9

9A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy* or ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,7*
☐ *Partnership - Pages 1,2,5,7*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,7*
☐ *Sole Owner – Pages 1,2,6,7*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Catalent Pharmacy Services (PHL)

Physical Address: 3031 Red Lion Road

Mailing Address: Same as Physical Address

City: Phiadelphia State: PA Zip Code: 19114

Telephone: 215-613-3056 Fax: 215-253-5745

Toll Free Number: 855-573-2144 (Required per NAC 639.708)

E-mail: PHL.pharmacy@catalent.com Website: N/A

Managing Pharmacist: Michelle S. Giovannucci, R.Ph License Number: RP440876

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☒ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds_____)	☐	☒ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☐	☒ Community	☐	☒ Long Term Care
☒	☐ Other: Closed door	☐	☒ Sterile Compounding **
		☐	☒ Non Sterile Compounding
	All boxes must be checked	☐	☒ Mail Service Sterile Compounding **
	For the application to be complete	☐	☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

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, site 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.

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 pharmacy 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.

Michelle Giovannucci R.Ph
Original Signature of Person Authorized to Submit Application, no copies or stamps

Michelle S. Giovannucci, R.Ph
Print Name of Authorized Person

9-13-19
Date

Board Use Only Date Processed:_____ Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Catalent Inc. (Ultimate Parent Company)

Corporation Name: Catalent Pharma Solutions, LLC

Mailing Address: 14 Schoolhouse Road

City: Somerset State: NJ Zip: 08873

Telephone: 732-537-6200 Fax: 732-537-6480

Contact Person: Steven Fasman

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

Date of Incorporation: 03/14/2007

Registration number issued: 4318008

Stock Exchange: CTLT

Hours of Operation for the pharmacy:

Monday thru Friday 8 am 5 pm Saturday 9 am 2 pm

Sunday Closed am pm 24 Hours N/A

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

Must be included with the application for a publicly traded corporation

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

List of officers and directors.

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Michelle S. Giovannucci, R.Ph

Responsible Person of Catalent Pharmacy Services (PHL)

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Michelle Giovannucci RPh

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

Michelle S. Giovannucci, RPh

Print Name of Authorized Person

9-13-19

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF PA)
) ss.
Philadelphia COUNTY)

I, Michelle S. Giovannucci, R.Ph, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Director/Pharmacist-in-Charge/ Authorized Signer for Catalent Pharmacy Services (PHL) (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Michelle S. Giovannucci, R.Ph, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Michelle Giovannucci R.Ph
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
13 day of September, 2019.

NOTARY PUBLIC

Commonwealth of Pennsylvania - Notary Seal
EMILY LARSON, Notary Public
Philadelphia County
My Commission Expires July 20, 2022
Commission Number 1335631

CATALENT PHARMA SOLUTIONS, LLC

OFFICER'S CERTIFICATE

The undersigned, Steven L. Fasman, Secretary of Catalent Pharma Solutions, LLC, a Delaware limited liability company (the "***Company***"), hereby certifies that:

Effective immediately, the undersigned hereby delegates to Michelle Giovannucci, Director, Pharmacist in Charge the powers and authority to negotiate and execute agreements relating to the Pharmacy that is part of the Philadelphia manufacturing site, in the ordinary course of business, including without limitation applications for initial issuances of pharmacy permits together with any subsequent renewals and reinstatements thereof, in accordance with and subject to the limitations set forth in the Company's Transaction Approval Policy and Signature Authority Policy.

IN WITNESS WHEREOF, the undersigned has duly executed this certificate on this 25 day of July, 2019.

By: _____
Name: Steven L. Fasman
Title: Secretary

Please note:

The Pennsylvania Board of Pharmacy now uses an online system, that will send an official verification directly to Nevada via email. I have attached the confirmation page for the requested verification.

Pennsylvania is also a primary verification state. I have attached printed copies of online verifications.

Giovannucci, Michelle

From: RA-STPALSNOTIFY@pa.gov
Sent: Wednesday, September 4, 2019 6:01 PM
To: Giovannucci, Michelle
Subject: PALS Payment Receipt - MICHELLE GIOVANNUCCI

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

Dear MICHELLE GIOVANNUCCI :

This letter acknowledges receipt of your request. You can access www.pals.pa.gov website and check the status of your request using the UserID and Password you have created when you submit your request.

Payment Receipt

RECEIPT NUMBER: PAID0001273860
RECEIVED DATE: Sep 4 2019 5:58PM
RECEIVED FROM: Michelle Giovannucci
RECEIVED AMOUNT: $ 30.00
PAYMENT TYPE: Credit Card
APPLICANT NAME: MICHELLE GIOVANNUCCI

Application No / Transaction No	Fee Type	Fee Amount	Full Name
TN0012598402 (Pharmacist-RP440876)	Verification/Certification of License	15.00	MICHELLE GIOVANNUCCI
TN0012598405 (Pharmacy-PP482896)	Verification/Certification of License	15.00	MICHELLE GIOVANNUCCI

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

09/04/2019

License Information

MICHELLE S GIOVANNUCCI

Shamong, New Jersey 08088

Board/Commission:	State Board of Pharmacy	Status Effective Date:	03/20/2006
LicenseType:	Pharmacist	Issue Date:	03/20/2006
Specialty Type:		Expiration Date:	09/30/2020
License Number:	RP440876	Last Renewal:	09/06/2018
Status:	Active		

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

09/04/2019

License Information

CATALENT PHARMACY SERVICES (PHL)

3031 RED LION ROAD
Philadelphia, Pennsylvania 19114

Board/Commission:	State Board of Pharmacy	Status Effective Date:	06/03/2019
LicenseType:	Pharmacy	Issue Date:	06/03/2019
Specialty Type:		Expiration Date:	08/31/2021
License Number:	PP482896	Last Renewal:	
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
MICHELLE S GIOVANNUCCI	Pharmacist Manager	Pharmacist	RP440876	Active	06/03/2019	09/30/2020

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

CATALENT PHARMACY SERVICES

3031 RED LION ROAD

Philadelphia, PA, 19114

Phone:

Owner:

LICENSE

License No: AA0001241780
Profession: Pharmacy
License Type: Pharmacy
Inspection Type: New Business
Inspection Date: 06/03/2019
Inspection Result: Passed

Remarks: Pharmacy is compliant with current BOP regulations. Closed pharmacy. Pharmacy Permit assigned PP482896

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

If this is a New Business Inspection, this PASS inspection form will serve as a temporary authority to operate pending final review and approval by the State Board. The temporary authority must be prominently displayed and will expire upon receipt of a properly issued license or six months from the date of inspection.

Barry Bova

BARRY BOVA
Signature of Inspector

6/3/2019 10:33:27 AM
Date/Time

Michelle Giovannucci - RP440876
Signature of Owner/Representative

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

CATALENT PHARMACY SERVICES

3031 RED LION ROAD

Philadelphia, PA, 19114

Phone:

Owner:

LICENSE

License No: AA0001241780
Profession: Pharmacy
License Type: Pharmacy
Inspection Type: New Business
Inspection Date: 06/03/2019
Inspection Result: Passed

Remarks: Pharmacy is compliant with current BOP regulations. Closed pharmacy. Pharmacy Permit assigned PP482896

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	NO
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

1160

Commonwealth of Pennsylvania Department of State
Bureau of Professional and Occupational Affairs

Pharmacist

License Number
RP440876

Expiration Date
09/30/2020

Active

MICHELLE S GIOVANNUCCI
54 DELLETT COURT
SHAMONG, NJ 08088

OFFICIAL DOCUMENT

READ THE FOLLOWING INFORMATION CAREFULLY CONCERNING YOUR LICENSE:

1. SIGN THE WALLET CARD AND CERTIFICATE WHERE INDICATED.
2. DETACH THE WALLET CARD AND CERTIFICATE AT PERFORATION.

Pennsylvania Licensing System (PALS)

Visit our website at: www.pals.pa.gov to renew your license, change your personal or license address, or order duplicate licenses.

MICHELLE S GIOVANNUCCI
54 DELLETT COURT
SHAMONG, NJ 08088

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO BOX 2649 Harrisburg PA 17105-2649

19 0230212

License Type
Pharmacist

MICHELLE S GIOVANNUCCI
54 DELLETT COURT
SHAMONG, NJ 08088

License Status
Active

Initial License Date
03/20/2006

Expiration Date
09/30/2020

License Number
RP440876

Commissioner of Professional and Occupational Affairs

Signature

ALTERATION OF THIS DOCUMENT IS A CRIMINAL OFFENSE UNDER 18 PA.C.S.§. 4911

1385

Commonwealth of Pennsylvania Department of State
Bureau of Professional and Occupational Affairs

Pharmacy

License Number
PP482896

Expiration Date
08/31/2021

Active

CATALENT PHARMACY SERVICES (PHL)
MICHELLE S GIOVAN
3031 RED LION ROAD
PHILADELPHIA, PA 19114

OFFICIAL DOCUMENT

READ THE FOLLOWING INFORMATION CAREFULLY CONCERNING YOUR LICENSE:

1. SIGN THE WALLET CARD AND CERTIFICATE WHERE INDICATED.
2. DETACH THE WALLET CARD AND CERTIFICATE AT PERFORATION.

Pennsylvania Licensing System (PALS)

Visit our website at: www.pals.pa.gov to renew your license, change your personal or license address, or order duplicate licenses.

CATALENT PHARMACY SERVICES (PHL)
MICHELLE S GIOVAN
3031 RED LION ROAD
PHILADELPHIA, PA 19114

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

19 0749380

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO BOX 2649 Harrisburg PA 17105-2649

License Type
Pharmacy

CATALENT PHARMACY SERVICES (PHL)
MICHELLE S GIOVANNUCCI
3031 RED LION ROAD
PHILADELPHIA, PA 19114

License Status
Active

Initial License Date
06/03/2019

Expiration Date
08/31/2021

License Number
PP482896

Acting Commissioner of Professional and Occupational Affairs

Signature

ALTERATION OF THIS DOCUMENT IS A CRIMINAL OFFENSE UNDER 18 PA.C.S.S. 4911

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1:3
73/656

CATALENT PHARMACY SERVICES (PHL)
3031 RED LION RD
PHILADELPHIA, PA 19114-1123

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC8417594	08-31-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	06-06-2019

CATALENT PHARMACY SERVICES (PHL)
3031 RED LION RD
PHILADELPHIA, PA 19114-1123

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

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

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

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

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC8417594	08-31-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	06-06-2019

CATALENT PHARMACY SERVICES (PHL)
3031 RED LION RD
PHILADELPHIA, PA 19114-1123

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

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

Form DEA-223 (9/2016)

Catalent.

14 Schoolhouse Road
Somerset, NJ 08873
catalent.com

+ 1 888 SOLUTION (76588466)

Explanations of Disciplinary Actions for Catalent Pharma Solutions, LLC and subsidiaries and affiliates.

Please note: Catalent Pharmacy Services (PHL), has no disciplinary actions.

1. Florida Department of Business & Professional Regulation – ST PETERSBURG
   Catalent Pharma Solutions, LLC, St. Petersburg, FL

   In August 2014, the Catalent Pharma Solutions, LLC site in Saint Petersburg, FL, resolved alleged violations of Chapter 499 of the Florida Statutes with the Florida Department of Business & Professional Regulation pursuant to a Settlement Agreement and Final Order. The Settlement Agreement does not constitute discipline against the facility's Florida permits. See Florida Department of Business & Professional Regulation Case No. 2014-008409.

2. Alabama Board of Pharmacy – ST PETERSBURG
   Catalent Pharma Solutions, LLC, St. Petersburg, FL

   On June 27, 2017, the Catalent Pharma Solutions, LLC site located in St Petersburg, FL paid a $6,000.00 fine to the Alabama Board of Pharmacy in settlement of a matter involving the discipline received from the Florida BOP. According to the Alabama Board, a violation of any other state's licensing regulations (in this case, Florida's regulations) constitutes a violation of Alabama's regulations.

3. Alabama Board of Pharmacy – PHILADELPHIA
   Catalent Pharma Solutions, LLC, Philadelphia, PA

   On July 25, 2017, the Catalent Pharma Solutions, LLC site located in Philadelphia, PA (Red Lion Road) paid a $1,500 fine to the Alabama Board of Pharmacy in settlement of a matter involving the discipline from the South Carolina BOP regarding the shipment of clinical trial product into South Carolina without a license. According to the Alabama Board, a violation of any other state's licensing regulations (in this case, South Carolina's regulations) constitutes a violation of Alabama's regulations.

4. Alabama Board of Pharmacy – KANSAS CITY
   Catalent CTS, LLC – Kansas City, MO

   On July 25, 2017, the Catalent CTS, LLC site located in Kansas City, M paid a $1,500 fine to the Alabama Board of Pharmacy in settlement of a matter involving the discipline from the South Carolina BOP regarding the shipment of clinical trial product into South Carolina without a license. According to the Alabama Board, a violation of any other state's licensing regulations (in this case, South Carolina's regulations) constitutes a violation of Alabama's regulations.

5. South Carolina Board of Pharmacy – PHILADELPHIA
   Catalent Pharma Solutions, LLC, Philadelphia, PA

   On April 25, 2017, the Catalent Pharma Solutions, LLC site located in Philadelphia, PA (Red Lion Road) paid a $5,000 fine to the South Carolina Board of Pharmacy in settlement of a matter involving the shipment of clinical trial product into South Carolina without a license.

Catalent

6. South Carolina Board of Pharmacy – KANSAS CITY
Catalent CTS, LLC – Kansas City, MO

On April 25, 2017, the Catalent CTS, LLC site located in Kansas City, MO paid a $5,000 fine to the South Carolina Board of Pharmacy in settlement of a matter involving the shipment of clinical trial product into South Carolina without a license.

7. South Carolina Board of Pharmacy – MALVERN
Catalent Micron Technologies, Inc.

On September 27, 2018, Catalent Micron Technologies, Inc. paid a $5,000 fine to the South Carolina Board of Pharmacy in settlement of a matter involving the shipment of drugs into South Carolina without a license.

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
CATALENT PHARMA SOLUTIONS, LLC	)	
	)	**CASE NO: 17-L-0011**
Manufacturer/Wholesaler/ Distributor Applicant	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Catalent Pharma Solutions, LLC (hereinafter referred to as "Catalent") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement, which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Catalent, through its counsel, engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds that Catalent has violated the provisions of the applicable Board Rule based upon the conduct set out in the Statement; however, the Board grants the application of Catalent for a Manufacturer/Wholesaler/Distributor permit for the location at 2725 Scherer Drive North, St. Petersburg, Florida 33716 expressly contingent upon the payment of a fine in the amount of Six Thousand and NO/100 Dollars ($6,000.00) within thirty (30) days from the effective date of the Consent Order, which is the date it is signed on behalf of the Board. This payment shall not be subject

to discharge in bankruptcy nor shall Catalent attempt to discharge the same.

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

3. That Catalent agrees that any future violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

4. By execution of this Consent Order, Catalent hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Catalent acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Catalent 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 5 day of JUNE, 2017.

Catalent Pharma Solutions, LLC

BY: Scott Gunther

ITS: SR. VP Quality + Regulatory

SCOTT GUNTHER

Michael Whisonant, Attorney for
Catalent Pharma Solutions, LLC

DONE this the 27th day of June, 2017.

ALABAMA STATE BOARD OF PHARMACY

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

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

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

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
CATALENT PHARMA SOLUTIONS, LLC	)	**CASE NO: 17-L-0011**
Manufacturer/Wholesaler/ Distributor Applicant	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: **Catalent Pharmacy Solutions, LLC**
2725 Scherer Drive North
St. Petersburg, Florida 33716

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1 and § 34-23-92 (12), and Code of Alabama (1975), § 41-22-12, you are hereby notified and required to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on June 27th, 2017 at 1:00 p.m., at the Board office located at 111 Village Parkway, Birmingham, Alabama 35243 and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine whether the 2015/2016 Manufacturer/Wholesaler/Distributor Application for New Permit should be granted based upon any or all of the following:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(I)(3) mandates the Board to consider, at a minimum, certain factors to include:

   (a) The applicant's past experience in the manufacturing or distribution of drugs, including controlled substances (Board Rule 680-X-2.23(I)(3)(iii)).

