC 99824, issued to Wells Pharmacy Network LLC;

3. Ordering Wells Pharmacy Network LLC to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

4. Taking such other and further action as deemed necessary and proper.

DATED: 10/14/16

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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[2] A pyrogen is any substance or agent that causes fever.

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).

products. 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.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY REFERENCES

5. Section 4301 of the Code states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> ...
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

6. Section 4300.1 of the Code states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

7. Section 4127.7 of the Code states:

> On and after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:
>
> (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
>
> (b) An ISO class 5 cleanroom.
>
> (c) A barrier isolator that provides an ISO class 5 environment for compounding.

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

Exhibit A

Accusation No. 5887

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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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorneys, Steven L. Simas and Daniel Tatick. I understand the stipulation and the effect it will have on the Non-Resident Pharmacy Permit and the Non-Resident Sterile Compounding Permit held by Wells Pharmacy Network LLC. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 05/23/17

STACY SHAPIRO, GENERAL COUNSEL
WELLS PHARMACY NETWORK LLC
Respondent

I have read and fully discussed with Respondent Wells Pharmacy Network LLC the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 5/23/17

STEVEN L. SIMAS
DANIEL TATICK
Attorneys for Respondent

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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8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 5887, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident Pharmacy Permit and its Non-Resident Sterile Compounding Permit.

10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.

11. Respondent agrees that its Non-Resident Pharmacy Permit and its Non-Resident Sterile Compounding Permit are subject to discipline and agrees to be bound by the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

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.

///

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Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
DAVID E. BRICE
Deputy Attorney General
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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 Sterile Compounding Permit No. NSC 99824** Respondent.	Case No. 5887 OAH No. 2017011087 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by David E. Brice, Deputy Attorney General.

2. Wells Pharmacy Network LLC (Respondent) is represented in this proceeding by attorneys Steven L. Simas and Daniel Tatick, whose address is: Simas and Associates, 3835 North Freeway Blvd., Suite 228, Sacramento, CA 95834.

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

When this legislation passes as expected, the very basis of the Board's Accusation will no longer exist. We believe this, along with WPN's responsiveness and corrections, was a major factor in the Board relenting on more serious discipline.

Clearly, WPN's use of an ISO 7 cleanroom had no adverse impact on the end product, nor did it negatively affect the patients consuming its drugs. The Board sought to punish WPN for actions that will, in all likelihood, no longer be violations of the Board's regulations. Thus, the Board relented with merely a public reproval.

Conclusion

To conclude, WPN has been operating its Tennessee facility without incident. The Board was overzealous in its prosecution and failed to realize the acts with which it sought to punish WPN would no longer be punishable offenses. WPN continues to deliver high quality pharmaceutical products but understands its obligation to report any disciplinary action taken against it, no matter how minimal, to other Boards of Pharmacy across the country. WPN respectfully requests this letter serve as satisfaction of its reporting requirements.

If you have additional questions and/or concerns, please direct them to WPN directly. Thank you.

Sincerely,

Daniel J. Tatick
Simas & Associates, Ltd.

DJT:ms

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

hearing. The parties exchanged discovery and the matter was set to be heard at the Office of Administrative Hearing by an Administrative Law Judge over four (4) days, June 13-16, 2017.

Settlement and Public Reproval

On or about May 23, 2017, WPN entered into a stipulated settlement with the Board agreeing to the issuance of a Letter of Public Reproval. As the result of a number of factors impacting its case, the Board settled for the lowest possible form of discipline, a public reproval.

Although technically discipline, a reproval does not, in any way, restrict or impact WPN's ability to continue to manufacture its product and ship those products to California. WPN's license is not on probation; nor does it have to provide the board with quarterly reports, have a monitor, or otherwise limit its operations. Because the Board's ultimate obligation is to ensure public safety and a reproval has minimal impact on a licensee, the Board does not issue reprovals freely. By doing so, the Board has agreed WPN poses no risk to the public's safety and should be permitted to continue its operation without the checks and balances seen in a probationary license.

In the face of legislative changes impacting the very code section the Board was seeking to enforce and the swift remediation and response of WPN, the Board was willing to relent on its pursuit of serious license discipline.

Due to the significant costs and uncertainty involved with taking the case to hearing, WPN agreed to the reproval due to its minimal impact and because it provided a smooth transition into obtaining a 503b Outsourcing Facility license.

WPN's Immediate Response and Remediation

Immediately after receiving the inspector's report and seven (7) months before the Accusation was even issued, WPN shut down all its manufacturing operations to California patients. WPN instituted and changed every itemized finding of the inspector including, but not limited to, constructing an ISO 5 cleanroom, updating and/or creating its standard operating procedures and revamping its on-line training database. WPN further submitted reports from its third-party vendor(s) responsible for conducting the sterility testing,

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

SIMAS & ASSOCIATES
LTD
GOVERNMENT AND ADMINISTRATIVE LAW

TELEPHONE
916.789.9800

FACSIMILE
916.789.9801

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

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

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

- Rx [redacted]-invoice indicates that the product was shipped to an address other than the patient's residence or prescriber office/home.

- Rx [redacted]-Invoice indicates that the product was shipped to an address other than the patient's residence or prescriber office/home. Sterility testing was conducted using 4 X 3mL vials from a batch of 250 X 10mL vials. Verifying pharmacist is not documented in the compounding record.

Rx [redacted] (office use)-compounding record indicates a kit lot number of 02282014@9 with BUD 8-31-2014. The kit includes Chorionic Gonadotropin, Lyophylized 2,000 Unit vial Lot 02192014@11 with BUD 8-31-2014. The compounding record for lot 02192014@11 includes the following components:
Sodium Phosphate, Monobasic, USP Anhydrous Lot C152858, expiration date 5-1-2014
Sodium Phosphate Dried Dibasic Powder Lot WWC150510, expiration date 5-30-2014

- As indicated, these two components have expiration dates that occur prior to the BUD stated for the compounded item as well as the kit. Sterility testing results do not include the number of containers/ total volume tested.

- Rx [redacted]-Sterility testing results do not include the number of containers/ total volume tested.