   (b) Compliance with licensing requirements under previously granted

licenses (680-X-2.23(3)(vi)).

(c) Any other factors or qualifications the Board considers relevant to and consistent with public health and safety (680-X-2.23(3)(vii)).

3. Board Rule 680-X-2.23(I)(4) provides the Board reserves the right to deny a license to an applicant if it determines that the granting of such would not be in the public interest.

4. Board Rule 680-X-2.23(k)(1) provides it shall be a violation of the Rule to operate in such a manner as to endanger the public health.

5. Board Rule 680-X-2.253(k)(2) provides that a violation of the Rule may be grounds for a refusal to issue the applicable permit and/or allows the imposition of a fine not to exceed One Thousand Dollars ($1,000.00) for each such violation.

6. Board Rule 680-X-2.23(k)(3) provides wholesale drug distributors shall operate in compliance with applicable State laws or regulations.

COUNT ONE

The Board alleges you have violated the above referenced provisions and/or it would not be in the public interest to grant you the referenced permit based upon the Final Order, Settlement Agreement and Notice of Violation attached hereto as Exhibit "A", or the purchase of an API, i.e. Tipranavir-BI from an unauthorized source located in Germany, that is a person not authorized under Florida law to distribute prescription drugs and/or including the same into a finished manufactured drug which was then shipped for distribution.

The Board alleges that each occurrence described herein is a separate and distinct violation or deficiency.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 22nd day of March, 2017.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT A

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATI

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION,

Petitioner,

Case No. 2014-008409

v.

CATALENT PHARMA SOLUTIONS, LLC,

Respondent.
_____/

FINAL ORDER

The Department of Business & Professional Regulation (Department), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Catalent Pharma Solutions, LLC (Respondent) and the Department, attached hereto and incorporated by reference. This Final Order and Settlement Agreement are to resolve alleged violations of Section 499.005(14), Florida Statutes (2013), the purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that person or recipient; Section 499.005(4), Florida Statutes (2013), the sale, distribution, purchase, trade, holding, or offering of any drug is unlawful; Section 499.006(10), Florida Statutes (2013), a drug that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law is adulterated; Section 499.0121(14), Florida Statutes (2013), each prescription drug wholesale distributor, out-of-state prescription drug wholesaler-distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distributor of controlled

substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03; Section 499.0121, Florida Statutes (2013), a wholesale distributor must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs; and Rule 61N-1.012, Florida Administrative Code, records to document the movement of drugs, devices, or cosmetics must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department of Business & Professional Regulation as indicated on this Final Order.

DONE and ORDERED this 29th day of August, 2014, in Tallahassee, Florida.

KEN LAWSON, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____
Reginald D. Dixon
Division Director
Drugs, Devices and Cosmetics

Prepared by:

Bart O. Moore, Senior Attorney
Department of Business & Professional Regulation
Division of Drugs, Devices and Cosmetics

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by United States Mail to: counsel for Respondent, Timothy Cerio, Esquire, Gray Robinson, 301 S. Bronough Street, Suite 600, Tallahassee, Florida 32301, this 3rd day of September, 2014.

By: Brenda M. Nichols
Agency Clerk's Office

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION,

Petitioner,

v. Case No.: 2014-008409

CATALENT PHARMA SOLUTIONS, LLC,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (this "agreement") as disposition of the alleged violations described in the Notice of Violation case number 2014-008409 (the "allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation (hereafter, "Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. Catalent Pharma Solutions, LLC (hereafter, "Catalent" or "Respondent") is permitted by the Department as a prescription drug manufacturer, permit number 20:117; over the counter drug manufacturer, permit number 20:116; product registrant, permit number 08:1723; and as a diethyl ether purchaser, permit number 10:1300003.

2. Catalent address of record is 2725 Scherer Drive North, St. Petersburg, Florida 33716.

3. Catalent was issued a Notice of Violation on June 13, 2014, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted pursuant thereto.

CONCLUSIONS OF LAW

4. Catalent by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Catalent admits that the allegations, if proved, would constitute violations of Chapter 499, Florida Statutes.

6. Catalent neither admits nor denies the allegations set forth in the Notice of Violation, but is entering into this settlement to resolve the issues raised by the Department.

SETTLEMENT TERMS

7. Catalent agrees to immediately cease any practices that are in violation of Chapter 499, Florida Statutes.

8. Catalent agrees to pay a settlement amount of SIX THOUSAND DOLLARS ($6,000.00). Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 1940 North Monroe Street, Suite 26A, Tallahassee, Florida, 32399-1047, Attention: Janetta

Sampson, Senior Legal Assistant. Catalent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Catalent are absolute conditions precedent to Petitioner's execution of this agreement.

9. Catalent affirms that the violations alleged in the Notice of Violation letter issued in case number 2014-008409, have been corrected.

10. The Department agrees that this agreement will not be deemed to constitute discipline against the permits within the meaning of Section 499.066, Florida Statutes, and Rule 61N-1.024, Florida Administrative Code, and that this agreement will not be considered in any future claim, action, or proceeding against Catalent Pharma Solutions, LLC by the Department. Nothing herein shall be construed to limit, restrict or otherwise affect the Department's rights to (i) inspect under Section 499.051, Florida Statutes, (ii) examine, sample, test, embargo, seize, detain, condemn or destroy any drug, device, or cosmetic in accordance with Sections 499.06, 499.0632, and 499.065, Florida Statutes, or (iii) seek injunctions and take any other action authorized by Section 499.066 and 499.0661, Florida Statutes, in the event of a public health emergency or any immediate and substantial threat, hazard or danger to public health.

STANDARD PROVISIONS

11. It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

12. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. The

final order shall operate to close case number 2014-008409. The final order shall be final disposition in this proceeding, and shall constitute final agency action with respect thereto.

13. Catalent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of this Settlement Agreement and the final order in which the agreement is incorporated.

14. Catalent waives the right to seek any attorney's fees or costs from the Department in connection with this proceeding.

15. This agreement may be executed in any number of counterparts including, without limitation, telecopies, and facsimile transmission copies, all of which together shall constitute a single document.

16. The parties agree that this agreement represents a fair, appropriate and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

17. The terms and provisions of this agreement are severable, and if any term or provision is declared or deemed void, invalid, illegal or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

18. It is expressly understood that this settlement agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts the settlement and adopts it in a final order.

19. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals, and as duly designated representatives, to fully bind such principals.

CATALENT PHARMA SOLUTIONS, LLC	FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION
By:	By:
Name: ARIS GENNADIOS	Name: REGINALD D DIXON
Title: PRESIDENT, SOFTGEL TECHNOLOGIES	Title: DIVISION DIRECTOR
Date: 19AUG2014	Date: AUGUST 29, 2014

Florida Department of
Business & Professional Regulation

Drugs, Devices and Cosmetics
1940 North Monroe Street
Tallahassee, Florida 32399-1047
Phone: 850.717.1890
Fax: 850.414.8240

Ken Lawson, Secretary

Rick Scott, Governor

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

NOTICE OF VIOLATION
Case No.: 2014-008409

July 10, 2014

Corporation Service Company, Registered Agent for
Catalent Pharma Solutions, LLC
1201 Hays Street
Tallahassee, FL 32301-2525

Ms. Linda Vick, Senior Quality/ Regulatory Affairs Specialist
Catalent Pharma Solutions, LLC
2725 Scherer Drive North
St. Petersburg, FL 33716

Re: Department of Business & Professional Regulation v. Catalent Pharma Solutions, LLC, Case Number 2014-008409

Dear Sir/Madam:

On or about March 17, 2014 through March 19, 2014, the Department of Business & Business Professional Regulation, Drugs, Devices, and Cosmetics Division (hereafter "Department"), conducted an on-site inspection of Catalent Pharma Solutions, LLC (hereafter "Catalent") located 2725 Scherer Drive, St. Petersburg, Florida 33716. Catalent is permitted by the Department to operate as a prescription drug manufacturer, permit number 20:117; over the counter drug manufacturer, permit number 20:118; product registrant, permit number 08:1723, all of which expire on November 30, 2014, and as a diethyl ether purchaser, permit number 10:1300003, which expires on September 30, 2014.

During the on-site inspection, the Department determined that Catalent is a contract manufacturer for Boehringer Ingelheim, Binger Strabe 173, 55216 Ingelheim am, Rhein Germany (hereafter "BI-Germany"). Catalent received prescription drugs from BI-Germany for the manufacturing of finished dosage forms of the prescription drugs, BI-Germany is not permitted by the Department, and does not qualify for an exemption from licensure.

The Department determined that Catalent, received, shipped, manufactured and/or distributed prescription drug active pharmaceutical ingredient (API) from an

unauthorized source and failed to register and report the distribution of controlled substances.

The Department is authorized by Rule 61N-1.024(8), Florida Administrative Code, to issue a Notice of Violation for any alleged violations of Chapter 499, Florida Statutes, in order to facilitate the uncontested settlement of all issues related to a complaint or investigation. The Notice of Violation is to be done at the completion of the investigation and prior to filing of any Administrative Complaint. The Notice of Violation will advise the alleged violator of the statutory violation and provide a proposed penalty for settlement of the disciplinary matter related to a complaint.

The Department believes Catalent committed the following violations of Chapter 499, Florida Statutes and the administrative Rules promulgated pursuant thereto:

1. Section 499.005(14), Florida Statutes (2013), provides that the purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient is unlawful.

During the on-site inspection, the Department obtained purchasing and receiving specification sheets for prescription drugs, and/or active pharmaceutical ingredients (API); Catalent received that identify the distributor as BI-Germany. Records show Catalent was in receipt of four shipments from BI-Germany as follows:

1. Item number OET 00309819-Tipranavir-BI, dated 11/1/13; lot number 7648849, supplier/manufacturer lot number 1044065, 200kg.

2. Item number OET 00309819-Tipranavir-BI, dated 11/1/13; lot number 7648845, supplier/manufacturer lot number 1043891, 20kg.

3. Item number OET 00309819-Tipranavir-BI, dated 11/1/13; lot number 7646848, supplier/manufacturer lot number 1043888, 60kg.

4. Item number OET 00309819-Tipranavir-BI, dated 9/12/13; lot number 7490105, supplier/manufacturer lot number 1043891, 280kg.

Because BI-Germany manufactured the prescription drug API Tipranavir, in Germany, and distributed it to Catalent, located in Florida, without having a permit to do so, Catalent received prescription drugs from an unauthorized source in violation of Section 499.005(14), Florida Statutes (2013).

Range of Penalty per violation: An Administrative Complaint with a fine ranging from $1000 to $3000 per violation and up to permanent suspension or revocation of permit(s).

Fine assessed by the Department: $6,000

2. Section 499.006(10), Florida Statutes, (2013), provides that a drug is adulterated that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so. Section 499.005(1), Florida Statute (2013), provides that the manufacture, repackaging, sale, delivery or holding or offering for sale of any drug that is adulterated or misbranded is unlawful.

Catalent informed the Department it receives the prescription drug API, Tipranavir, manufacturered by the unauthorized source BI-Germany. Catalent manufactures the commercial prescription drug into a finished dosage form and ships it to Roxane Laboratories, Inc., located at 1809 Wilson Road, Columbus, Ohio 43288. Because BI-Germany, located in Germany, is not authorized to distribute prescription drugs into Florida, and Catalent manufacturered the unauthorized prescription drugs, Catalent caused them to become adulterated.

Catalent violated Section 499.005(1), Florida Statutes (2013), by manufacturing the adulterated prescription drug Tipranavir, on at least four occasions, received from BI-Germany, within the meaning of Section 499.006(10), Florida Statutes (2013).

Range of Penalty per violation: An Administrative Complaint with a fine ranging from $1,000 to $3,000 per violation and up to permanent suspension or revocation of permits.

Fine assessed by the Department: $3,000

3. Section 499.006(10), Florida Statutes (2013), provides that a drug is adulterated that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so. Section 499.005(4), Florida Statutes (2013), provides that the sale, distribution, purchase, trade, holding, or offering of any drug is unlawful.

Catalent distributed the adulterated prescription drug API Tipranavir, on at least four occasions, to Roxane Laboratories, in violation of Section 499.005(4), Florida Statutes (2013), within the meaning of Section 499.006(10), Florida Statutes (2013.

Range of Penalty per violation: An Administrative Complaint with a fine ranging from $1000 to $3000 per violation and up to permanent suspension or revocation of permit(s).

Fine assessed by the Department: $3,000

4. Section 499.0121(14), Florida Statutes (2013), provides:

(14) DISTRIBUTION REPORTING.—Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy

drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgment page must be displayed to confirm receipt. The report must contain the following information:

(a) The federal Drug Enforcement Administration registration number of the wholesale distributing location.
(b) The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.
(c) The transaction code that indicates the type of transaction.
(d) The National Drug Code identifier of the product and the quantity distributed or received.
(e) The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System identifier on all Schedule II transactions.
(f) The date of the transaction.

The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity's clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity's clinical needs to determine whether violations of chapter 893 have occurred.

Catalent advised the Department they had registered to report controlled substances but failed to report in a timely matter since August of 2012.

Catalent violated Section 499.0121(14), Florida Statutes (2013), by failing to register and report the distribution of control substances monthly to the Department as required, from August 2012 through July 2013.

Range of Penalty per violation: An Administrative Complaint with a fine ranging from $1000 to $3000 per violation and up to permanent suspension or revocation of permits.

Fine assessed by the Department: $3,000

5. Section 499.0121, Florida Statutes (2013), provides:

(4) EXAMINATION OF MATERIALS AND RECORDS.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(c) The recordkeeping requirements in subsection (6) must be followed for all incoming and outgoing prescription drugs.

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(a) Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

2. The name, principal address, and state license, permit or registration number of the person authorized to purchase prescription drugs; [Emphasis supplied].

Rule 61N-1.012 provides:

(1)(a) Records to document the movement of drugs, devices or cosmetics must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component. A complete audit trail includes records which document each transaction or step in the receipt, manufacture, shipping, transfer, or other steps in the channel of trade of that person, whether or not physical possession or handling of the product or component occurs. At a minimum, records shall consist of invoices from the supplier or source which document acquisition of each product by the person and invoices of sale or other transfer by the person to the recipient. Retail sales transactions to the consumer of over-the-counter drugs, non-restricted devices, or cosmetics are exempt from the requirements of this rule. Additional recordkeeping is required for persons permitted by the department as further stated in this rule.

(b) A person engaged in the distribution of drugs, devices, or cosmetics is not required to maintain documentation from a common carrier that the designated recipient received the product shipped; however, the person must obtain such documentation from the common

carrier and make it available to the department upon specific request of the department.

(2) Any person engaged in the manufacture of prescription drugs, the wholesale distribution of prescription drugs, or otherwise receiving or distributing prescription drugs must maintain records as follows:

(a) For each step in the channel of trade, records containing the information required by Section 499.0121(6)(a), F.S., and the Florida permit or license number which authorizes the source to possess and transfer prescription drugs in or into Florida must appear on one document. If delivery of prescription drugs is made to a person other than the purchaser, the name, address or location where the prescription drugs are delivered, and the state license, permit or registration number for that location must be included also. [Emphasis supplied].

Invoices and packlists for the prescription drug API Tipranavir provided to Catalent from BI-Germany failed to contain Catalent's Florida permit number, in violation of Section 499.0121(4)(c), Florida Statutes (2013), within the meaning of Section 499.0121(6)(a)2., Florida Statutes (2013), and Rule 61N-1.012, Florida Administrative Code.

Range of Penalty per violation: An Administrative Complaint with a fine ranging from $1,000 to $3,000 per violation and up to permanent suspension or revocation of permits.

Fine assessed by the Department: $1,000

In order to resolve this matter, the Department proposes the following alternatives, either of which must be accomplished by your company within twenty-one (21) days of receipt of this letter:

1. If your company does not contest the findings in this letter, and further agrees to waive its right to an administrative hearing pursuant to Sections 120.569 and 120.57, Florida Statutes, the Department and Catalent Pharma Solutions, LLC may resolve this matter. If you agree to a resolution, please sign and date the enclosed Settlement. Return the following items to my attention, at the address on this letterhead:

(a) The original signed Stipulation,

(b) A corporate check, cashier's check, or money order for SIXTEEN THOUSAND DOLLARS. ($16,000.00) made payable to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Drugs, Devices and Cosmetics Division, 1940 North Monroe Street, Suite 26A, Tallahassee, Florida, 32399-1047, Attention: Janetta Sampson, Senior Legal Assistant.

Upon receipt of the above-mentioned items, a final order incorporating the terms of the Stipulation will be entered.

2. However, if you believe circumstances exist that the Department should consider before concluding this investigation, you may provide the Department your rationale and evidence to support your position within twenty-one (21) days of receipt of this letter.

If the Department does not concur, or we are unable to reach a satisfactory resolution of this matter, the Department may initiate appropriate legal action after expiration of the above referenced 21-day time period given. Appropriate legal action may include:

(a) Filing and serving an administrative complaint for a hearing pursuant to Chapter 120, Florida Statutes (2011). This may result in the imposition of an administrative fine up to five thousand dollars ($5,000.00) per violation per day. Each day the violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. An Administrative Complaint also becomes a matter of public record.
(b) Revocation or suspension of the company permit.
(c) Seizure for destruction of adulterated or misbranded products.
(d) Seeking an injunction in Circuit Court to obtain compliance.
(e) Initiating any other remedy authorized by law.

If you have any questions regarding this matter, or need further assistance in this matter, please contact me at the address on this letterhead or by telephone at (850) 717-1803.

Sincerely,

Bart O. Moore
Senior Attorney

Enclosure: Stipulation

BOM/jes

IN THE MATTER OF:	)	**BEFORE THE ALABAMA**
	)	
CATALENT PHARMACY SOLUTIONS	)	**STATE BOARD OF PHARMACY**
	)	
Manufacturer/Wholesaler/ Distributor Applicant	)	**CASE NO: 17-L-0071**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Catalent Pharma Solutions, LLC (hereinafter referred to as "Catalent") relating to disciplinary action in the State of South Carolina.

Pursuant to Code of Alabama (1975) § 41-22-12(f) the parties, through counsel, have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that Catalent has violated the provisions of the applicable Board Rule based upon the conduct set out above; however, the Board grants the application of Catalent for a Manufacturer/Wholesaler/Distributor permit for the location at 3031 Red Lion Road, Philadelphia, PA 19114 expressly contingent upon the payment of a fine in the amount of One Thousand Five Hundred and NO/100 Dollars ($1,500.00) within thirty (30) days from the effective date of the Consent Order, which is the date it is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Catalent attempt to discharge the same.

2. That Catalent expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to a statement or notice of charges, the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Catalent further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Catalent 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 complaint.

5. That Catalent agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Catalent acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Catalent acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the 1 day of August, 2017.

CATALENT PHARMA SOLUTIONS, LLC

By: _____
Its: VP & Secretary GC

_____
Michael Whisonant, Attorney for Catalent Pharma Solutions, LLC

DONE this the _____ day of 8/8/2017.

ALABAMA STATE BOARD OF PHARMACY

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

By: _____
James S. Ward
Its Attorney

WARD & WILSON, LLC.
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

IN THE MATTER OF:	)	**BEFORE THE ALABAMA**
	)	
CATALENT CTS, LLC	)	**STATE BOARD OF PHARMACY**
	)	
Manufacturer/Wholesaler/ Distributor Applicant	)	**CASE NO: 17-L-0072**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Catalent CTS, LLC (hereinafter referred to as "Catalent") relating to disciplinary action in the State of South Carolina.

Pursuant to Code of Alabama (1975) § 41-22-12(f) the parties, through counsel, have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that Catalent has violated the provisions of the applicable Board Rule based upon the conduct set out above; however, the Board grants the application of Catalent for a Manufacturer/Wholesaler/Distributor permit for the location at 10245 Hickman Mills Drive, Kansas City, MO 64137 expressly contingent upon the payment of a fine in the amount of One Thousand Five Hundred and NO/100 Dollars ($1,500.00) within thirty (30) days from the effective date of the Consent Order, which is the date it is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Catalent attempt to discharge the same.

2. That Catalent expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-

20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to a statement or notice of charges, the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Catalent further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Catalent 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 complaint.

5. That Catalent agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Catalent acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Catalent acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the 1 day of August, 2017.

Catalent CTS, LLC

By: _____
Its: VP & Deputy GC

_____
Michael Whisonant, Attorney for Catalent CTS, LLC

DONE this the _____ day of 8/8/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

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

By: _____
James S. Ward
Its Attorney

WARD & WILSON, LLC.
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION
BEFORE THE STATE BOARD OF PHARMACY

In the Matter of:	
Catalent CTS, LLC,	**ORDER**
Applicant.	

This matter first came before the Nonresident Permit Subcommittee ("Committee"), appointed by the State Board of Pharmacy ("Board"), on April 25, 2017, for a hearing on the application of the above-named applicant ("Applicant") for a nonresident wholesaler/distributor/manufacturer permit. The Applicant appeared before the Committee through its designated representative, Terry Jackson, as well as its Associate General Counsel for Regulatory Matters, Robert Ciolek, Esquire. Applicant was represented by Jon Wallace, Esquire. At its June 14, 2017, meeting with a quorum present, the Board considered the Committee's recommendation and the transcript of the Committee's hearing. The Board adopted the Committee's recommendation that the application be approved, and the permit be issued subject to the prior payment of a civil penalty in the amount of Five Thousand and 00/100 ($5,000.00) Dollars for shipping into South Carolina without a permit. Since the hearing, Applicant has tendered the fine to the Board.

Applications of this type are governed by S.C. Code §§ 40-43-83, 40-43-86, 40-43-89 (2011, as amended), and/or Reg. 99-43, as amended.

FINDINGS OF FACT

1. Applicant applied for a permit for its facility located in Kansas City, Missouri.

2. Applicant is a manufacturer of clinical supply materials.

3. Applicant's representative admitted that Applicant has previously shipped prescription drugs to South Carolina without first obtaining a permit from this Board.

4. Applicant otherwise meets the requirements for the Permit for which it applied.

CONCLUSIONS OF LAW

In an application hearing, "(t)he applicant shall demonstrate to the satisfaction of the board that the applicant meets all requirements for the issuance of a license." S.C. Code Ann. § 40-1-130 (2011, as amended). Thus, the burden of proof in an application for licensure or certification is on the Applicant to provide full, complete, and accurate responses to all questions on the application

and to demonstrate that it is qualified for the license sought.

S.C. Code Ann. §40-43-83(I)(2011) requires a permit for the sale or distribution of legend (prescription) drugs in this state, and expressly includes manufacturers within or without the state. S.C. Code Ann. § 40-43-89 (2011) requires a facility located outside of this State that distributes prescription drugs or devices in this State to have a permit issued by the Board prior to distribution. S.C. Code Ann. § 40-43-140(A)(3) states that facilities requiring permits may not operate unless a permit has been issued by the board. Pursuant to S.C. Code Ann. § 40-43-140(A)(1)(2011), the Board may suspend, revoke, deny, or refuse to renew the permit or impose disciplinary action authorized for violations of the Pharmacy Act. Pursuant to S.C. Code Ann. §§ 40-43-140(A)(2), a person who distributes or delivers drugs or devices in this State without a required permit is subject to a fine imposed by the Board not to exceed one thousand dollars for each offense, in addition to such other disciplinary action the Board may take.

Applicant has met the qualifications for the permit, but violated the Pharmacy Practice Act by regularly distributing prescription drugs or devices into this State without a permit. Therefore, the Board concludes that it is appropriate to issue the permit subject to the prior payment of a civil penalty in the amount of Five Thousand and 00/100 ($5,000.00) Dollars.

NOW, THEREFORE, IT IS ORDERED THAT:

The Application is approved, and the permit shall be issued subject to the prior payment of a civil penalty in the amount of Five Thousand and 00/100 ($5,000.00) Dollars, receipt of which is hereby acknowledged by the Board.

AND IT IS SO ORDERED.

STATE BOARD OF PHARMACY

Carole Small Russell

CAROLE SMALL RUSSELL, R.Ph.
Board Chair

June 16, 2017

South Carolina Department of Labor, Licensing & Regulation

STATE OF SOUTH CAROLINA

COUNTY OF LEXINGTON

In the Matter of:

CATALENT CTS, LLC
PY . 17233

CERTIFICATE OF SERVICE BY MAIL

This is to certify that the undersigned has this date, June 16, 2017, served the Order in the above entitled action upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, or in the Interagency Mail Service addressed to the party(ies) or their attorney(s) to the following address:

CATALENT CTS, LLC
10245 HICKMAN MILLS DR
KANSAS CITY MO 64137

JONATHAN A. WALLACE, ESQUIRE
715 KING STREET
CHARLESTON, SC 29403

Karen Y Newton

Karen Y. Newton
Administrative Coordinator
SC Department of Labor, Licensing
and Regulation

South Carolina
Department of Labor, Licensing and Regulation

Board of Pharmacy

Henry D. McMaster
Governor

Emily H. Farr
Director

110 Centerview Drive
Post Office Box 11927
Columbia. SC 29211-1927
Phone: (803) 896-4700
FAX: (803) 896-4596

www.llronline.com/POL/Pharmacy

September 27, 2018

Catalent Micron Technologies, Inc.
333 Phoenixville Pike
Malvern PA 19355

Dear Steven Fasman:

Your application for a South Carolina Non-Resident Pharmacy permit was reviewed by the Non-Resident Application Review Committee at its September 26, 2018, meeting. The Committee's recommendations will be presented to the Board for approval or denial of the permit applications at its 11/15/2018, board meeting.

The Committee is recommending your permit application for approval pending the following:

Upon payment of fine $5000 for shipments into SC in 2017 and 2018.

Requested documents may be emailed to chelsi.swartz@llr.sc.gov. Once the above conditions have been met, your permit will be issued.

Sincerely,

Traci Collier

Traci Collier, PharmD
Administrator and Chief Drug Inspector
SC Board of Pharmacy

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION
BEFORE THE STATE BOARD OF PHARMACY

In the Matter of:	
Catalent Pharma Solutions, LLC,	**ORDER**
Applicant.	

This matter first came before the Nonresident Permit Subcommittee ("Committee"), appointed by the State Board of Pharmacy ("Board"), on April 25, 2017, for a hearing on the application of the above-named applicant ("Applicant") for a nonresident wholesaler/distributor/manufacturer permit. The Applicant appeared before the Committee through its designated representative, Terry Jackson, as well as its Associate General Counsel for Regulatory Matters, Robert Ciolek, Esquire. Applicant was represented by Jon Wallace, Esquire. At its June 14, 2017, meeting with a quorum present, the Board considered the Committee's recommendation and the transcript of the Committee's hearing. The Board adopted the Committee's recommendation that the application be approved, and the permit shall issued subject to the prior payment of a civil penalty in the amount of Five Thousand and 00/100 ($5,000.00) Dollars for shipping into South Carolina without a permit. Since the hearing, Applicant has tendered the fine to the Board.

Applications of this type are governed by S.C. Code §§ 40-43-83, 40-43-86, 40-43-89 (2011, as amended), and/or Reg. 99-43, as amended.

FINDINGS OF FACT

1. Applicant applied for a permit for its facility located in Philadelphia, PA.

2. Applicant manufactures clinical supply materials.

3. Applicant's representative admitted that Applicant has previously shipped prescription drugs to South Carolina without first obtaining a permit from this Board.

4. Applicant otherwise meets the requirements for the Permit for which it applied.

CONCLUSIONS OF LAW

In an application hearing, "(t)he applicant shall demonstrate to the satisfaction of the board that the applicant meets all requirements for the issuance of a license." S.C. Code Ann. § 40-1-130 (2011, as amended). Thus, the burden of proof in an application for licensure or certification is on the Applicant to provide full, complete, and accurate responses to all questions on the application

and to demonstrate that it is qualified for the license sought.

S.C. Code Ann. §40-43-83(I)(2011) requires a permit for the sale or distribution of legend (prescription) drugs in this state, and expressly includes manufacturers within or without the state. S.C. Code Ann. § 40-43-89 (2011) requires a facility located outside of this State that distributes prescription drugs or devices in this State to have a permit issued by the Board prior to distribution. S.C. Code Ann. § 40-43-140(A)(3) states that facilities requiring permits may not operate unless a permit has been issued by the board. Pursuant to S.C. Code Ann. § 40-43-140(A)(1)(2011), the Board may suspend, revoke, deny, or refuse to renew the permit or impose disciplinary action authorized for violations of the Pharmacy Act. Pursuant to S.C. Code Ann. §§ 40-43-140(A)(2), a person who distributes or delivers drugs or devices in this State without a required permit is subject to a fine imposed by the Board not to exceed one thousand dollars for each offense, in addition to such other disciplinary action the Board may take.

Applicant has met the qualifications for the permit, but violated the Pharmacy Practice Act by regularly distributing prescription drugs or devices into this State without a permit. Therefore, the Board concludes that it is appropriate to issue the permit subject to the prior payment of a civil penalty in the amount of Five Thousand and 00/100 ($5,000.00) Dollars.

NOW, THEREFORE, IT IS ORDERED THAT:

The Application is approved, and the permit shall be issued subject to the payment of a civil penalty in the amount of Five Thousand and 00/100 ($5,000.00) Dollars, receipt of which is hereby acknowledged by the Board.

AND IT IS SO ORDERED.

STATE BOARD OF PHARMACY

Carole Small Russell

CAROLE SMALL RUSSELL, R.Ph.
Board Chair

June 16, 2017

South Carolina Department of Labor, Licensing & Regulation

STATE OF SOUTH CAROLINA

COUNTY OF LEXINGTON

In the Matter of:

CATALENT PHARMA SOLUTIONS, LLC
PY . 17234

CERTIFICATE OF SERVICE BY MAIL

This is to certify that the undersigned has this date, June 16, 2017, served the Order in the above entitled action upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, or in the Interagency Mail Service addressed to the party(ies) or their attorney(s) to the following address:

CATALENT PHARMA SOLUTIONS, LLC
3031 RED LION RD
PHILADELPHIA PA 19114

JONATHAN A. WALLACE, ESQUIRE
715 KING STREET
CHARLESTON, SC 29403

Karen Y Newton

Karen Y. Newton
Administrative Coordinator
SC Department of Labor, Licensing
and Regulation

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATI

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION,

Petitioner,

Case No. 2014-008409

v.

CATALENT PHARMA SOLUTIONS, LLC,

Respondent.
_____/

FINAL ORDER

The Department of Business & Professional Regulation (Department), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Catalent Pharma Solutions, LLC (Respondent) and the Department, attached hereto and incorporated by reference. This Final Order and Settlement Agreement are to resolve alleged violations of Section 499.005(14), Florida Statutes (2013), the purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that person or recipient; Section 499.005(4), Florida Statutes (2013), the sale, distribution, purchase, trade, holding, or offering of any drug is unlawful; Section 499.006(10), Florida Statutes (2013), a drug that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law is adulterated; Section 499.0121(14), Florida Statutes (2013), each prescription drug wholesale distributor, out-of-state prescription drug wholesaler-distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distributor of controlled

substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03; Section 499.0121, Florida Statutes (2013), a wholesale distributor must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs; and Rule 61N-1.012, Florida Administrative Code, records to document the movement of drugs, devices, or cosmetics must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department of Business & Professional Regulation as indicated on this Final Order.

DONE and ORDERED this 29th day of August, 2014, in Tallahassee, Florida.