Rx [redacted] (office use)- compounding record indicates a kit lot number of 12092013@68 with BUD 6-30-2014. The kit includes Chorionic Gonadotropin, Lyophylized 11,000 Unit vial Lot 12042013@63 with BUD 6-30-2014. The compounding record for lot 12042013@63 includes the following components:
Sodium Phosphate, Monobasic, USP Anhydrous Lot C152858, expiration date 5-1-2014
Sodium Phosphate Dried Dibasic Powder Lot C152701, expiration date 5-1-2014

- As indicated, these two components have expiration dates that occur prior to the BUD stated for the compounded item as well as the kit. Sterility testing results do not include the number of containers/ total volume tested.

A copy of a letter dated October 14, 2014 was received announcing that WPN will no longer be providing sterile compounded products for office use.

Potential concerns/Violations:

Breach of sterile garbing SOP by technician in ante room.
SOPs may not be indicative of current practices
Lack of pharmacist verification during each step of compound preparation.
Provision of patient written information not consistent.

Multiple inconsistencies in documentation practices of LFW and FW including:
- BUD
- Sterile filtration
- Sterility sampling
- Quality Assurance verification

Sterility sampling not compliant with USP<71> requirements for number of containers/total volume tested.
Position of Quality Manager currently filled by a technician when pharmacist required by SOP.
Beyond Use Date of compounds in excess of component Beyond Use Date/Expiration Date.

- 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

- 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.

Following a review of the SOP index, several SOPs were requested.

- The majority of SOPs have not been reviewed within the past two years. Of note:
- SOP 5.040 Patient Counseling of Compounded Preparations-section 9.4 states that patient instructions and information shall be distributed with the preparation if available. This is not in compliance with Arizona requirements.
- SOP 8.010 Sterilization and Depyrogenation-section 9.2.8 requires bubble integrity testing when filtration is performed on high risk compounds. This was not documented for the above mentioned Hyaluronidase compound.
- SOP 9.040 Formula Worksheet-section 5.1 indentifies the Quality Assurance Manager as a qualified pharmacist. The current Quality Manager is Travis Wood, CPhT: Section 9.7.6 requires a pharmacist to prepare the first formulation of a complex preparation which is then verified and approved by the Quality Manager which is not currently a pharmacist.

Ten random prescriptions/orders from the Arizona report were selected. Filling and compounding documentation was requested. Of note:

- Rx [redacted]-the compounding records contains no documentation of quality assurance verification of the capsule preparation.
- Rx [redacted] (office use)-preparation is autoclaved in bulk, and then placed in final container. Item was tested for sterility and endotoxins, but procedure for how and when to obtain samples for testing is not documented. It appears that 4 x 10mL syringes were obtained from a 3000mL bulk.
- Rx [redacted] (office use)-compounding record indicates that 5 syringes were tested for sterility and endotoxins from a batch size of 790 syringes.
- Rx [redacted] (office use)-compounding record indicates that 5 syringes were tested for sterility and endotoxins from a batch size of 780 syringes.
- Rx [redacted] (office use)-compounding record indicates that 2 vials were tested for sterility and endotoxins from a batch size of 710 vials.
- Rx [redacted]-compounding record indicates that 2 vials were tested for sterility and endotoxins from a batch size of 480 vials.
- Rx [redacted]-compounding record indicates that 4 vials were tested for sterility and endotoxins from a batch size of 600 vials.
- Rx [redacted]-documentation of filter lot number/expiration date and bubble point testing not indicated in the compounding record. Sampling plan for sterility/endotoxin testing not indicated.
- Rx [redacted]-the compounding records contains no documentation of quality assurance verification of the tablet preparation.

- 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 Test – (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.

introduced. He is a pharmacist in the compounding area and is responsible for sterility testing utilizing the ScanRDI instrumentation.

- While observing activity in the ante room, a technician was viewed exiting the ante room, in full garb, to obtain items from a cart. The technician then crossed back over the line of demarcation within the ante room without re-garbing. When this observation was shared with Mr. Wood and Dr. Campbell, they indicated that this not in compliance with WPN SOPs. A few moments later, the same technician was observed working in the ante room without gloves or a mask in an area where those items were required.

Components are purchased primarily from PCCA, Medisca, Letco and Attix. One outdated item was found. The item, Flumethasone Pivolate, was labeled as manufactured by Farmabios from Italy. A Certificate of Analysis was requested but not available. It was stated that this item was obtained during the purchase of the pharmacy from Franck's Pharmacy. A computer search found that the item had not been used in any compounded items since March 2012. The item was removed from active stock and placed in quarantine. One individual is responsible for performing outdate checks and items are pulled from inventory with less than 30 days dating. Compounded items in anticipation of prescriptions/orders were properly labeled. At the rear of the building is a warehouse area that is not climate-controlled. This area houses non-drug items as well as a labeled quarantine area for expired/damaged items.

During the tour, the workflow of the compounding area was described. The Logged Formula Worksheet is the compounding record. The technicians weigh components on scales (+/- 3%) and the results are recorded in the compounding software. The technician proceeds to complete the compounded product and a pharmacist performs a final check.

- Although a pharmacist is present within the general compounding area, they do not perform/document a verification of components/weights prior to completion of the finished product.

Following final pharmacist check, the orders/prescriptions are packaged for shipment via UPS and Fed Ex. When asked about patient written information, WPN does not provide written information with every order. This was explained as a software issue that is being addressed.

Training records of technicians were reviewed and were found to be in order. Technicians may perform low and medium risk compounding as determined by their level of training. WPN explained that technicians are registered in Florida and are not required to have additional certification. Florida does have a 3:1 technician:pharmacist ratio. Technicians are required to obtain continuing education. WPN sends technicians to a 40 hour compounding course provided by the Florida Pharmacist Association as well as on-the-job training.

Media fill testing results were in order. Fingertip/surface testing results were in order. Clean room and hood certifications were current and were conducted under operational (dynamic) conditions. All cleaning and equipment calibration is documented electronically.

A random sampling of compounding records were reviewed. The following were noted:

Lot 09022014@1 Trimix 17.65mg/0.59mg/5.9mcg Injectable 10mL
Beyond Use Date (BUD) indicated as 50 days after compounding date
Final container indicated as sterile vial but size/lot of the vial was not recorded
Storage indicated as Refrigerate

Lot 09022014@2 Trimix 30mg/2mg/20mcg Injectable 5ml
BUD indicated as 180 days after compounding date
Storage indicated as Refrigerate

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

paragraph), complete compliance on any given day may be unrealistic. Accordingly, we would appreciate some clarification regarding these issues.