KEN LAWSON, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____

Reginald D. Dixon
Division Director
Drugs, Devices and Cosmetics

Prepared by:

Bart O. Moore, Senior Attorney
Department of Business & Professional Regulation
Division of Drugs, Devices and Cosmetics

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by United States Mail to: counsel for Respondent, Timothy Cerio, Esquire, Gray Robinson, 301 S. Bronough Street, Suite 600, Tallahassee, Florida 32301, this 3rd day of September, 2014.

By: Brandon M. Nichols
Agency Clerk's Office

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION,

Petitioner,

v.

Case No.: 2014-008409

CATALENT PHARMA SOLUTIONS, LLC,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (this "agreement") as disposition of the alleged violations described in the Notice of Violation case number 2014-008409 (the "allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation (hereafter, "Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. Catalent Pharma Solutions, LLC (hereafter, "Catalent" or "Respondent") is permitted by the Department as a prescription drug manufacturer, permit number 20:117; over the counter drug manufacturer, permit number 20:118; product registrant, permit number 08:1723; and as a diethyl ether purchaser, permit number 10:1300003.

2. Catalent address of record is 2725 Scherer Drive North, St. Petersburg, Florida 33716.

3. Catalent was issued a Notice of Violation on June 13, 2014, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted pursuant thereto.

CONCLUSIONS OF LAW

4. Catalent by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Catalent admits that the allegations, if proved, would constitute violations of Chapter 499, Florida Statutes.

6. Catalent neither admits nor denies the allegations set forth in the Notice of Violation, but is entering into this settlement to resolve the issues raised by the Department.

SETTLEMENT TERMS

7. Catalent agrees to immediately cease any practices that are in violation of Chapter 499, Florida Statutes.

8. **Catalent agrees to pay a settlement amount of SIX THOUSAND DOLLARS ($6,000.00). Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 1940 North Monroe Street, Suite 26A, Tallahassee, Florida, 32399-1047, Attention: Janetta**

Sampson, Senior Legal Assistant. Catalent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Catalent are absolute conditions precedent to Petitioner's execution of this agreement.

9. Catalent affirms that the violations alleged in the Notice of Violation letter issued in case number 2014-008409, have been corrected.

10. The Department agrees that this agreement will not be deemed to constitute discipline against the permits within the meaning of Section 499.066, Florida Statutes, and Rule 61N-1.024, Florida Administrative Code, and that this agreement will not be considered in any future claim, action, or proceeding against Catalent Pharma Solutions, LLC by the Department. Nothing herein shall be construed to limit, restrict or otherwise affect the Department's rights to (i) inspect under Section 499.051, Florida Statutes, (ii) examine, sample, test, embargo, seize, detain, condemn or destroy any drug, device, or cosmetic in accordance with Sections 499.06, 499.0632, and 499.065, Florida Statutes, or (iii) seek injunctions and take any other action authorized by Section 499.066 and 499.0661, Florida Statutes, in the event of a public health emergency or any immediate and substantial threat, hazard or danger to public health.

STANDARD PROVISIONS

11. It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

12. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. The

final order shall operate to close case number 2014-008409. The final order shall be final disposition in this proceeding, and shall constitute final agency action with respect thereto.

13. Catalent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of this Settlement Agreement and the final order in which the agreement is incorporated.

14. Catalent waives the right to seek any attorney's fees or costs from the Department in connection with this proceeding.

15. This agreement may be executed in any number of counterparts including, without limitation, telecopies, and facsimile transmission copies, all of which together shall constitute a single document.

16. The parties agree that this agreement represents a fair, appropriate and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

17. The terms and provisions of this agreement are severable, and if any term or provision is declared or deemed void, invalid, illegal or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

18. It is expressly understood that this settlement agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts the settlement and adopts it in a final order.

19. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals, and as duly designated representatives, to fully bind such principals.

CATALENT PHARMA SOLUTIONS, LLC

By: _____

Name: ARIS GENNADIOS

Title: PRESIDENT, SOFTGEL TECHNOLOGIES

Date: 19AUG2014

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____

Name: REGINALD D. DIXON

Title: DIVISION DIRECTOR

Date: AUGUST 29, 2014

FEIN 13-4268760

Corporate Officers

Name	Title	Home Address	Business Address	Phone Number	DOB	SS#
John Chiminski	Chairman, CEO	Pineville Road Newtown, PA 18940	14 Schoolhouse Road Somerset, NJ 08873	732-537-6401 (work) (cell)		
Alessandro Maselli	President & COO	Holocombe House Gardens, Sunningdale, Berkshire, UK SL5 0FD	14 Schoolhouse Road Somerset, NJ 08873	011-44-1793-548-298		N/A - Italian Citizen
Joseph, Wettney	Senior VP, Chief Financial Officer & Asst. Treasurer	Candace Lane Chatham, NJ 07928	14 Schoolhouse Road Somerset, NJ 08873	732-537-6200 (work) (home)		
Steven Fasman	Senior VP, General Counsel & Secretary	Club Pointe Dr. White Plains, NY 10605	14 Schoolhouse Road Somerset, NJ 08873	732-537-5958 (work) (cell)		
Thomas Castellano	Vice President & Treasurer	Hildebrandt Road Lebanon, NJ 08833	14 Schoolhouse Road Somerset, NJ 08873	732-537-6175 (work) (cell)		

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CATALENT PHARMA SOLUTIONS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF JULY, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CATALENT PHARMA SOLUTIONS, LLC" WAS FORMED ON THE FIFTH DAY OF NOVEMBER, A.D. 2003.

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

Jeffrey W. Bullock, Secretary of State

3724407 8300

SR# 20195824826

Authentication: 203160877

Date: 07-05-19

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

9B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy* or ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***
Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,7* ☐ *Partnership - Pages 1,2,5,7*

☒ *Non Publicly Traded Corporation – Pages 1,2,4,7* ☐ *Sole Owner – Pages 1,2,6,7*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: **GABECARE DIRECTRX, INC. d/b/a DIRECTRX PHARMACY**

Physical Address: **830 KIRTS BLVD. SUITE 300**

Mailing Address: **830 KIRTS BLVD. SUITE 300**

City: **TROY** State: **MI** Zip Code: **48084**

Telephone: **248-273-0474** Fax: **877-891-4007**

Toll Free Number: **855-362-3397** (Required per NAC 639.708)

E-mail: **AIVEZAJ@DIRECTRX.COM** Website: **WWW.DIRECTRX.COM**

Managing Pharmacist: **AMANDA BERISHAJ** License Number: **5302035045 [MICHIGAN]**

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☐	☒ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds_____)	☐	☒ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☐	☒ Community	☐	☒ Long Term Care
☒	☐ Other: **MAIL ORDER/SPECIALTY**	☐	☒ Sterile Compounding **
		☐	☒ Non Sterile Compounding
All boxes must be checked		☐	☒ Mail Service Sterile Compounding **
For the application to be complete		☐	☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

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, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐ SEE ATTACHED

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.

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 pharmacy 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.

Amanda L Berisha

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

Amanda Berishaj — Print Name of Authorized Person

10/10/2019 — Date

Board Use Only Date Processed:_____ Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: MICHIGAN

Parent Company if any: N/A

Mailing Address: 830 KIRTS BLVD

City: TROY State: MI Zip: 48084

Telephone: (248) 273-0474 Fax: (248) 793-9332

Contact Person: ALBAN IVEZAJ

For any corporation non publicly traded, disclose the following:

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

a) AMANDA BERISHAJ (Name) FERNDALE AVE. BIRMINGHAM, MI 48009 (Address)

b) GABLAN ZAWAIDEH (Name) HILLS DR. BLOOMFIELD HILLS, MI 48009 (Address)

c) JALAL ZAWAIDEH (Name) PILGRIM BIRMINGHAM, MI 48009 (Address)

d) LOUIS ZAWAIDEH (Name) VINEWOOD BIRMINGHAM, MI 48009 (Address)

2) Provide the number of shares issued by the corporation. CLASS A: 1,000; CLASS B: 7,013

3) What was the price paid per share? $45.00

4) What date did the corporation actually receive the cash assets? 01/01/2018

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

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9:00 am 5:30 pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours _____

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

Must be included with the application for a non publicly traded corporation

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

List of officers and directors

SEE BELOW:

Name	Title
Marko Berishaj	President
Amanda Berishaj	Vice President/Shareholder
Gablan Zawaideh	Shareholder
Jalal Zawaideh	Shareholder
Louis Zawaideh	Shareholder

STOCK REGISTER/OWNERSHIP TABLE
FOR
GABECARE DIRECTRX, INC.
AS OF JANUARY 1, 2018

Shareholder	Class of Stock	Number of Shares	Percentage Ownership
Amanda Berishaj	Class A (Voting)	1,000	12%
Amanda Berishaj	Class B (Non-Voting)	4,610	58%
Gablan Zawaideh	Class B (Non-Voting)	801	10%
Jalal Zawaideh	Class B (Non-Voting)	801	10%
Louis Zawaideh	Class B (Non-Voting)	801	10%
	TOTAL	**8,013**	**100%**

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify That

GABE CARE DIRECT RX, INC.

was validly incorporated on August 6 , 1985 as a Michigan DOMESTIC PROFIT CORPORATION, and said corporation is validly in existence under the laws of this state.

This certificate is issued pursuant to the provisions of 1972 PA 284 to attest to the fact that the corporation is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 20th day of September , 2019.

Julia Dale, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 19095654920

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.

GRETCHEN WHITMER
GOVERNOR

ORLENE HAWKS
DIRECTOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

VERIFICATION OF LICENSURE

MICHIGAN BOARD OF PHARMACY

VERIFICATION OF LICENSURE AS OF 10/02/2019

NAME: **Gabecare Direct Rx Inc**
ADDRESS: 830 Kirts Blvd Ste 300
Troy, MI 48084

STATUS: Active

LICENSE TYPE: Pharmacy License

LICENSE NUMBER: 5301006411

ORIGINAL DATE: 04/09/1996
EXPIRATION DATE: 04/09/2022
SPECIALTY: None

EXAM DATE	EXAM TYPE	EXAM RESULTS
	None	

OPEN FORMAL COMPLAINTS

No

DISCIPLINARY ACTION	START DATE	END DATE
None		

Brian DeBano, Division Director
Bureau of Professional Licensing
Licensing Division
(517) 241-0199

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

GRETCHEN WHITMER
GOVERNOR

N930268

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
PHARMACY LICENSE

GABECARE DIRECT RX INC
830 KIRTS BLVD STE 300
TROY, MI 48084

LICENSE NO.
5301006411

EXPIRATION DATE
4/9/2022

19157080648

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Michigan)
) ss.
Oakland COUNTY)

I, AMANDA Bershaj, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the VP for GABBE ALLEN ELECTRIX, INC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, AMANDA Bershaj, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Amanda Y Bersh
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
8th day of October, 2019.

Judy A VanOrsdal
NOTARY PUBLIC

JUDY A. VAN ORSDAL
NOTARY PUBLIC, STATE OF MI
COUNTY OF MACOMB
MY COMMISSION EXPIRES May 24, 2020
ACTING IN COUNTY OF Oakland

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Amanda Berishaj

Responsible Person of Gabe Care DirectRx

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Amanda Berishaj

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

Amanda Berishaj — Print Name of Authorized Person

10/10/19 — Date

GABECARE DIRECT RX INC
830 KIRTS BLVD STE 300
TROY, MI 48084-4897

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BG4827765	09-30-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	08-13-2019

GABECARE DIRECT RX INC
830 KIRTS BLVD
STE 300
TROY, MI 48084-4897

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

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

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

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

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GABECARE DIRECT RX INC
830 KIRTS BLVD
STE 300
TROY, MI 48084-4897

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

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

Form DEA-223 (9/2016)

DirectRx
PHARMACY

October 10, 2019

DirectRx Pharmacy
830 Kirts Blvd #300
Troy, MI 48084

Re: Administrative Fees by State Boards of Pharmacies

DirectRx, Inc is a privately held Specialty Pharmacy that is accredited by URAC, ACHC, NABP and WBENC.

The company has a long history of dedicated delivery of care and therapy management for chronically ill patients that includes Medication Therapy Management, Medication Compliance Monitoring & Patient Education. The organization primarily focuses on specialty treatment for patients with Respiratory Conditions and Electrolyte Imbalances. DirectRx, Inc does not compound or outside the state of Michigan, fill for control substances.

DirectRx has not been subject to any license/permit revocations, suspensions or probations. Yet, to the extent that an "administrative fee" constitutes a "administrative action", DirectRx wishes to disclose the following:

2018 Texas State Board of Pharmacy Administrative Fee

In August 2018, DirectRx was subject to an administrative fee from the Texas State Board of Pharmacy.

Said fee was related to a Texas application for licensure where DirectRx, due to misunderstanding an application question, failed to disclose a historic administrative fee. This fee was due to an administrative error and not to delivery of care and/or treatment of patients.

DirectRx continues to be licensed as an out-of-state pharmacy in 38 states, including Texas, and maintains its accreditations with URAC, ACHC, NABP and WBENC.

Thank you.

Alban Ivezaj

Director of Legal & Compliance

9C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy* or ☐ ***Ownership Change*** *(Provide current license number if making changes: **PH**_____*
Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,7*	☐ *Partnership - Pages 1,2,5,7*
☑ *Non Publicly Traded Corporation – Pages 1,2,4,7*	☐ *Sole Owner – Pages 1,2,6,7*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Empower Pharmacy

Physical Address: 200 Westlake Park Blvd Ste 1800, Houston, TX 77079

Mailing Address: 5980 W Sam Houston Pkwy N Ste 300

City: Houston State: TX Zip Code: 77041

Telephone: (832) 678-4417 Fax: (832) 678-4419

Toll Free Number: (877) 562-8577 (Required per NAC 639.708)

E-mail: shaunnoorian@gmail.com Website: empowerpharmacy.com

Managing Pharmacist: Kathryn Lenz License Number: 58293

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☑ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds_____)	☐	☑ Parenteral **
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☐	☑ Mail Service
☑	☐ Community	☐	☑ Long Term Care
☑	☐ Other: Central Order Processing	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☑	☐ Other Services: Central Order Processing

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

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, site 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.

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 pharmacy 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.

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

Shaun Noorian
Print Name of Authorized Person

10/25/2019
Date

Board Use Only Date Processed:_____ Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Texas

Parent Company if any: Empower Clinic Services, LLC

Mailing Address: 5980 W Sam Houston Pkwy N Ste 300

City: Houston State: TX Zip: 77041

Telephone: (832) 678-4417 Fax: (832) 678-4419

Contact Person: Shaun Noorian

For any corporation non publicly traded, disclose the following:

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

a) Shaun Noorian (Name) 5980 W Sam Houston Pkwy N Ste 300, Houston, TX 77041 (Address)

b) _____ (Name) _____ (Address)

c) _____ (Name) _____ (Address)

d) _____ (Name) _____ (Address)

2) Provide the number of shares issued by the corporation. 1

3) What was the price paid per share? $25,000

4) What date did the corporation actually receive the cash assets? 2009

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

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday	7:30 am	7:30 pm	Saturday	Closed am	Closed pm
Sunday	Closed am	Closed pm	24 Hours	_____	

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

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Shaun Noorian

Responsible Person of Empower Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

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

Shaun Noorian
Print Name of Authorized Person

10/25/2019
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Texas)
) ss.
Harris COUNTY)

I, Shaun Noorian, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Sole Officer, Owner for Empower Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Shaun Noorian, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Shaun Noorian
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
25 day of October, 2019.

NOTARY PUBLIC

PEJMON JONATHAN ABRARPOUR
NOTARY PUBLIC
ID# 131477203
State of Texas
Comm. Exp. 03-06-2022

Re: List of Officers and Directors

Ownership Type: LLC

Corporate Name: Empower Clinic Services, LLC
Doing Business As: Empower Pharmacy

Name: Shaun Noorian
Titles: Business owner, Sole LLC officer
Business Address: 5980 W Sam Houston Pkwy N, Ste 300, Houston, TX 77041
Home Address: [redacted] Kelliwood Oaks Dr, Katy, TX 77450
Business Phone: (832) 678-4417
Home Phone: [redacted]

Re: Inspection Exemption

The Texas State Board of Pharmacy approved the issuance of our Order Processing Pharmacy Permit (TX BOP License# 32769) without requiring an initial on-site inspection due to the applicant, Shaun Noorian, currently holding an ownership interest in a compliant, Texas based Community Independent Pharmacy (TX BOP License# 26444).