Finally, Paragraph 6 on page 8 of the Consent Agreement states that if Wells "violates this Order in any way or fails to fulfill the requirements of this Order, Board, after giving the Respondent notice and the opportunity to be heard, make [sic] take disciplinary action against Respondent's permit. The issue at such a hearing will be limited solely to whether this Order has been violated." Again, we are unclear whether not passing an inspection would constitute a violation of the Consent Agreement or a failure to fulfill its requirements, thereby resulting in further disciplinary action, which may include a suspension or revocation of Wells' permit. For these reasons, we would appreciate clarification regarding these issues.

Again, thank you for making time to speak with me last month and for the opportunity to submit Wells' responses. We appreciate the Board's consideration and we look forward to resolving this matter.

Very truly yours,

MILLIGAN LAWLESS, P.C.

By B.S. Bailey
Bryan S. Bailey

BSB/mc

Enclosures

cc: William Mc Millen, Managing Member
Kris Fishman, Sr. VP, Operations
Travis Weaver, Director of QA/QI

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

Wells recently retained a consultant (Lou Diorio, RPh, LDT Health Solutions Inc.), with experience in both compounding and manufacturing to achieve a higher standard of quality. Based on the consultant's recommendations, Wells has changed sterile gloves to another model with better resistance to alcohol permeation, and Wells is experimenting with different labeling and documentation processes to minimize mislabeling.

Wells regrets its prior documentation discrepancies. However, we hope the Board will recognize the strides Wells has made to correct the issues causing the deficiencies and to minimize the risk of future discrepancies.

V. **"Sterility sampling not compliant with USP <71> requirements for number of containers/total volume tested."**

The Compliance Officers noted in their report that most "sterility testing is performed inhouse utilizing ScanRDI technology" and that "[t]esting and control protocols were provided as well as an article comparing ScanRDI reliability to USP <71>."

Wells mistakenly believed that its inhouse sterility testing with ScanRDI technology complied with USP <71>. Based on the Compliance Officers' comments, Wells recognized its error and, as a result of the inspection, it updated its sample sizes in compliance with USP <71>. Enclosed as Exhibit G are tables identifying the sample sizes Wells has been following since the inspection. Again, Wells regrets and apologizes for this error.

VI. **"Beyond Use Date of compounds in excess of component Beyond Use Date/Expiration Date."**

The Compliance Officers conducted a random sampling of Wells' compounding records regarding the Beyond Use Date (BUD) for several lots of Trimix injectable and found the BUD was later than certain components' BUD/expiration date.

The Board's cGCP acknowledge that, depending on the pharmacist's professional judgment, a compounded product's BUD may be later than its components' BUD/expiration dates. Specifically, A.A.C. R-4-23-410(B)(3)(d) states:

> "A beyond-use-date [is] based on the pharmacist's professional judgment, but not more than the maximum guidelines recommended in the Pharmacy Compounding Practices chapter of the official compendium unless there is published or unpublished stability test data that shows a longer period is appropriate."

The Board's cGCP are consistent with USP <797> which states that "BUDs for compounded preparations are usually assigned on the basis of professional experience."

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.

was preparing for and following the NABP's recommendations, in preparation for the NABP inspection. Unfortunately, in an effort to comply with the regulations and the NAPB recommendations, Wells' current procedures got ahead of its SOPs, such that certain of Wells' current procedures differed from its written SOPs. As Wells explained to the Compliance Officers, at the time of the inspection, Wells was reviewing and, as appropriate, updating its SOPs to both ensure compliance and to ensure its SOPs were consistent with its current procedures.

Since the Board's inspection, Wells has updated a substantial number of SOPs, including each SOP noted by the Compliance Officers. Enclosed as Exhibit D is a copy of a portion of Wells' "SOP Change Request Number Log", which identifies a number of SOPs that have been updated following the inspection. Enclosed as Exhibit E are SOPs 5.040 and 9.040. You will note that SOP 5.040 now complies with A.A.C. R-4-23-402(I) and R-4-23-410(I)(5) regarding patient information, and SOP 9.040 no longer requires the Quality Manager to be a pharmacist.

III. "Lack of pharmacist verification during each step of compound preparation."

The Compliance Officers observed that the pharmacist in the general compounding area was not performing or documenting verification of the components or weights prior to the completion of the finished product. Rather, as the Compliance Officers also observed, the "technicians weigh components on scales (+/- 3%) and the results are recorded in the compounding software. The technician proceeds to complete the compounded product and a pharmacist performs a final check." We are confused by the Compliance Officers' finding and we respectfully request clarification.

Specifically, A.A.C. R-4-23-410(I)(2) states:

> "2. Components for pharmaceutical product compounding are accurately weighed, measured, or subdivided. To ensure that each weight, measure, or subdivision is correct as stated in the compounding procedures, a pharmacist:
>
> a. Checks and rechecks, or assumes responsibility for checking and re-checking, the operations at each stage of the compounding process; and
>
> b. Documents by hand-written initials or signature the completion and accuracy of the compounding process."

This is consistent with A.A.C. R-4-23-410(C)(1), which also states, among other things, that a pharmacist may assume responsibility for these items and document his initial or signature in the compounding record. In other words, neither regulation requires a pharmacist to perform or

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

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January 26, 2015

VIA U.S. MAIL AND
EMAIL: hwand@azpharmacy.gov

Hal Wand, RPh MBA
Executive Director
Arizona State Board of Pharmacy
1616 West Adams, Suite 120
Phoenix, Arizona 85005

Re: Wells Pharmacy Network – Pharmacy Permit No. Y005709
Board Case No. 14-0019-PHR

Dear Director Wand:

Thank you again for the opportunity to submit this response to the "potential concerns/violations" identified by the Board's Compliance Officers as a result of the October 7 and 8, 2014 inspection and the additional time to respond to the Board's proposed Consent Agreements. Before responding to these items, I would like to clear up a potential misunderstanding and update the Board regarding Wells Pharmacy Network's ("Wells") recent inspection by the National Association of Boards of Pharmacy (NABP).