Attached is a copy of the ***Texas State Board of Pharmacy Central Prescription Drug or Medication Order Processing Pharmacy (Class G) License Application Instructions*** confirming this inspection exemption, as well as the ***Pre-Inspection Checklist*** that was included along with our Texas Order Processing Pharmacy application.

We are also attaching the ***latest home state inspection*** **of our Community Independent Pharmacy (TX BOP License# 26444).** The Texas State Board of Pharmacy referenced this document to confirm that the level of compliance we have historically exhibited, while operating our Community Independent Pharmacy (TX BOP License# 26444), qualified our new Order Processing Pharmacy (TX BOP License# 32769) for the on-site inspection exemption.

Texas State Board of Pharmacy License Application Instructions
Central Prescription Drug or Medication Order Processing Pharmacy (Class G)

- **Submit this checklist as a cover sheet and include each and every item listed below.** Documents submitted with a separate or similar application previously will not be retrieved for completion of this application. **Official review does not begin until all required items are received.**
- Applicants will be notified of any items missing from the application within **4 to 6 weeks.** Allow a ***minimum*** of 90 days from the time your application packet is complete (all missing items received), for review and final license issuance.
- Applications are considered withdrawn if missing items are not submitted to complete an application within a year of the date initially received at TSBP.
- **NOTICE: the application will be cancelled and a new application packet, including application fee, must be submitted, if a change in officer, owner, or location occurs while the application is under review by TSBP.**

☑ 1. **Pharmacy License Application – Submit Form LIC-Class G**
The name of the pharmacy in Box 1 of this form should match the name on the prescription label.

☑ 2. **Ownership Information:**
- **If owned by Partnership or Individual – Submit Form LIC-006; or**
- **If owned by Corporation or Limited Liability Company – Submit Form LIC-007 and attach the following documents:**
  - ☑ Articles of Incorporation (for Corporation); or Articles of Organization (for LLC) or Certificate of Formation.
  - ☑ Current Texas Franchise Tax Status. (If the Corp/LLC is registered w/TX Secretary of State)
- **If owned by Government – Submit Form LIC-008.**
- If a closely-held corporation, a list of all owners.
- If a publicly-held corporation, a copy of the corporation's 10K Filing with the Security and Exchange Commission.

☑ 3. **Managing Officer – Submit Form LIC-021** which provides information and questions regarding the "background" to be submitted by each of the top four Managing Officers. Attach a copy of a current driver's license or state issued identification card and a copy of the social security card for each individual owner(s), managing officer(s) or partners that are not a Texas licensed pharmacist.

☑ 4. **Lease Agreement/Property Ownership** - Attach a copy of lease agreement between the owner of the pharmacy and the owner of the building in which the pharmacy is located. The pharmacy address listed on the lease agreement must match the pharmacy address listed on all required forms. The tenant listed on the lease agreement must match the name of the pharmacy owner listed on all required forms. If you are subleasing the space, submit a copy of the sublease agreement along with the master lease agreement.

☑ 5. **New Pharmacy Checklist – Submit Form LIC-018** lists the minimum infrastructure requirements needed to apply for a new pharmacy license and must be submitted with a New Pharmacy Application.

I/A ☐ 6. **Credit Worthiness Document:** Provide a letter from a primary wholesaler with proof of credit worthiness.

Prior to the issuance of a license for a pharmacy located in Texas, the board shall conduct an on-site inspection of the pharmacy in the presence of the pharmacist-in-charge and owner or representative of the owner, to ensure that the pharmacist-in-charge and owner can meet the requirements of the Texas Pharmacy Act and Board Rules

☑ 7. **COMPLETE AND SUBMIT** the Pre-Inspection Checklist (form # LIC-000A) to indicate the pharmacy is ready for an on-site inspection. ***Note:*** The on-site pre-inspection may not be required if the prospective owner has an ownership interest in any other pharmacy in Texas at the time of application. This exemption applies only to the pre-inspection requirement.

SUBMIT THIS CHECKLIST AS A COVER SHEET WITH ALL ITEMS LISTED – KEEP COPIES FOR YOUR RECORDS

TEXAS STATE BOARD OF PHARMACY

333 Guadalupe Street, Ste. 3-500 ★ Austin, Texas 78701
512-305-8021 ★ 512-305-8082 (fax) ★ www.pharmacy.texas.gov

PHARMACY CHECKLIST

(Submit this form only after all the items on this checklist are complete)

PHARMACY NAME & LOCATION ADDRESS (Street, City, ZIP)

Empower Pharmacy

200 Westlake Park Boulevard Ste 1800

Houston, TX 77079

- [x] A building with space adequate for the size and scope of pharmaceutical services provided by the pharmacy.
- [x] An area dedicated for the prescription department, including an area suitable for confidential patient counseling if the pharmacy serves the general public.
- [x] Water supply exists.
- [x] Electrical supply exists
- [x] Fixtures (i.e. shelving, counter tops, etc.) for storage of drugs, equipment and supplies, necessary to operate a pharmacy have been ordered.

Does the prospective owner currently have ownership interest in any other pharmacy in Texas? [x] YES [ ] NO

If yes, please provide the name, address, and license number of the pharmacy(s):

Empower Pharmacy (License: 26444)

5980 W Sam Houston Pkwy N Ste 300, Houston, TX 77041

X _____

Signature of Owner / Managing Officer

6/3/2019

Date Signed

TEXAS STATE BOARD OF PHARMACY

333 Guadalupe Street, Ste. 3-600 ★ Box 21 ★ Austin, Texas 78701
512-305-8021 ★ 512-305-8082 (fax) ★ www.tsbp.state.tx.us

PRE-INSPECTION CHECKLIST

☒ 1. The prescription department has space adequate for the size and scope of pharmaceutical services provided by the pharmacy.

☒ 2. Fixtures (i.e., shelving, counter tops, etc.) for storage of drugs, equipment and supplies, necessary to operate a pharmacy are installed.

☒ 3. A sink with hot and cold running water available exclusive of the restroom facilities.

☒ 4. Pharmacy arranged in an orderly fashion and kept clean.

☒ 5. The prescription department is complete and contains the following required equipment and supplies including, but not limited to:

- X a. data processing system including a printer or comparable equipment;
- N/A b. refrigerator to be maintained within a range compatible with the proper storage of drugs requiring refrigeration;
- N/A c. adequate supply of child-resistant, light-resistant, tight, and if applicable, glass containers;
- X d. adequate supply of prescription labels with name, address, and telephone number of pharmacy;
- X e. appropriate equipment necessary for the proper preparation of prescription drug orders;
- X f. metric-apothecary weight and measure conversion charts;
- N/A g if the pharmacy serves the public, the word "pharmacy" or a similar word or symbol as determined by the board, is displayed in a prominent place on the front of the pharmacy.

☒ 6. A reference library is on site and current:

- X a. Texas Pharmacy Laws and Regulations (publication year 2019)
- X b. Drug Interactions Reference (publication year 2019)
- X c. General Information Reference (publication year 2019)
- N/A d. Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations (if pharmacy is compounding non-sterile preparations)
- X e. General reference text on veterinary drugs (if the pharmacy dispenses veterinary prescriptions)
- X f. Basic Antidote Information and telephone number of the nearest Regional Poison Control Center.

[ ] N/A 7. If the pharmacy is compounding sterile preparations the following references are also required:

- N/A a. United States Pharmacopeia/National Formulary or USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding-Sterile Preparations
- N/A b. Chaper 71 of the USP/ NF concerning Sterility Tests
- N/A c. Chapter 85 of the USP/ NF concerning Bacterial Endotoxins Test
- N/A d. Chapter 1163 of the USP/ NF concerning Quality Assurance in Pharmaceutical Compounding
- N/A e. Handbook on Injectable Drugs (publication year _____)
- N/A f. Specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy (e.g. if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs)

☒ 8. Security requirements can be met to assure the pharmacy will be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site.

☒ 9. Pharmacy has basic alarm system with off-site monitoring and perimeter and motion sensors. (Alarm must be activated)
*If your city requires an alarm permit, please attach a copy of the alarm permit.

☒ 10. Written policies and procedures for the pharmacy's security that meet the requirements of rule 291.33(b)(2)(E).

[ ] N/A 11. An area suitable for confidential patient counseling if pharmacy serves the general public.

[ ] N/A 12. If compounding sterile preparations, the pharmacy has a controlled area that meets the

requirements in rule 291.133 (d)(6)(A) if the pharmacy is compounding low- and medium-risk preparations or rule 291.133 (d)(6)(B) if high-risk preparations are being compounded.

[ ] N/A 13. Certified primary engineering control device (e.g. laminar airflow work benches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators).

[ ] N/A 14. Certified clean room(s) (e.g. ante area, buffer area).

Submit this form only after all items on this check-list are complete.

A TSBP Inspector will contact you regarding the required pre-inspection, only after the inspector receives a completed pre-inspection checklist. Please provide all contact information below for the owner or owner's representative and Pharmacist-in-charge:

Empower Pharmacy — Pharmacy Name

200 Westlake Park Boulevard Ste 1800, Houston, TX 77079 — Pharmacy Address

Arta Shaun Noorian — Name of Owner or Owner's Representative

 — Signature of Owner or Owner's Representative

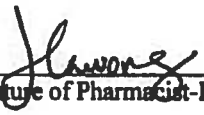
_____ Home

_____ Cell

(832) 678-4417 Work

Contact Telephone Numbers (8:00a.m.-5:00p.m./Mon.-Fri.)

Ha Wong — Name of Pharmacist-In-Charge

 — Signature of Pharmacist-In-Charge

_____ Home

_____ Cell

(832) 678-4417 Work

Contact Telephone Numbers (8:00a.m.-5:00p.m./Mon.-Fri.)

_____

For TSBP Use Only—Date Pre-inspection Completed

TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT

CLASS: A (A-S) B C C-S (BEDS____) D Other_____

Name of Pharmacy EM Power Pharmacy
Pharmacist in Charge Souchi Nanthavongdouangsy
Personnel

TSBP License # 26444
Lic 425 24 Exp 4/30/20
Lic_____ Exp_____
Lic_____ Exp_____
Lic_____ Exp_____
Lic_____ Exp_____

KEY: Circled items need improvement, √ items in Column One Refer to Legal Division (R/L) for review and possible discipline.
√ items in Column Two receive a Warning Notice (W/N).
For an explanation of specific violations noted, refer to remarks section of inspection report.

R/L		W/N		R/L		W/N		R/L		W/N	
	1		Licenses not posted				Date of last inventory 5-11-18 CMS		10		Rxs not separated
	2		Insufficient Equipment		15		No PIC inventory		35		Invoices not separated
	3		Orderly/Clean		69		No annual inventory		67		No written information
	4	√	Balance Failed		68		No change of ownership inventory		21		Computer records incomplete
	5		Equipment Inspection 21 BP Meters		31		Closed Phcy/Change of owner improper		22		Computer system noncompliance
	6		Inadequate Library		17		Incomplete inventory		82		PMR Incomplete
	7		Improper security		18		Records not available		83		PMR Absent
	8		Environment		46		Improper distribution		84		No drug regimen review
	9		Delinquent licenses/certifications		54		Improper prepackaging procedures		16		No perpetual inventory
	36		No notification of substitution		24		Theft/Loss not reported N/A		27		Improper inpatient records
	90		No complaint notification		30		Invoices not dated/initialed		51		Improper ER dispensing
	38		Area for non sterile compounding		86		Absence of RPh pick up records		75		Improper absence of RPh procedures
	43		Records for non sterile compounding		19		Rx lacks proper information		70		No P&P manual
	47		Out of date/mislabeled drug stock		25		No documentation of refill authorization		(71)		Incomplete P&P manual
	48		Improper drug storage		32		Rx label is incorrect		72		Improper procedures for IV preparation
	53		Illegal possession of C/S		40		Non emergency C-II Rx		81		Area for preparation of sterile products
	57		Corresponding Responsibility		26		C II Rx noncompliance		85		Patient Care Guidelines incomplete
	59		Improper drug destruction		37		Illegal dispensing		87		Quality Control/Assurance
	61		Improper supervision of supportive personnel		45		Improper dispensing/ labeling		88		Cytotoxic/Biohazardous Procedures
	62		Aiding and abetting		44		Refill CIII-V over 5x/6mo		89		Refrigerator Temperature Log
	65		Improper registration procedures		55		Refill prn past one year		28		No provision log
	66		Grey Market diversion/ Samples		78		Counseling area		29		Incomplete provision log
	76		No PIC		80		No counseling by RPh		52		Improper provision/ dispensing in Class D
	34		Notification Violation		56		Improper transfer of Rx		63		Prohibited drugs in Class D pharmacy
	79		Nametags		50		Out of state verbal Rx for C/S		64		Violation of limited formulary
	60		Improper doc-umentation of training		49		Substitution noncompliance		91		RPh visits/contact documentation
	92		Improper automated dispensing procedures		33		Rx records not in numerical order		73		Formulary not complete

Remarks

(11) Advised to update written security P5 - P55;

It Appears that the three broken balances were removed from operation to be sent for Repair.

Action Taken

(1) ✓ Inspection
(2) ___ Pre-Inspection
(3) ___ Partial Inspection
(4) ___ Visit
(5) ___ Other _____

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Agent of the Texas State Board of Pharmacy

Authorized Individual for the Pharmacy

April 17, 2019
Date

Time of Exit

Souchinda Nanthavongdouangsy PIC 42524
Printed Name and Title of Authorized Individual

Texas State Board of Pharmacy

Inspection Report for Pharmacies Compounding Sterile Preparations

Circle One: (Class A-S) Class B Class C-S

Name of Pharmacy Empower Pharmacy TSBP License # 26444

Deficiency key: Circled items need improvement (N/I); Refer to Legal Division (R/L) for review and possible discipline; and Warning Notices (W/N) require corrective action within a designated timeframe. For an explanation of specific violations noted, refer to remarks section of inspection report. Note: "M" = Multiple Codes

R/L	Code	W/N	
			Environment
	M		Is cleanroom clean/free of objects that shed particles? (109) Contain only appropriate supplies? (119) Used only for sterile preps? (110)
	M		Does ante-area provide at least ISO Class 8 under dynamic conditions? (101) Contain a hands-free sink with hot/cold running water? (115)
	M		Does buffer area provide at least ISO Class 7 under dynamic conditions? (102) Area free from sources of water (e.g., sink/floor drains)? (106)
	108		Is there hands-free access to the buffer area?
	113		Are floors, walls, ceilings & fixtures smooth/impervious and free from cracks & crevices? Does floor covering enable regular disinfection (112)?
	118		Are supplies stored above the floor to permit adequate floor cleaning?
	127		Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area/room and ante-area/room and between the ante-area/room and the general environment? Pressure between ISO 7 & general environment shall not be less than 0.02" water column.
	M		Are temperature and humidity monitored (documented) and within required range? (116) Thermometer available for cleanroom and refrigerator? (167)
			Primary Engineering Control (PEC) Device - i.e., Laminar Air Flow Hood, BSC, CAI, or CACI
	126		Is the Laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02-0.05" water?
	121		Is the PEC able to maintain at least ISO Class 5 conditions, while compounding sterile preparations?
	M		Are hazardous drugs prepared in a Class II or III vertical flow BSC or CACI located in an ISO 7 area physically separated from other areas? (246) Does the BSC or CACI have not less than 0.01" negative pressure adjacent to the positive pressure ISO 7 environment? (247)
	M		Does the CAI provide unidirectional flow? (105) If the CAI or CACI is used for high risk compounded sterile preparations, then is the CAI/CACI placed in an ISO 8 environment? (104)
	122		If the CAI is not required to be placed in an ISO 7 environment, does the pharmacy maintain documentation from the manufacturer?
	M		PEC certified by independent contractor every 6 months & when relocated? (124) Are prefilters inspected periodically & replaced as needed? (125)
	128		Are differential pressures monitored and documented at least every work shift (minimum daily) or by a continuous recording device?
			Equipment and Supplies
	M		Does the pharmacy have disposable needles, syringes, and other required or applicable supplies? (174) Does the pharmacy have lint-free towels or wipes? (177) Does the pharmacy have masks, caps, gowns with tight cuffs, shoe covers, and beard covers? (180)
	M		Does pharmacy have handwashing agents w/ bactericidal action? (176) Disinfectant cleaning solutions and dedicated cleaning supplies? (175)
	M		Does the pharmacy have hazardous spill kits, if applicable (179)? Appropriate disposal containers for needles and syringes? (171)
	170		Does the pharmacy have sterile IPA, sterile gloves, and waterless alcohol-based surgical hand scrub?
	178		Does the pharmacy have appropriate filters and filtration equipment?
	181		If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy on a daily basis-is it documented?
	172		Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations?
			High-Risk Sterile Preparations (CSPs)
	103		If high-risk CSPs are compounded, does buffer area provide physical separation from other compounding areas?
	M		Is sterility testing performed under the following conditions: CSPs prepared in groups > 25? (231); MDV prepared for multiple pts or when exposed > 12 hrs at 2-8°C before sterilized? (232); Exposed > 6 hrs at warmer than 8° C before sterilized? (233)
	237		Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with sterile, pyrogen free water, and then thoroughly drained or dried immediately before use for high-risk compounding?
	238		Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2 micron filter to remove particulate matter? Sterilization by filtration shall be performed with a sterile 0.2 micrometer or 0.22 micrometer pore size filter within an ISO Class 5 environment or better.
	165		Are filter integrity tests being performed and documented (e.g., bubble point)?
	239		Are pre-sterilization procedures (weighing & mixing) completed in an ISO Class 8 environment or better?
			Library
	M		Does the pharmacy have: Reference on injectable drugs (154), Specialty Reference (155), Applicable USP Chapters (156)?