Wells has the utmost respect for the Board and its Compliance Officers and we are concerned the Board may have misunderstood Wells' August 1, 2014 response to the Board's July 11, 2014 letter and proposed Consent Agreement. In Wells' letter it declined the Board's offer to enter into the Consent Agreement and Wells requested a formal hearing, although Wells preferred not to submit to a formal hearing. Wells' request was based on its concerns with certain language in the Consent Agreement and its understanding that a formal hearing was the only means available to resolve its concerns.

Wells meant no disrespect to the Board and, again, it had no desire to escalate the matter. In fact, as mentioned in the Compliance Officers' report, at the time of the inspection, Wells was in the process of obtaining an inspection by the NABP, as required by the proposed Consent Agreement.[1]

The NABP inspection took place on December 9, 2014. The NABP's findings were overwhelmingly positive, with the NABP finding Wells' pharmacy "Substantially Compliant" with all but a few items, in which case the NABP found Wells' "Somewhat Compliant" (there

[1] Prior to renewing Wells' Texas pharmacy license, the Texas State Board of Pharmacy required Wells to be inspected by the NABP. Based on the NABP's findings, the Texas Board has since renewed Wells' license.

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

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

Doc #4200554

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

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

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 [redacted], Rx [redacted] Rx [redacted], Rx [redacted], Rx [redacted] and Rx [redacted] 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).

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

ACCEPTED AND AGREED BY RESPONDENT

Wells Pharmacy Network Dated: 3-31-15

by Ben Davis 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 Davis, on behalf of Wells Pharmacy Network.

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

Bret J Phillips
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

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.

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.

THOMAS C. HORNE
Attorney General
(Firm State Bar No. 14000)

MONTGOMERY LEE
Assistant Attorney General
State Bar No. 005658
1275 W. Washington, CIV/LES
Phoenix, Arizona 85007-2997
Tel: (602) 542-7980
Fax: (602) 364-3202

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.

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

that Wells has documented training deficiencies and cleaning deficiencies, and it further allowed technicians to verify products for the final visual check. The Board does note that Wells produced satisfactory standard operating procedures that Mr. Fishman stated employees will now be following. However, given Wells' failure to have sufficient procedures in place for so long and its failure to adopt the 797s, the Board is not confident yet that Wells will adequately comply with these standard operating procedures. The Board also has concerns that Wells just learned at the hearing of New Hampshire's restriction on distributing directly to veterinary practices.

For the reasons stated above, the Board finds that the five mitigating factors in Ph 905.01(c) have not all been met. Based on Wells' history of having insufficient procedures in place, the Board does not yet have confidence that the action is unlikely to occur again. The Board is also concerned that Wells was distributing directly to veterinary practices, in violation of RSA 318:14-a, III and Ph 404.02. Wells' application for renewal is therefore denied.

Lyophilization

The Board next considers whether, by engaging in lyophilization, Wells was engaged in the practice of manufacturing, thus necessitating a 503B permit. Mr. Fishman stated that Wells lyophilizes in order to keep the correct drug potency. He further stated Wells' average batch size when lyophilizing is 250–500 vials. Ph 404.04(b) specifically states that "[w]hen a compounder prepares more than 50 dosage units for non-patient specific preparations, the compounder shall be registered as a drug manufacturer or 503B with the FDA." Therefore, if Wells wishes to continue lyophilizing, when it re-applies it must apply for and obtain as a 503B permit.

Conclusion

For the reasons stated above, the renewal application of Wells Pharmacy, Ocala Florida is DENIED.

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

Ph 404.04(b) and (c) Regulatory Requirements for Sterile Compounding

(b) When a compounder prepares more than 50 dosage units for non-patient specific preparations the compounder shall be registered as a drug manufacturer or 503B with the FDA.

(c) Compounders supplying limited quantities, less than 50 dosage units, to providers for administration use shall have an MOU with the provider for each compounded product they supply to the provider. When a compounder provides a practitioner a non-patient specific preparation, the compounder shall provide the practitioner a copy of the test result for each lot provided to the practitioner.

Ph 404.02(u) Definitions

(u) "Limited quantities" means a batch with 50 or less dosage units provided to a hospital or practitioner to administer to their own patient.

Findings of Facts and Rulings of Law

In arriving at the decision below, the Board considered the original application packet from Wells, the documents Wells provided in anticipation of the hearing, and the testimony of Mr. Fishman.

Recent Disciplinary Action

The Board first considered, in light of the Board denying Wells' application due in part to the recent disciplinary actions of other states under Ph 905.01(a), whether all five mitigating factors if Ph 905.01(c) had been met.

The Board first finds that under Ph 905.01(c)(1), no harm resulted from the Wells' actions. Mr. Fishman testified that Wells took action to recall any affected drugs and notify the approximately 25,000 patients that were affected. Mr. Fishman testified that there were zero major adverse effects reported. When asked to clarify whether there were any adverse effects reported, Mr. Fishman stated that there were no adverse effects reported at all. On the basis of

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.

place for so long. Mr. Fishman explained that the business changed hands in 2011, and he was not hired until 2014. Mr. Fishman stated that once he started at the company, he began establishing standard operating procedures, hitting the 797 standards or higher. Mr. Fishman explained that Wells had been working to improve its policies.

Commissioner Stout then asked about a citation in the NABP report concerning Wells shipping products for office use. Mr. Fishman explained that that citation was for veterinary products, and he stated that there was no regulation with this restriction for veterinary products. The Board clarified that here in New Hampshire, there is such a regulation, and stated that Wells is thus out of compliance with various Board statutes and rules.

Commissioner Rochefort asked Mr. Fishman about how Wells' pharmacists are trained on lyophilization, as it is not traditionally taught in schools. Mr. Fishman explained that Wells' head pharmacist had been Wells' pharmacist for 15 years, and he learned to lyophilize on the job. Mr. Fishman stated that after the lyophilized products are made, they are tested and verified. Commissioner Rochefort asked if this pharmacist had trained any others; Mr. Fishman answered that in the last three years the pharmacist has only trained two others.

Relevant Law

RSA 318:1

III-a. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device as a result of a practitioner's prescription drug order or initiative based on the pharmacist-patient-prescriber relationship in the course of professional practice or, for the purpose of, or as an incident, to research, teaching, or chemical analysis, but not selling or dispensing. "Compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. "Compounding" shall not include the reconstitution of powdered formulations before dispensing or the addition of flavoring.

318:14-a Compounding.

I. Products that are not commercially available may be compounded for hospital or office use

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

Mr. Fishman explained why the other states had disciplined Wells. According to Mr. Fishman, in February 2016 Wells staff tested one of Wells' compounding rooms for contamination and the room tested positive for airborne mold. Wells sent the sample to a lab and determined it was pennicilium. Wells disinfected and cleaned the facility, and a few weeks later there was no sign of the mold. Then, in late March 2016, the compounding room again tested positive for airborne mold. When Wells sent this sample for testing, they learned that there was both pennicilium and a different type of fungal growth present. Wells staff again disinfected and cleaned the facility. At some point in the future, Wells staff again determined there was an airborne mold in the compounding room, and Wells then shut that specific compounding room down.

Mr. Fishman explained that the company had already scheduled to demo the room to get it fully up to 797 standards and convert it to an 800 room. After the demo was started, Wells employees discovered the source of the mold — a small leak around a pipe that ran from the ceiling to about twenty feet above the ceiling tiles to the room. Mr. Fishman explained that no one had found that leak because no one had thought to pop the ceiling tiles.

Mr. Fishman explained that the room was completely remodeled to higher standards before being put back into use. He further explained that Wells worked with the Florida Board of Pharmacy and the FDA to recall their products, notifying the approximately 25,000 patients that were affected. He stated that throughout the recall process, there were zero adverse effects reported. Mr. Fishman further explained that Wells took all its products from its store room and sent them out for testing; there were zero concerns with sterility. He explained that Wells now tests the air continuously and tests for viables during batch time, which is every day.

Before the New Hampshire
Board of Pharmacy
Concord, NH 03301

In the Matter of: Docket No: 2017-01

Wells Pharmacy, NR0198

(Show Cause Hearing for renewal of NRMO Pharmacy Application)

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.

Carey McRae, attorney for Wells Pharmacy Network, LLC

DONE this the_____ of 6/13/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

By: Buddy Bunch
Buddy Bunch, R.Ph., President

By:
James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

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: _____

ITS: _____

_____
Carey McRae, attorney for Wells Pharmacy Network, LLC

WELLS PHARMACY NETWORK, LLC
PERMIT NO: 113982

BY: _____

ITS: _____

registration or similar authority issued by the Board or which seeks to conduct or engage in any activities regulated by the Board nor o in the future.

4. The provisions of Paragraphs 2 and 3 shall not apply to the permit of Wells Specialty Pharmacy, Inc., Permit No. 112752 upon the express condition that said pharmacy does not and shall not in the future engage in any compounding of any drug products or medications.

5. Wells agrees to pay costs to the Board in the amount of Ten Thousand and No/100 Dollars ($10,000) within thirty (30) days of the effective date of this Consent Order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

6. Wells acknowledges and understands the Board is required to report this action to the National Practitioner Data Bank, which said reporting shall not include Robert Kilfeather who was mistakenly included in the charges involving Permit No. 113948.

7. Based expressly upon the representations and agreements set forth herein, the Board agrees to dismiss the pending charges against both Permit No. 113948 and Permit No. 113982 with prejudice.

8. Wells expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and

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

Respondent understands or was fully and completely informed of Respondent's right to due process by an attorney of Respondent's choosing; that the Respondent fully understands those rights; and that the Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Scott Greenwell, President
Kentucky Board of Pharmacy

8 June 2017
Date

Sr. VP of operations
Wells Pharmacy Network LLC
Respondent

06/06/2017
Date

Colleen Stacy Shapiro
Respondent's Attorney

06/06/17
Date

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

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within fully executed **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 18th day of May 2017, addressed as follows:

Wells Pharmacy Network, LLC
Attn: Diane Raum
1210 SW 33rd Ave.
Ocala, FL 34474-2853
Email: regulatoryaffairs@wellsrx.com

Victoria E. Lovato, Esq.
Silver & DeBoskey, P.C.
Email: lovatov@s-d.com

Agent of the Board

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.

My commission expires: 11/4/2018

BRET JONATHAN PHILLIPS
NOTARY PUBLIC
STATE OF FLORIDA
Comm# FF173681
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 Geissler~~ Wendy Anderson
~~Acting~~ Program Director

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

11. **Acknowledgments**. The undersigned Authorized Representative of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is 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. **Integration and Severability**. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

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

14. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative.

15. **Effective Date**. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Pharmacy at Respondent Pharmacy's address of record with the Board, or (b) service by electronic means on Respondent Pharmacy at Respondent Pharmacy's electronic address of record with the Board. Respondent Pharmacy hereby consents to service by electronic means if Respondent Pharmacy has an electronic address on file with the Board.

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.

a. Observation of a technician exiting and re-entering the ante room without re-garbing and later observation of the same technician working in the ante room without gloves or a mask.

b. 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.

c. There were discrepancies with compliance with sterility, endotoxin, and sterile filtration testing results records.

d. A review of ten (10) random prescription orders from the Arizona report revealed a failure 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.

e. Discrepancies were noted regarding the records, documentation, compliance, standard operating procedures, testing procedures, sampling procedures, and shipping procedures involving six (6) prescriptions.

7. Respondent Pharmacy admits that its conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and provides ground for disciplinary action against Respondent Pharmacy's Colorado registration as a prescription drug outlet:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct – grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this Article, including commission of an act declared unlawful in section 12-42.5-126;

(II) The lawful rules of the board[.]