R/L Code W/N

			Hazardous Sterile Preparations
	M		Do personnel wear protective apparel (242); use safety/containment techniques (243); dispose of waste appropriately (244); affix proper label (245)?
	248		If using a BSC or CACI, does pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?
	249		Does pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment?
	250		Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?
			Personnel Cleansing, Garbing and Hand Hygiene
	M		Does hand sanitizing and gowning occur in the ante-area (outside the buffer area)? (202) Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around wrist and enclosed at the neck. Is the order of garbing appropriate? (180)
	M		Do personnel remove: cosmetics (194); hand, wrist, and body jewelry or piercings (195); Are natural nails kept neat and trim (no artificial nails)? (196) Do personnel remove debris underneath fingernails using nail cleaner under warm water? (200)
	192		Are personnel with apparent illness or open lesions compounding sterile preparations?
	241		When personnel temporarily exit the ISO 7 environment, are re-donning procedures properly followed?
	M		Do personnel engage in proper hand hygiene? (201) Do personnel dry hands and forearms using lint-free disposable towels or hand-dryer? (203)
	204		Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside buffer area & prior to donning sterile gloves?
	206		Is sterile IPA applied to gloves throughout the day & when non-sterile surfaces are touched?
			Cleaning and Disinfection Procedures
	182		Does pharmacy have written procedures regarding cleaning & disinfecting (e.g., beginning of shift; every 30 minutes; before each batch; & spills)?
	230		Is cleaning performed by trained personnel using approved agents (described in written SOPs)?
	228		Are supplies and equipment that are removed from shipping cartons wiped with a disinfecting agent - such as sterile 70% IPA?
	M		Are all areas properly cleaned? Daily (floors, DCA)? (226) Weekly, Monthly (walls, ceilings, shelving)? (227) Does pharmacy maintain documentation of cleaning procedures [i.e., date/time of cleaning, type of cleaning, and name(s) of person(s) carrying out the cleaning]? (229)
			Environmental Sampling
	M		Is surface sampling conducted in all ISO classified areas on a periodic basis? Are these results evaluated and addressed? (270) i.e. Action Levels followed? (271)
	M		Is viable air sampling performed? (272) And documented by properly trained individuals for all risk levels every 6 months? (273)
			Records of Compounded Sterile Preparations
	252		Does the pharmacy maintain records relating to CSPs for a minimum of 2 years?
	M		Do records include: date (253); formula (254); who prepared (255); who checked (256); quantity (257); container used and number of units prepared (258); criteria for BUD (259); and documentation of performance of quality control procedures? (260) Other?
	M		Are batch compounding records complete? (261) Are master worksheets developed and approved by RPh (262)?
			General Operational Requirements
	166		Is RPh available at all times (24/7)?
	M		Are written SOPs followed to ensure accountability, accuracy, quality, safety, and uniformity? (187) Does pharmacy have all required written procedures (e.g., pharmaceutical care services, viable air sampling plan, and recalls)? Does pharmacy follow recall procedures? (188)
	158		If pharmacy compounds commercially available products, does pharmacy meet requirements for such compounding?
	275		Does pharmacy dispense prescriptions to patients in other states without proper licensure in those states?
			Office Use Compounding/Distribution
	163		Does pharmacy have written agreement with prescriber? Does written agreement meet all requirements?
	162		If pharmacy is distributing compounded sterile preparations to another pharmacy, does pharmacy meet requirements for such distribution?
			Quality Control and Verification of Compounding Accuracy
	M		Does a RPh review all compounding records for accuracy and perform final check? (207) Are periodic in-process checks defined in written procedures? (185)
	191		Are all drug components manufactured in an FDA-registered facility? Are Certificates of Analysis available, if applicable?
			Label
	M		Is CSP properly labeled to include: generic name (209); compounded by pharmacy (210); BUD (211) If prepared in batch, do labels contain: unique lot# (213); quantity (214); cautionary statements (215); and device-specific instructions, if applicable (216)?
	220		Are CSPs assigned a beyond-use-date that is based upon the specified labeling for the drug, appropriate literature sources, and/or direct testing?
			Training and Competency Testing
	129		Has each pharmacist completed the required education and training prior to engaging in sterile compounding?
	130		Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?
	142		Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation and testing (e.g., media fill testing, gloved fingertip/thumb testing)? Does pharmacy have an on-the-job training program?
	144		Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel?

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, Texas 78701
(512) 305-8000

WARNING NOTICE OF VIOLATION(S) REQUIRING CORRECTION

Name of Pharmacy Empower Pharmacy	
Pharmacy License Number 26444	**Date of Inspection** April 17, 2019

Notice is hereby given that you are not in compliance with the following laws and rules governing the practice of pharmacy. Unless the conditions noted below are corrected, disciplinary action may be instituted against the pharmacy license and the license of the pharmacist-in-charge.

I hereby acknowledge that the laws and/or rules cited in the Warning Notice below have been explained to me by the Board of Pharmacy Officer/Inspector.

Signed: [signature] **Date:** 4/17/2019

1. ***Law/Rule:*** 291.10(c)(2) ***Code:*** 4

Explanation of Violation and Correction Needed:
Failure to properly maintain prescription balances. Either reduce or replace, or have reversed by the authorized person, immediately.

Due Date for Completed Correction: May 17, 2019

2. ***Law/Rule:*** _____ ***Code:*** _____

Explanation of Violation and Correction Needed:

Due Date for Completed Correction: _____

Warning Notice Page 1 of 1

CERTIFICATE No. 00

RECEIVED CERTIFICATE No. _____

DATED Jan 14, 2009

FOR 100 PERCENTAGE INTEREST

ON _____

ISSUED TO

NAME _____

ADDRESS _____

00 | ORGANIZED UNDER THE LAWS OF THE STATE OF TEXAS | PERCENTAGE INTEREST 100

Percentage Interest

Empower Clinic Services, L.L.C.

A LIMITED LIABILITY COMPANY

This Certifies That Shaun Noonan *is the owner of* 100 *Percentage Interest of the above Limited Liability Company transferable only on the books of the Limited Liability Company by the holder hereof in person or by duly authorized attorney upon surrender of this Certificate properly endorsed, and is entitled to the full benefits and privileges of such membership subject to the duties and obligations, as more fully set forth in the Company's Certificate of Formation/Operating Agreement/Regulations for this Limited Liability Company. Transfer of this Percentage Interest is subject to restrictions in the books of the Limited Liability Company.*

In Witness Whereof, *The said Limited Liability Company has caused this Certificate to be executed by its duly authorized Member(s)/Manager(s) and its Limited Liability Company Seal to be hereunto affixed, this* 14th *day of* Jan *A.D.,* 2009

Curt Groom

Curt Groom

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Ruth R. Hughs
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Empower Clinic Services, L.L.C. (file number 801062724), a Domestic Limited Liability Company (LLC), was filed in this office on December 12, 2008.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on September 08, 2019.

Ruth R. Hughs
Secretary of State

This certifies that the pharmacy named below is hereby licensed to operate as a Class **G** pharmacy.

License No. **32769** Expiration Date: **8/31/2021**

Balances: **0**

EMPOWER PHARMACY
200 WESTLAKE PARK BLVD STE 1800
HOUSTON TX 77079

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Re:	Empower Pharmacy
Address:	200 Westlake Park Boulevard Suite 1800 Houston, Texas 77079
License No.:	32769
Date Issued:	August 2, 2019
Licensure Status:	Active
Expiration Date:	August 31, 2021
Type of Pharmacy:	Central Processing Pharmacy – Class G
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Empower Pharmacy (Texas Pharmacy License #32769) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Megan G. Holloway

Megan G. Holloway
Assistant General Counsel
Texas State Board of Pharmacy

September 20, 2019
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

TEXAS STATE BOARD OF PHARMACY

Pharmacist-in-Charge Attestation:

I hereby attest the following statements are true and accurate (*initial each statement below*):

SN I am the Pharmacist-in-Charge (PIC) of Empower Pharmacy (*Name of Pharmacy*) pharmacy license number 26444 (*Pharmacy License Number*) and I ☒ was / ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on April 17, 2019 (*Date of Inspection*);

SN I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector;

SN I reviewed the document titled *Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF* (on the reverse side of this attestation);

SN If applicable, the Warning Notice issued contains 1 deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice;

SN I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please mail, email, or fax this completed form to the Board office within 7 days of the date of the inspection:

Texas State Board of Pharmacy
Attn: Compliance Division
333 Guadalupe St., Suite 3-500
Austin, Texas 78701
Email: inspections@pharmacy.texas.gov
Fax: 512-305-8082

Signed: _____ (*Signature of PIC*) **Date:** 4/17/2019

Printed Name: Suchinda Nuntharongdouangsy **License No.:** 42524

Notification of Agreed Order

Empower Pharmacy entered into an Agreed Order with the Oklahoma State Board of Pharmacy regarding allegations involving the compounding of what the Oklahoma State Board of Pharmacy considered essential copies under Oklahoma law. Please note that our home state Board, the Texas State Board of Pharmacy, did not consider these compounds essential copies (see attached). FDA also did not consider these compounds essential copies by their final guidance issued in January 2018 (see attached) and evidenced through FDA's most recent inspection of Empower Pharmacy in January 2018.

In the attached Agreed Order with Oklahoma, Empower did not admit or deny violating any law or the Board's rules. The Agreed Order also does not constitute a restriction on Empower's pharmacy license, and, most importantly, the Informal Disposition is not considered discipline in Oklahoma. The Oklahoma State Board of Pharmacy also refrained from taking administrative or other action against Empower for the alleged conduct. Although the agreement with the Oklahoma State Board of Pharmacy is not considered discipline or a restriction on Empower's license we hereby inform you, out of an abundance of caution given diverse reporting requirements of state boards, of the attached Agreed Order.

TEXAS STATE BOARD OF PHARMACY

December 19, 2018

Empower Pharmacy
c/o Souchinda Nanthavongdouangsy, R.Ph.
Pharmacist-in-Charge
5980 W Sam Houston Pkwy N, Ste 300
Houston, TX 77041

RE: Empower Pharmacy, License #26444
Complaint #2019-00426

The Texas State Board of Pharmacy (Board) received a copy of the Agreed Findings of Fact, Conclusions of Law and Final Order of the Oklahoma State Board of Pharmacy entered June 13, 2018, which imposed a non-disciplinary deferral of probation against the license and a $37,200 fine. The Order of the Oklahoma State Board of Pharmacy references allegations the pharmacy compounded commercially available medication and medication that was essentially a copy of a commercially available product. This violation is addressed in Section 565.002(a)(3) of the Texas Pharmacy Act, Tex. Occ. Code Ann., Title 3, Subtitle J; and Section 291.133(d)(1)(C) and (D) of the Texas Pharmacy Board Rules, 22. Tex. Admin. Code.

Following Board staff's review of this matter, this complaint was closed with this letter specifically notifying you of applicable Texas pharmacy law and rules. A copy of the referenced pharmacy laws and rules are attached for your review. Board staff encourages you to develop and implement policies and procedures to ensure compliance with pharmacy compounding requirements. If additional information indicates you may have violated Texas laws, the laws of another state, or the United States, you may be subject to further review and action by the Board.

A reply to this letter is not required. If you choose to reply, please include the complaint number listed above in your written reply.

Sincerely,

David Meryman
Compliance Analyst

DM/hh

BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA

IN THE MATTER OF THE COMPLAINT AGAINST:	)	
Empower Pharmacy (99-7594) **5980 W. Sam Houston Pkwy, Ste 300** **Houston, TX 77041**	)	**Case No. 1510**

AGREED FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER

This matter came for hearing on June 13, 2018, before the Oklahoma State Board of Pharmacy ("Board"). Board members St. Cyr, Dudley, Spoon, Wilson, Adams, and Whitehead were present. President Whitehead presided. John M. Settle, Assistant Attorney General, served as prosecutor for the Board. Respondent appeared and was represented by legal counsel, Doug Rice of Derryberry & Naifeh, LLP.

The Complaint in this matter is incorporated by reference into this Order.

The Board and Respondent hereby agree to the following Findings of Fact, Conclusions of Law and Final Order. Respondent has been advised of the right to contest the allegations of the Complaint herein, to cross-examine witnesses, and to present witnesses and evidence in defense of the allegations of the Complaint. Respondent hereby knowingly and voluntarily waives these rights. In addition, Respondent understands and acknowledges that this document is a public record that must be provided to anyone requesting it.

Should this Order not be accepted by the Board, Respondent agrees that neither the presentation of the Order to the Board nor the Board's consideration of the Order will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participating in proceedings related to the matters set forth in the Order.

AGREED FINDINGS OF FACT

1. Respondent is licensed as a non-resident pharmacy in the State of Oklahoma and is located at 5980 W. Sam Houston Pkwy, Ste 300, Houston, TX 77041. Souchinda Nanthavongdouangsy, D.Ph. #15854, is Respondent's pharmacist-in-charge.

2. Respondent compounded the following products that the Board alleges are commercially available or essentially copies of commercially available FDA-approved drug products under Oklahoma law:

HCG 11,000 units/vial & units/vial kits	#287 prescriptions
HCG 5,000 units/vial & units/vial kits	#85 prescriptions

HCG injection in 5,000 units per vial is commercially available. HCG injection in 11,000 units per vial is essentially a copy of the HCG 10,000 units/vial.

AGREED CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter and over the Respondent pursuant to 59 O.S. §§ 353.7 and 353.26.

2. Any Finding of Fact which is properly a Conclusion of Law is hereby incorporated by reference and vice versa.

3. Respondent has neither admitted nor denied violating OAC 535:15-10-53(a) by compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product, as set forth in Counts 1 through 372 of the First Amended Complaint.

4. Pursuant to 59 O.S. §353.7(12), for any registrant who violates any provision of the Oklahoma Pharmacy Act including the Board's rules, the Board has authority to levy fines not to exceed Three Thousand Dollars ($3000.00) for each violation; to reprimand, place on probation or suspend or revoke the license of a licensee; to require extra hours of continuing education and to require participation in a rehabilitation program for the impaired. The Board may also impose as part of any disciplinary action the payment of costs expended by the Board for any legal fees and costs, including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees.