(g) Had had his license or her license to practice pharmacy in another state revoked or suspended, or is otherwise disciplined or has committed

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:

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 — Date: 12/28/16

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

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
Date

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

8-21-17
Date

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

Tracking # for payment: EV858918588US

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	STIPULATION
WELLS PHARMACY NETWORK LLC, RESPONDENT.	:	

0005454

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

Respondent Wells Pharmacy Network LLC., and the Division of Legal Services and Compliance, Department of Safety and Professional Services stipulate as follows:

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

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

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

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

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

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division

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

3. On September 27, 2016, Respondent entered into a voluntary agreement (FL Agreement) with the State of Florida, Department of Health (FL Board) to restrict practice of sterile compounding, which states in part as follows:

a. Respondent shall immediately cease compounding sterile products, and cease dispensing or shipping sterile products it has previously compounded;

b. Respondent agreed with the United States Food and Drug Administration (FDA) to cease sterile compounding until necessary corrective actions can be implemented to address the FDA's alleged concerns;

c. Respondent shall, under separate cover, submit to the Florida Board each of the corrective actions taken as well as any subsequent testing confirming the corrective actions to successfully resolve and address the FDA's alleged concerns and demonstrate compliance with the Florida Administrative Code; and

d. Respondent shall give the FL Board 72-hour advance notice of its intent to resume sterile compounding.

4. The FL Agreement of Respondent with the FL Board was based on the allegation that Respondent may have compounded sterile products without being in compliance with the standards of practice for compounding sterile products per Florida Administrative Code.

5. On November 4, 2016, the restrictions on Respondent's Florida license were lifted.

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

CONCLUSIONS OF LAW

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

2. By the conduct described in the Findings of Fact, Respondent engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(17), by having been subject to other disciplinary action by the State of Florida Board of Pharmacy.

3. As a result of the above violations, Respondent is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

1. The attached Stipulation is accepted.

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.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 27th day of October, 2017, I caused to be served a true and correct copy of the foregoing STIPULATION AND CONSENT ORDER by the following method to:

Jed W. Manwaring
Christy A. Kaes
Evans Keane, LLP
1161 West River Street, Suite 110
Boise, ID 83702

☒ U.S. Mail
☐ Hand Delivery
☒ Certified Mail, Return Receipt Requested
☐ Overnight Mail
☐ Facsimile:

Steven L. Olsen
Deputy Attorney General
Civil Litigation Division
P. O. Box 83720
Boise, ID 83720-0010

☐ U.S. Mail
☐ Hand Delivery
☐ Overnight Mail
☐ Facsimile:
☒ Email: steven.olsen@ag.idaho.gov
colleen.funk@ag.idaho.gov

Ellen Mitchell
Investigations Support Coordinator

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

I concur in this stipulation and order and recommend that the Board adopt the same.

DATED this 17 day of October, 2017.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

STEVEN L. OLSEN
Deputy Attorney General

I also concur in this stipulation and order and recommend the Board adopt the same.

DATED this 17th day of October, 2017.

IDAHO BOARD OF PHARMACY

By: Alex J. Adams
Alex J. Adams, PharmD, MPH
Executive Director

DATED this 18th day of October, 2017.

WELLS PHARMACY NETWORK, LLC

By: [illegible]
[illegible]
Its: Secretary
Authorized Representative for Respondent

DATED this 16 day of October, 2017.

EVANS KEANE, LLP

Jed W. Manwaring
Jed W. Manwaring
Attorneys for Respondent

[The remainder of this page is intentionally blank.]

submitted to the Board. .

6. In the event this Stipulation is rejected by the Board, Respondent waives any right it may have to challenge the Board's impartiality to hear the allegations in any subsequent administrative action based on the fact that the Board has considered and rejected this Stipulation.

7. Respondent understands the Board shall have the right to make full disclosure of this Stipulation and Consent Order to any state, agency or individual requesting information subject to any applicable provisions of the Idaho Public Records Act, title 9, chapter 3, Idaho Code.

8. Respondent understands this Stipulation and Consent Order is the resolution of a contested case and is a **public record**.

9. This Stipulation contains the entire agreement between the parties, and Respondent is not relying on any other agreement or representation of any kind, verbal or otherwise.

10. This Stipulation shall be presented to the Board with a recommendation for approval from the Executive Director of the Board and the Deputy Attorney General responsible for prosecution before the Board at the next regularly-scheduled meeting of the Board.

11. Except for Paragraph E.6., which becomes effective when Respondent signs this Stipulation, this Stipulation shall not become effective until it has been approved by a majority of the Board, and a Board member executes the attached Order incorporating this Stipulation.

12. Subsequent to the Board executing this Stipulation and Consent Order below, the Board shall not pursue an administrative complaint or disciplinary action against Respondent for any alleged violations predating the date of the Board's execution.

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

4. Upon receipt of full payment of the agreed-upon fine herein, the Board shall move for dismissal of the Amended Administrative Complaint filed in the pending administrative action. Each party shall bear its own attorneys' fees and costs incurred in the course of prosecuting or defending the administrative action.

5. Failure to comply with any of the terms of this Stipulation and Consent Order may result in additional action being taken against Respondent's mail service pharmacy license.

6. All costs associated with Respondent's compliance with the terms of this Stipulation and Order shall be borne solely by Respondent.

D. COMPLIANCE WITH STIPULATION AND CONSENT ORDER

1. The Board has authority to enforce compliance with the terms and conditions of this Stipulation. By signing this Stipulation, Respondent waives its ability to challenge the Board's lack of authority to enforce compliance on appeal to a district court. If there is reason to believe Respondent has violated any of the terms or conditions of this Stipulation, the Executive Director of the Board shall file an administrative complaint, setting forth the allegations of non-compliance and notifying Respondent, and its attorney, if applicable, that Respondent may request a hearing regarding the allegations of non-compliance. If Respondent does not request a hearing on the administrative complaint, any allegations of non-compliance will be deemed admitted.

2. If Respondent fails to comply with this Stipulation, Respondent's license may be subject to further discipline, up to and including suspension or revocation. Therefore, the Board retains jurisdiction over this proceeding until all matters are finally resolved as set forth in this Stipulation. Any action taken by the Board to enforce compliance with this Stipulation shall be in accordance with this section.

3. Any additional costs and/or attorney fees incurred by the Board in any enforcement action shall be borne solely by Respondent.

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.

laws and rules of the state of Idaho. Respondent denies these allegations and contends that: it requires prescriber-physicians to comply with all state and federal statutes; it cannot interfere with the patient-physician relationship; and the Board should seek to administratively discipline the physicians if they are in violation rather than vicariously seek to punish the Respondent pharmacy which has no control over the physician's license and relationship with patients.