AGREED ORDER

1. Respondent, Empower Pharmacy, a non-resident pharmacy in the State of Oklahoma and holder of non-resident pharmacy license number 99-7594, neither admits nor denies guilt on all Three Hundred Seventy-two (372) Counts. In order to resolve this dispute outside of a hearing on the merits, however, Respondent agrees as follows:

2. Respondent is hereby fined One Hundred and no/100 Dollars ($100.00) for each Count 1 through 372 of the Complaint for a total fine on said Counts 1 through 372 of Thirty-seven Thousand Two Hundred and no/1 00 Dollars ($37,200.00).

3. The total amount of fines due from Respondent is Thirty-seven Thousand Two Hundred and no/1 00 Dollars ($37,200.00). This fine is due on June 13, 2018.

4. This Agreed Order is not considered "discipline" by the Board, but instead is a deferral of the same pending a probationary period of two years. After a period of two years, any discipline by the Board shall be suspended unless Respondent has violated this Agreed Order, or any Oklahoma Board of Pharmacy rule. This deferred penalty is intended to ensure continued compliance with the Oklahoma Board of Pharmacy rules.

5. Failure of Respondent to abide by any of the terms of this Agreed Order could result in disciplinary action as allowed by the Oklahoma Pharmacy Act or the Board's rules.

6. The Board retains jurisdiction over the instant case until all matters are finally resolved as set forth in this Order.

All participating members vote "Aye".

Kyle Whitehead, D.Ph., President
Oklahoma State Board of Pharmacy

State of Oklahoma)
) ss.
County of Oklahoma)

Subscribed and sworn before me on this the 13th day of June, 2018.

[SEAL]

Melissa Reichert
Notary Public

My Commission Expires: 3/13/22

Commission No: 18002597

I, Shaun Noorian, Founder and Chief Executive Officer, of Empower Pharmacy, have read the above Agreed Findings of Fact, Conclusions of Law and Agreed Order. I understand that by its terms Empower Pharmacy, will be waiving certain rights accorded under Oklahoma Law. I also understand that Empower Pharmacy, must comply with the terms and conditions of the Agreed Order or discipline will be imposed on Empower Pharmacy. On behalf of Empower Pharmacy, LLC., I agree to the above Agreed Order.

Dated this 11 day of June , 2018.

Shaun Noorian
Founder & Chief Executive Officer
Empower Pharmacy Respondent

State of Texas)
) ss.
County of Harris)

Subscribed and sworn before me on this the 11 day of June, 2018.

[SEAL]

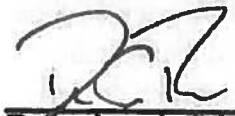
SUSAN VAN BERGEN
Notary Public, State of Texas
Comm. Expires 02-10-2020
Notary ID 130833332

Notary Public

My Commission Expires: 02-10-2020

Commission No: 130833332

AGREED AND APPROVED:



Douglas A. Rice, OBA #16927
DERRYBERRY & NAIFEH, LLP
4800 North Lincoln Boulevard
Oklahoma City, OK 73105
Telephone: (405) 528-6569
Facsimile: (405) 528-6462
Attorney for Respondent

Notification of Stipulation and Consent Order for Informal Disposition

Empower Pharmacy entered into a Stipulation and Consent Order for Informal Disposition with the Idaho State Board of Pharmacy regarding allegations involving Empower Pharmacy's filling of prescriptions for three patients from an out-of-state prescriber that allegedly did not attain appropriate licensure from the Idaho Medical Board as defined in the Idaho Telehealth Access Act, and allegedly did not have the requisite prescriber-patient relationship prior to issuing a prescription.

In the attached Stipulation and Consent Order for Informal Disposition with Idaho, Empower did not admit or deny violating any law or the Board's rules. The Informal Disposition also does not constitute a restriction on Empower's pharmacy license, and, most importantly, the Informal Disposition is not considered discipline in Idaho. The Idaho State Board of Pharmacy also refrained from taking administrative or other action against Empower for the alleged conduct. Although the disposition with the Idaho State Board of Pharmacy is not considered discipline or a restriction on Empower's license we hereby inform you, out of an abundance of caution given diverse reporting requirements of state boards, of the attached Informal Disposition.

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

In the Matter of the License of: EMPOWER PHARMACY, Mail Service Pharmacy License No. 36411MS, Respondent.	)	Case No. BOP 18-053 **STIPULATION AND CONSENT ORDER FOR INFORMAL DISPOSITION: I.C. § 67-5241(1) ("Stipulation")**

WHEREAS, information has been received by the Idaho Board of Pharmacy ("Board") that could constitute grounds for the initiation of an administrative case against Empower Pharmacy ("Respondent"); and,

WHEREAS, the Parties wish to expeditiously settle this matter of possible administrative violations relating to non-resident pharmacies dispensing controlled substances to Idaho residents, by Informal Disposition pursuant to Idaho Code § 67-5241(1);

NOW, THEREFORE, IT IS HEREBY STIPULATED AND AGREED between the undersigned Parties that this matter shall be settled and resolved upon the following terms:

A. JURISDICTION OF THE BOARD

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

2. Respondent is a licensee of the Board and holds Mail Service Pharmacy License No. 36411MS. Respondent's license is subject to the provisions of title 54, chapter 17, Idaho

Code, title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 27.01.01, *et seq*.

B. STIPULATED FACTS

1. Board staff's review of the PMP reports and records provided by Respondent revealed the following:

A. Idaho resident D.B. received from Respondent delivery of four (4) prescriptions fills for testosterone, a Schedule III controlled substance, which were issued in December 2016 through October 2017, by prescriber, J.S., located in Tampa, Florida.

B. Idaho resident J.S. received delivery of four (4) prescription fills for testosterone from Respondent, which were issued in October 2016 through September 2017 by prescriber, J.S., located in Tampa, Florida.

C. Idaho resident J.H. received delivery of six (6) prescription fills for testosterone from Respondent, which were issued in December 2016 through February 2018 by prescriber, J.S., located in Tampa, Florida.

2. Allegations arose from concerns of the Board that Respondent issued prescription drugs, including Schedule III controlled substances, to the above three (3) patients, based upon prescriptions which may have been invalid, the patients not having been seen in a face-to-face encounter by prescriber, J.S., in accordance with 21 U.S.C. § 829(e) prior to prescribing, and the prescriber not having been in compliance with the Idaho Telehealth Access Act, Title 54, Chapter 56, Idaho Code. Specifically, 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 Idaho Code § 54-5705 requires two-way audio and visual interaction between the provider and patient.

In addition, 21 U.S.C. § 802(54) states that if telemedicine is being practiced, the patient must be in the presence of an onsite practitioner who possesses a valid DEA controlled substance registration and state license, and Idaho Code § 37-2716(a) requires the distant provider to hold a state controlled substance registration in the state where the patient is located.

3. Respondent asserts that the prescriber, J.S., advised Respondent that he had seen these three (3) patients in Florida, prior to prescribing for them, in accordance with 21 U.S.C. § 829(e).

4. Respondent admits that its business practices are subject to the following statutes and rules: Idaho Code §§ 54-1726(1)(f) and (2), 54-1728(1)(f) and (2), 37-2718(a)(4), 37-2719(c), 37-2722(c), 37-2723, 37-2730A(2), 37-2733(a)(1); and IDAPA 27.01.01.110 and 27.01.01.501.

5. Without Respondent admitting or denying that facts support a basis for discipline, and in lieu thereof, the Parties agree to an Informal Disposition pursuant to Idaho Code § 67-5241(1), as settlement and compromise, which shall not be deemed admitting to any acts or omissions which may be alleged, and Respondent agrees, the Board may enter its final Order as set forth in Section C below.

C. STIPULATED, AGREED SETTLEMENT

1. Respondent shall pay a monetary sum of fifteen thousand dollars ($15,000).

2. This monetary sum shall become payable after the Board approves and executes its Order approving this Settlement, to be paid to the Board within 180 days of the date the Order is executed.

3. Commencing the date the Stipulation is executed by the Board, Respondent shall verify that all prescribers issuing prescriptions to Idaho residents to be filled by Respondent shall

have the required prescriber licenses and controlled substance registrations which allow the prescribers to issue 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.

4. Further, Respondent shall designate a representative of its management to whom the Board may direct its communications and inquiries and who shall be responsible for responding to such inquiries. This representative shall be designated in writing within thirty (30) days of the date the Order incorporating this Stipulation is executed.

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

6. All costs associated with Respondent's compliance with the terms of this Stipulation shall be borne solely by Respondent. Nothing relating to this Stipulation shall be considered a restriction of Respondent's licensure.

D. COMPLIANCE WITH STIPULATION

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 of its Order upon appeal to a district court. Thereafter, if there shall be reason to believe Respondent may have violated any terms or conditions of this Stipulation, the Executive Director of the Board may file an administrative complaint, setting forth the allegations of non-compliance and notifying Respondent that Respondent may request a hearing regarding the allegations of non-compliance. If Respondent does not request a hearing on such administrative complaint, any allegations of non-compliance may be deemed admitted.

2. If Respondent fails to comply with this Stipulation, Respondent's license may

then be subject to discipline, up to and including suspension or revocation. Accordingly, the Board retains jurisdiction over this proceeding, until all matters are finally resolved, as set forth in this Stipulation.

3. Any additional costs and/or attorney fees incurred by the Board in any future enforcement action based upon any allegation of this Stipulation shall be borne solely by Respondent.

E. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

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

1. The Board has jurisdiction to proceed in this matter.

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

3. Respondent acknowledges that, should the Board have brought a formal complaint in this matter, Respondent would have had certain rights, including but not limited to: the right to a full and complete hearing, pursuant to the Idaho Administrative Procedure Act; the right to confront and to cross examine witnesses; the right to present evidence, to call witnesses and to testify on its own behalf; the right to administrative reconsideration; the right to appeal any findings to the district court; and, any and other rights provided pursuant to the Idaho Administrative Procedure Act, statutes and rules governing the practice of pharmacy in Idaho, and otherwise as may be applicable pursuant to law. By entering into this Stipulation, Respondent agrees to forgo such rights and process and to waive same as part of the resolution of any allegations which may obtain.

4. Respondent understands that in signing this Stipulation, it agrees to the above terms without further process.

5. Respondent understands that, if approved as proposed, the Board shall execute and issue this Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation"), according to the aforementioned terms, and Respondent agrees to the above Stipulation for settlement of all allegations, which allegations are contested and which Respondent denies. If the Board approves this Stipulation subject to changes, and those changes are acceptable to Respondent, Respondent acknowledges the Stipulation shall take effect, and an order modifying the terms of the Stipulation shall be issued. If the changes are unacceptable, or the Board rejects this Stipulation, this Stipulation shall be of no force or effect. Admissions in this Stipulation and negotiations preceding the signing of this Stipulation shall not be admissible at any subsequent administrative hearing.

6. In the event this Stipulation is rejected by the Board, or any changes proposed by the Board are not accepted, Respondent waives any right it may have to challenge the Board's impartiality to hear the allegations in any subsequent administrative proceedings, based on that the Board had considered and rejected this Stipulation.

7. Respondent understands the Board shall have the right to make full disclosure of this Stipulation 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 by the Executive Director of the Board and the Deputy Attorney General responsible for this matter to the Board with a recommendation for approval at the next regularly scheduled meeting of the Board.

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

12. Each Party shall bear its own costs and fees associated with this matter.

DATED this 2nd day of July, 2019.

EMPOWER PHARMACY

By: _____

Printed: Shaun Noorian

Its: CEO

Authorized Representative for Respondent

I concur in this Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation") and recommend that the Board adopt the same by its Order.

DATED this 3 day of July, 2019.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

STEVEN L. OLSEN
Deputy Attorney General

I also concur in this Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation") and recommend the Board adopt the same by its Order.

DATED this 9th day of July, 2019.

IDAHO BOARD OF PHARMACY

By: Nicole Chopski
Nicole Chopski, PharmD
Executive Director

ORDER

Pursuant to Idaho Code § 54-1728 and § 37-2718, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation"), and it is hereby Ordered that the Parties shall comply with said terms and conditions.

DATED this 15 day of January, 2019.

Holly Henggeler, PharmD
Board Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 16th day of [illegible], 2019, I caused to be served a true and correct copy of the foregoing STIPULATION AND CONSENT ORDER FOR INFORMAL DISPOSITION: I.C. § 67-5241(1) ("Stipulation") by the following method to:

Ms. Souchinda Nanthavongdouangay
Empower Pharmacy
5980 W. Sam Houston Pkwy N, Suite 300
Houston, TX 77041

- ☒ 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

9D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY 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 Pharmacy* or ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** _____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,7*
☒ *Non Publicly Traded Corporation – Pages 1,2,4,7*
☐ *Partnership - Pages 1,2,5,7*
☐ *Sole Owner – Pages 1,2,6,7*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Golden Gate Pharmacy Services

Physical Address: 8 Digital Drive Suite 200, Novato, CA 94949

Mailing Address: 8 Digital Drive Suite 200

City: Novato State: CA Zip Code: 94949

Telephone: 415-455-9042 Fax: 415-455-9318

Toll Free Number: 1-888-308-4650 (Required per NAC 639.708)

E-mail: nicole.lofholm@ggprx.com Website: www.ggprx.com

Managing Pharmacist: Nicole Clausen License Number: CA 60056

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☒ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds_____)	☐	☒ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☒	☐ Community	☒	☒ Long Term Care e 10/9/19
☐	☐ Other: _____	☐	☒ Sterile Compounding **
		☐	☒ Non Sterile Compounding
	All boxes must be checked	☐	☒ Mail Service Sterile Compounding **
	For the application to be complete	☐	☐ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

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, site 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.

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 pharmacy 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.

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

Nicole Lofholm Clausen
Print Name of Authorized Person

10/15/2019
Date

Board Use Only	Date Processed:	Amount: $500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: CA

Parent Company if any: Golden Gate Pharmacy Services, Inc.

Mailing Address: 8 Digital Drive Suite 200

City: Novato State: CA Zip: 94949

Telephone: 415-455-9042 Fax: 415-455-9318

Contact Person: Nicole Lofholm Clausen

For any corporation non publicly traded, disclose the following:

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

a) Golden Gate Pharmacy Holdings, Inc, 8 Digital Drive Suite 200 Novato, CA 94949
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 3,000,000

3) What was the price paid per share? $1

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

List any physician shareholders and percentage of ownership.

Name: None %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 5 pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours X

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Nicole Lofholm Clausen

Responsible Person of Golden Gate Pharmacy Services

hereby acknowledge and understand that in addition to the.corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

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

Nicole Lofholm Clausen
Print Name of Authorized Person

10/10/19
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF California)
) ss.
Marin COUNTY)

I, Nicole Lofholm Clausen, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary for Golden Gate Pharmacy Services (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Nicole Lofholm Clausen, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
15th day of October, 2019.

NOTARY PUBLIC

JONATHAN NICOLAISEN
Notary Public - California
Marin County
Commission # 2239235
My Comm. Expires Apr 22, 2022

BOARD OF PHARMACY
1625 NORTH MARKET BLVD., SUITE N-219
SACRAMENTO, CA 95834
(916) 574-7900

Renewal Certificate

Retail Pharmacy Permit

LICENSE NO. PHY 56170
RECEIPT NO. 91680029

VALID UNTIL AUGUST 01, 2020

GOLDEN GATE PHARMACY SERVICES
8 DIGITAL DR STE 200
NOVATO CA 94949

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

18/19

18/19 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (12/31/05) PH

Rebecca Lofholm
President
Ralston Lane
Newcastle, CA 95658

Paul Lofholm
Vice President
Ralston Lane
Newcastle, CA 95658

Nicole Clausen
Secretary
Zandra Place
Novato, CA 94945

Erik Clausen
Chief Financial Officer
Zandra Place
Novato, CA 94945

Stock Transfer Ledger
Golden Gate Pharmacy Services, Inc.