6. The Board has authority and jurisdiction to discipline violations of the laws and rules governing the practice of pharmacy and controlled substances in the state of Idaho as follows:

a. Pursuant to Idaho Code §§ 54-1726(1) and 54-1728(1). the Board may suspend, revoke or restrict the license or registration of any person, and may impose an administrative fine and collect the costs of prosecution, upon the grounds of unprofessional conduct as defined by Board rule, or the grounds of violation of any provision of Title 54; Chapter 17;

b. Pursuant to IDAPA 27.01.01.501, the Board may suspend, revoke or restrict the registration of an individual on one or more of the grounds provided in Idaho Code § 54-1726;

c. Pursuant to IDAPA 27.01.01.500.01, negligence and dishonest dealings constitute unethical conduct;

d. Pursuant to IDAPA 27.01.01.500.04, supplying or diverting drugs, biologicals, and other medicines, substances, or devices legally sold in pharmacies that allows for the circumvention of laws pertaining to the legal sale of these articles constitutes diversion of drug products;

e. Pursuant to Idaho Code § 54-1733(5)(b), to knowingly dispense a legend drug pursuant to an invalid prescription drug order is a violation of this chapter;

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

b. Patient M.H. received ten prescriptions for Schedule III controlled substances from three prescribers located in Florida, only one of whom was licensed to practice medicine in Idaho, none of whom were registered for controlled substances in Idaho. The Board alleges that: Patient M.H. did not have an existing relationship with the prescribers; and had no face-to-face interaction with the prescribers. Patient M.H. did not have any contact with Respondent other than receiving the prescribed medications by mail.

c. Patient B.M. received eight 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 did not have an existing relationship with the prescribers; had no face-to-face interaction with the prescribers; and he had no telephone interaction with the prescribers, only with a representative. Respondent denies these allegations. Patient B.M. did not have any contact with Respondent other than receiving the prescribed medications by mail.

d. Patient R.W. received five prescriptions for Schedule III controlled substances from three prescribers located in Florida and Virginia, none of whom were licensed to practice nor registered for controlled substances in the state of Idaho. The Board alleges that: Patient R.W. did not have an existing relationship with the prescribers and had no face-to-face interaction with the prescribers, but did speak with two of them by telephone. Respondent denies these allegations. Patient R.W. did not have any contact with Respondent other than receiving the prescribed medications by mail.

3. In the course of its investigation of Respondent, the Board also found that at least one of Respondent's prescribers, V.D., is a licensed medical provider in the state of Idaho but does not have a valid Idaho Board of Pharmacy Controlled Substance Registration, nor a federal Drug

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.

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

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

WHEREAS, information has been received by the Idaho Board of Pharmacy ("Board") that constitutes sufficient grounds for administrative action against Wells Pharmacy Network, LLC ("Respondent"); and

WHEREAS, the parties wish to expeditiously settle this matter in lieu of proceeding to an administrative hearing before the Board.

NOW, THEREFORE, it is hereby stipulated and agreed between the Board and Respondent that this matter shall be settled and resolved upon the following terms:

A. JURISDICTION OF THE BOARD

1. The Board may regulate the practice of pharmacy in the state of Idaho in accordance with title 54, chapter 17, Idaho Code. The Board is further empowered by title 37, chapter 27, Idaho Code, to administer the regulating provisions of the Uniform Controlled Substances Act in the state of Idaho.

2. Respondent has been an active licensee of the Board since September 2012 and currently holds Mail Service Pharmacy License No. 19765MS. Respondent's license is subject to the provisions of title 54, chapter 17, Idaho Code, title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 27.01.01, *et seq.*

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

IT IS SO ORDERED.

DATE: November 6, 2017.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

By _____
LINCOLN STRAWHUN
HEARING OFFICER

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

PRELIMINARY ORDER (IDAPA 04.11.01.730):
This is a preliminary order of the hearing officer. It can and will become final without further action of the agency unless any party petitions for reconsideration before the hearing officer issuing it or appeals to the hearing officer's superiors in the agency. Any party may file a motion for reconsideration of this preliminary order with the hearing officer issuing the order within fourteen (14) days of the service date of this order. The hearing officer issuing this order will dispose of the petition for reconsideration within twenty-one (21) days of its receipt, or the petition will be considered denied by operation of law. Idaho Code 67-5243(3).

Within fourteen (14) days after (a) the service date of this preliminary order, (b) the service date of the denial of a petition for reconsideration from this preliminary order, or (c) the failure within twenty-one (21) days to grant or deny a petition for reconsideration from this preliminary order, any party may in writing appeal or take exceptions to any part of the preliminary order and file briefs in support of the party's position on any issue in the proceeding to the agency head (or designee of the agency head). Otherwise, this preliminary order will become a final order of the agency.

If any party appeals or takes exceptions to this preliminary order, opposing parties shall have twenty-one (21) days to respond to any party's appeal within the agency. Written briefs in support of or taking exceptions to the preliminary order shall be filed with the agency head (or designee). The agency head (or designee) may review the preliminary order on its own motion.

If the agency head (or designee) grants a petition to review the preliminary order, the agency head (or designee) shall allow all parties an opportunity to file briefs in support of or taking exceptions to the preliminary order and may schedule oral argument in the matter before issuing a final order. The agency head (or designee) will issue a final order within fifty-six (56) days of receipt of the written briefs or oral argument, whichever is later, unless waived by the parties or for good cause shown. The agency head (or designee) may remand the matter for further evidentiary hearings if further factual development of the record is necessary before issuing a final order.

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

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.

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing

GARY R. HERBERT
Governor
SPENCER J. COX
Lieutenant Governor

FRANCINE A. GIANI
Executive Director

MARK B. STEINAGEL
Division Director

Date: 1-16-2018

Dear Respondent,

You have been ordered to pay a fine to the Division of Occupational and Professional Licensing:

Your fine of 500 **is due** 4-16-2018.*

Your case number is DOPL- 2018-15 Wells Pharmacy Network LLC

*If you are unable to pay the fine as indicated in your Order or your Order indicates other arrangements, you must contact me or my co-worker Carol Inglesby within ten (10) days from the date of this letter. No special considerations will be granted for failure to contact us within the ten (10) day limit.

Make check(s) payable to DOPL and remit to:

DOPL
Attn: Disciplinary Files
P O Box 146741
Salt Lake City UT 84114-6741

Or you may pay with a Visa/Mastercard/American Express. Please mail your card number and expiration date to the above address or call (801)530-6088 and leave the information. Ms. Inglesby's phone number is (801)530-6626.

Please be sure to include your case number on any correspondence you send us.

Thank you,

Kim Lesh

Kim Lesh
Administrative Secretary

Disp/Fine letter 03/06

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

pyrogens of batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients. The circumstances are as follows:

14. Between May 2015 and March 2016, Respondent shipped about 2,890 batch-produced non-sterile to sterile compounded injectable drug products into California without documentation of end product sterility or pyrogen testing.[2]

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 1325, issued to Wells Pharmacy Network LLC;

2. Revoking or suspending Non-Resident Pharmacy Permit Number NSC 99824, issued to Wells Pharmacy Network LLC;

3. Ordering Wells Pharmacy Network LLC to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

4. Taking such other and further action as deemed necessary and proper.

DATED: 10/14/16

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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[2] A pyrogen is any substance or agent that causes fever.

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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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorneys, Steven L. Simas and Daniel Tatick. I understand the stipulation and the effect it will have on the Non-Resident Pharmacy Permit and the Non-Resident Sterile Compounding Permit held by Wells Pharmacy Network LLC. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 05/23/17

STACY SHAPIRO, GENERAL COUNSEL
WELLS PHARMACY NETWORK LLC
Respondent

I have read and fully discussed with Respondent Wells Pharmacy Network LLC the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 5/23/17

STEVEN L. SIMAS
DANIEL TATICK
Attorneys for Respondent

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.

///

///

///

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 5887, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident Pharmacy Permit and its Non-Resident Sterile Compounding Permit.

10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.

11. Respondent agrees that its Non-Resident Pharmacy Permit and its Non-Resident Sterile Compounding Permit are subject to discipline and agrees to be bound by the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

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.

///

EXHIBIT A

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
DAVID E. BRICE
Deputy Attorney General
State Bar No. 269443
1300 I Street, Suite 125
P.O. Box 944255
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 Sterile Compounding Permit No. NSC 99824** Respondent.	Case No. 5887 OAH No. 2017011087 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by David E. Brice, Deputy Attorney General.

2. Wells Pharmacy Network LLC (Respondent) is represented in this proceeding by attorneys Steven L. Simas and Daniel Tatick, whose address is: Simas and Associates, 3835 North Freeway Blvd., Suite 228, Sacramento, CA 95834.

EX A

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

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

BY: _____
JENNIFER ZAELIT
Bureau Manager

DATE: 1/12/2019

RESPONDENT

BY: _____
STACY SHAPIRO

DATE: 1/8/19

SEAN D. REYES
UTAH ATTORNEY GENERAL

BY: _____
L. MITCHELL JONES
Counsel for the Division

DATE: 16 Jan 19

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.

final compromise and settlement of this non-criminal administrative matter. Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of her having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement includes statements to one or more Board members during a meeting of the Board. Any such action or statement shall be considered a violation of this Stipulation and Order.

12. The accompanying Order becomes effective immediately upon the approval of this Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may subject Respondent to revocation or other sanctions.

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

2. Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to a hearing, the right to call witnesses on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to all administrative and judicial review as set forth in Utah Code Ann. §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R151-4-901 through R151-4-907. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation

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.

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing

GARY R. HERBERT
Governor
SPENCER J. COX
Lieutenant Governor

FRANCINE A. GIANI
Executive Director

MARK B. STEINAGEL
Division Director

Date: 1-16-2018

Dear Respondent,

You have been ordered to pay a fine to the Division of Occupational and Professional Licensing:

Your fine of 500.* **is due** 4-16-2018.*

Your case number is DOPL- 2018-14 WELLS PHARMACY NETWORK

*If you are unable to pay the fine as indicated in your Order or your Order indicates other arrangements, you must contact me or my co-worker Carol Inglesby within ten (10) days from the date of this letter. No special considerations will be granted for failure to contact us within the ten (10) day limit.

Make check(s) payable to DOPL and remit to:

DOPL
Attn: Disciplinary Files
P O Box 146741
Salt Lake City UT 84114-6741

Or you may pay with a Visa/Mastercard/American Express. Please mail your card number and expiration date to the above address or call (801)530-6088 and leave the information. Ms. Inglesby's phone number is (801)530-6626.

Please be sure to include your case number on any correspondence you send us.

Thank you,

Kim Lesh

Kim Lesh
Administrative Secretary

Disc-Fine letter 03/06

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

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

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

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

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).

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

ACCEPTED AND AGREED BY RESPONDENT

Wells Pharmacy Network Dated: 3 31.15

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

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.

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.

THOMAS C. HORNE
Attorney General
(Firm State Bar No. 14000)

MONTGOMERY LEE
Assistant Attorney General
State Bar No. 005658
1275 W. Washington, CIV/LES
Phoenix, Arizona 85007-2997
Tel: (602) 542-7980
Fax: (602) 364-3202

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.

EX A

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

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

BY: _____
JENNIFER ZAELIT
Bureau Manager

DATE: 1/12/2018

RESPONDENT

BY: _____
STACY SHAPIRO

DATE: 1/8/18

SEAN D. REYES
UTAH ATTORNEY GENERAL

BY: _____
L. MITCHELL JONES
Counsel for the Division

DATE: 16 Jan 18

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.

9. Upon approval by the Director of the Division this Stipulation and Order shall be the final compromise and settlement of this non-criminal administrative matter. Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of her having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement includes statements to one or more Board members during a meeting of the Board. Any such action or statement shall be considered a violation of this Stipulation and Order.

12. The accompanying Order becomes effective immediately upon the approval of this Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may

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.

2. Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to a hearing, the right to call witnesses on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to all administrative and judicial review as set forth in Utah Code Ann. §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R151-4-901 through R151-4-907. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation

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.

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.

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

ACCEPTED AND AGREED BY RESPONDENT

[illegible] Dated: [illegible]

by [illegible], 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 Daniel, on behalf of Wells Pharmacy Network.

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

[signature]
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.

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RECEIVED
PROFESSIONAL & VOCATIONAL
LICENSING DIVISION

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ORDER

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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

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
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Respondent

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

Doc #4200554