NAME OF STOCKHOLDER	PLACE OF RESIDENCE	DATE BECAME OWNER	CERTIFICATE # ISSUED	# OF SHARES ISSUED	FROM WHOM SHARES TRANSFERRED	CERTIFICATE # SURRENDERED	# OF SHARES SURRENDERED	DATE OF TRANSFER OF SHARES	TO WHOM SHARES ARE TRANSFERRED
December 11, 2014: Recapitalization of stock from 100,000 authorized shares to 3,001,000 authorized shares; New share certficate issued									
Paul W. Lofholm and Rebecca Ellen Lofholm, Trustees of The Paul W. and Rebecca Ellen Lofholm 1992 Trust dated December 3, 1992 as restated February 21, 2008	California	12/11/2014	1	3,000,000	Rebecca Ellen Loholm (Reissue after recapitalization)	1	3,000,000	12/31/2015	Golden Gate Pharmacy Holdings, Inc.
Golden Gate Pharmacy Holdings, Inc.	California	12/31/2015	2	3,000,000	Paul W. Lofholm and Rebecca Ellen Lofholm, Trustees of The Paul W. and Rebecca Ellen Lofholm 1992 Trust dated December 3, 1992 as restated February 21, 2008				

Stock Transfer Ledger
Henley-Putnam University

Series B Preferred Stock

NAME OF STOCKHOLDER	PLACE OF RESIDENCE	DATE BECAME OWNER	CERTIFICATE # ISSUED	# OF SHARES ISSUED	FROM WHOM SHARES TRANSFERRED	CERTIFICATE # SURRENDERED	# OF SHARES SURRENDERED	DATE OF TRANSFER OF SHARES	TO WHOM SHARES ARE TRANSFERRED

74/339 1:6

GOLDEN GATE PHARMACY
8 DIGITAL DR STE 200
NOVATO, CA 94949-8705

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BG4451251	09-30-2022	$731
SCHEDULES	**BUSINESS ACTIVITY**	**ISSUE DATE**
2,2N, 3,3N,4,5	RETAIL PHARMACY	08-19-2019

GOLDEN GATE PHARMACY
8 DIGITAL DR STE 200
NOVATO, CA 94949-8705

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

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

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

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

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BG4451251	09-30-2022	$731
SCHEDULES	**BUSINESS ACTIVITY**	**ISSUE DATE**
2,2N, 3,3N,4,5	RETAIL PHARMACY	08-19-2019

GOLDEN GATE PHARMACY
8 DIGITAL DR STE 200
NOVATO, CA 94949-8705

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

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

Form DEA-223 (9/2016)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

October 3, 2019

GOLDEN GATE PHARMACY SERVICES
8 DIGITAL DR STE 200
NOVATO CA 94949

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: GOLDEN GATE PHARMACY SERVICES

License Type: PHARMACY

License Number: PHY 56170

Status: ACTIVE

Issue Date: 08/18/18

Expiration Date: 08/01/20

Address of Record: 8 DIGITAL DR STE 200 NOVATO CA 94949

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Interim Executive Officer

By

Barbera Schleicher
Public Inquiry Analyst
(916) 518-3081
Barbera.Schleicher@dca.ca.gov

State of California
Secretary of State
CERTIFICATE OF STATUS

ENTITY NAME:

GOLDEN GATE PHARMACY SERVICES, INC.

FILE NUMBER:	C1919883
FORMATION DATE:	01/03/1995
TYPE:	DOMESTIC CORPORATION
JURISDICTION:	CALIFORNIA
STATUS:	ACTIVE (GOOD STANDING)

I, ALEX PADILLA, Secretary of State of the State of California, hereby certify:

The records of this office indicate the entity is authorized to exercise all of its powers, rights and privileges in the State of California.

No information is available from this office regarding the financial condition, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of October 02, 2019.

ALEX PADILLA
Secretary of State

TAW

GOLDEN GATE
PHARMACY SERVICES

phone 415.455.9042
fax 415-455-9318
8 Digital Dr Suite 200, Novato, CA 94949

10/09/2009

Nevada Board of Pharmacy

Re: Golden Gate Pharmacy Services – CA Permit PHY 56170
Application for Out-of-State Pharmacy Permit/License

Dear Sir or Madam:

Please accept this letter as additional information related to Golden Gate Pharmacy Services application for out-of-state pharmacy license in the state of Nevada. Specifically, as it relates to the inquiry whether the pharmacy or its owners and corporate officers entered into a settlement agreement with any government regulatory agency or whether the owners or corporate officers were subject to any administrative or disciplinary action by licensing agency within the last five (5) years.

On or about March 31, 2017; the owners of Golden Gate Pharmacy Holdings, Inc., the parent company of Golden Gate Pharmacy Services, entered into a Settlement Agreement (hereinafter "Agreement") with the United States of America for the purpose of resolving allegations of record keeping deficiencies that occurred at facilities held under the corporate umbrella of Golden Gate Pharmacy Holdings., Inc.

The Agreement was entered into by all parties without any admission of wrongdoing and solely for the purpose of expedient resolution of the matter.

Subsequently, shareholders Rebecca Lofholm and Nicole Lofholm-Clausen were cited by the California State Board of Pharmacy in February of 2018 for the same deficiencies that gave rise to the aforementioned settlement. Please note that Citation or Citation & Fine are not disciplinary actions in the State of California. Attached hereto, please find copies of the aforementioned Agreement and citations.

Please feel free to contact me with any questions or concerns related to this matter.

Sincerely,

Nicole Lofholm Clausen
Chief Executive Officer and Secretary
Pharmacist-in-Charge

United States Attorney
Northern District of California

9th Floor, Federal Building
450 Golden Gate Ave., Box 36055
San Francisco, CA 94102-3495

(415)436-7200
FAX: (415) 436-6748

August 11, 2016

VIA CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Erik M. Clausen
Golden Gate Pharmacy Holdings, Inc.
1525 Francisco Boulevard East, Suite 2-C
San Rafael, CA 94901

Dear Mr. Clausen:

The Drug Enforcement Administration ("DEA") has advised the United States Attorney's Office that it believes Golden Gate Pharmacy Holdings, Inc. ("GGP") has violated certain provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (also known as the Controlled Substances Act or "CSA"), 21 U.S.C. § 801 *et seq.*

The CSA creates a closed system of distribution for those authorized to handle controlled substances and listed chemicals and is designed to prevent diversion of controlled substances by, among other things, requiring DEA registrants to create, keep and maintain certain records. The CSA's provisions require DEA registrants to, among other things: (1) take and record an accurate physical biennial inventory; (2) maintain accurate and complete receiving, manufacturing, and distribution records; (3) retain records with the complete names and number of units or volumes of the controlled substances' finished forms; (4) maintain records of the quantities and strength of controlled substances acquired from suppliers; (5) maintain records documenting the customer's DEA registration number and registered location for outbound shipments; (6) maintain properly completed DEA Form 222s; (7) maintain complete and accurate records of commercial or bulk containers shipped to purchasers; and (8) maintain complete and accurate records of commercial or bulk containers received from suppliers. When registrants fail to discharge these obligations under the CSA, there is an increased risk of diversion of controlled substances.

On September 4, 2014, the DEA initiated an investigation of GGP in accordance with the Diversion Scheduled Investigation Work Plan for Fiscal Year 2014. DEA diversion investigators conducted the investigation at GGP until November 21, 2014. As a result of its on-

site investigation, the DEA identified approximately 4,750 recordkeeping and other violations of the CSA by GGP. The DEA identified violations of the CSA in each of the areas described above; the violations show systemic and pervasive recordkeeping deficiencies.

A brief summary of the violations that DEA found in the 2014 investigation follows: GGP engaged in the unauthorized manufacture of controlled substances and medicinal doses to supply practitioners with stock for office-based dispensing, failed to complete a biennial inventory that accurately accounted for all controlled substances on hand, failed to maintain records documenting manufacture of controlled substances, failed to maintain a record of the date controlled substances were received, failed to maintain a record of the number of units or volume of finished form of controlled substances it compounded, failed to maintain a record of the number of units of finished form of controlled substances it distributed, failed to maintain records of customers' return of controlled substances, failed to maintain a record of the DEA registration number of the registrant to whom it distributed controlled substances, failed to record information required for Form 222 records, failed to execute Form 222 records, failed to maintain purchaser or supplier copies of Form 222 records, filled prescriptions issued for the purpose of obtaining controlled substances for general office dispensing, filled prescriptions issued by an unauthorized person, and filled improperly executed prescriptions, among other violations.

The CSA and its regulations prohibit a person from distributing controlled substances except pursuant to a written order "made on a form to be issued by the Attorney General," *i.e.*, DEA Form 222. 21 U.S.C. § 828(a). 21 U.S.C. § 842(a)(5) provides that it is unlawful for a person to "refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II" of the CSA. A person or entity who violates the CSA shall be subject to civil penalties of $10,000 or $25,000 per violation, depending on the type of violation. As discussed above, in the 2014 investigation, the DEA found approximately 4,750 violations by GGP of the CSA.

We are considering filing a complaint against GGP in U.S. District Court to recover the civil penalties resulting from these apparent violations. If GGP is interested in resolving this matter prior to the commencement of litigation, please contact the undersigned within 14 days of receipt of this letter. If GGP has an attorney to represent it in this matter, please have your attorney contact the undersigned instead.

Very truly yours,

BRIAN STRETCH
United States Attorney

JONATHAN U. LEE
Assistant United States Attorney

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into by and between the United States of America ("United States"), acting through the United States Attorney's Office for the Northern District of California, Civil Division ("USAO") (collectively the "United States"), and Golden Gate Pharmacy Holdings, Inc.; Golden Gate Pharmacy Services, Inc.; Ross Valley Compounding Pharmacy, Inc.; Paul W. Lofholm, and Rebecca E. Lofholm (collectively the "Lofholm Parties"), through their authorized representatives. All parties to the Agreement are collectively referred to as "the Parties."

II. RECITALS

The Parties agree to the following recitals:

1. The Drug Enforcement Administration ("DEA") is the component agency of the United States Department of Justice primarily responsible for administering the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("the Act"), and is vested with the responsibility for investigating violations of the Act.

2. Golden Gate Pharmacy Services, Inc. and Ross Valley Compounding Pharmacy ("Ross Valley Pharmacy") are wholly-owned subsidiaries of Golden Gate Pharmacy Holdings, Inc. Golden Gate Pharmacy Services, Inc., d/b/a Golden Gate Pharmacy ("Golden Gate Pharmacy") is registered as a retail pharmacy with the DEA, under registration number BG4451251, with current authorization to handle Schedules II, III, IIIN, IV, and V controlled substances, and are subject to periodic audits and inspections.

3. Ross Valley Compounding Pharmacy, Inc. ("Ross Valley Pharmacy") is registered as a retail pharmacy with the DEA, under registration number FR5051216[1], with current authorization to handle Schedules II, III, IIIN, IV, and V controlled substances, and is subject to periodic audits and inspections. Ross Valley Pharmacy currently identifies as a compounding-only pharmacy, following the sale of its retail pharmacy operation in June 2013.

4. Golden Gate Pharmacy and Ross Valley Pharmacy are each required to operate in accordance with the statutory provisions of the Act and its implementing regulations.

5. The Attorney General, through the United States Attorney's Office, has primary authority to bring civil actions to enforce the Act. *See* 21 U.S.C. § 871 *and* 28 C.F.R. § 0.55(c).

6. The Act creates a closed system of distribution for those authorized to handle controlled substances and listed chemicals. The Act is designed to prevent diversion of controlled substances by, among other things, requiring DEA registrants to maintain and keep certain records.

7. The Act provides that it is unlawful for a person to "refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter" of the Act. 21 U.S.C. § 842(a)(5). By creating this closed system of distribution and the attendant recordkeeping requirements and imposing penalties for recordkeeping violations, the Act seeks to prevent harm to the general public and threats to the public safety created by

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[1] At the time of the Scheduled Investigation, Ross Valley's DEA registration number was BG3090848.

diversion of controlled substances from the Act's permitted distribution scheme to prohibited uses of the controlled substances.

8. A registrant may not distribute to locations other than DEA-registered locations. 21 C.F.R. § 1301.12(a). A registrant may not engage in unauthorized manufacture of controlled substances to supply practitioners with stock for office-based dispensing. 21 C.F.R. § 1301.13(e). A registrant may not include Schedule III controlled substances on Schedule II inventory. 21 C.F.R. § 1304.04(h)(1). A registrant must account for all controlled substances on hand when the inventory is taken. 21 C.F.R. § 1304.11(a). A registrant must take inventory of a controlled substance on the effective date classifying it as a controlled substance. 21 C.F.R. § 1304.11(d). A registrant must include the finished form of each controlled substance on the biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iii)(B). A registrant must include the number of units or volume of each finished form of controlled substance in each container on the biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iii)(C). A registrant must include the number of commercial containers of each finished form of controlled substances on the biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iii)(D). A registrant must include accurate weights on bulk forms. 21 C.F.R. § 1304.11(e)(1)(iv)(B). A registrant must include reasons for expired controlled substances being maintained and whether substances could be used in manufacture in biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iv)(C).

9. A registrant must keep records documenting the receipt, manufacture, or distribution of controlled substances. 21 C.F.R. § 1304.21(a). A registrant must keep records including the number of units or volume of finished form of any controlled substances; acquisition records including the number of units, date, name, address and registration number;

and distribution records including the number of units, date, name, address and registration number. 21 C.F.R. §§ 1304.22(a)(2)(ii), 1304.22(a)(2)(iv), 1304.22(a)(2)(vii).

10. A registrant must keep records of the date shipped and number of packages shipped on the DEA Form 222; must complete and execute accurate DEA Form 222s; must retain the Purchaser Copy of the executed DEA Form 222; must retain the Supplier Copy of the DEA Form 222; must retain the Purchaser Copy of the executed electronic DEA Form 222; and must not distribute a Schedule II controlled substance without the requisite DEA 222 Form at the time of distribution. 21 C.F.R. §§ 1305.13(b), 1305.15(a), 1305.17(a), 1305.17(b), 1305.27(a), 1305.03.

11. A registrant must not fill a prescription issued for the purpose of obtaining controlled substances for general office dispensing, must not fill prescriptions signed by an individual without prescribing authority and must not fill improperly executed prescriptions. 21 C.F.R. §§ 1306.04(a), 1306.05(f).

12. A registrant must take and record a biennial inventory and must keep accurate and complete records of power of attorney designations matching the name of the person who signed the application for re-registration. 21 C.F.R. §§ 1304.11(c), 1305.05(d).

13. On September 4, 2014, the DEA initiated a Scheduled Investigation of Golden Gate Pharmacy and Ross Valley Pharmacy (the "Scheduled Investigation"). In the Scheduled Inspection, DEA reviewed the records of Golden Gate Pharmacy and Ross Valley Pharmcy covering a two year period from September 4, 2012 through September 4, 2014. The Scheduled Investigation revealed alleged record-keeping violations of the Act, which are described in the following paragraphs as the conduct covered by this Agreement.

14. The United States alleges that, between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy and Ross Valley Pharmacy failed to keep and maintain adequate records pertaining to controlled substances, as required by 21 C.F.R. § 1304, *et seq.*

15. The United States alleges at least 4,777 violations by Golden Gate Pharmacy of the Act's recordkeeping requirements for the period in question – September 4, 2012 through September 4, 2014. For example, the United States alleges that, in at least 3,271 instances between September 4, 2012 and September 4, 2014, Golden Gate Pharmacy failed to keep records documenting the manufacture of controlled substances, in violation of 21 C.F.R. § 1304.21(a). The United States further alleges that, in at least 369 instances between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy engaged in the unauthorized manufacture of controlled substances to supply practitioners with stock for office-based dispensing, in violation of 21 C.F.R. § 1301.13(e). By way of further example, the United States alleges that in at least 355 instances between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy failed to keep distribution records including the number of units, date, and name, address and registration number of the recipient, in violation of 21 C.F.R. § 1304.22(a)(2)(vii). The United States also alleges that in at least 347 instances between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy failed to keep records including the number of units or volume of finished form, in violation of 21 C.F.R. § 1304.22(a)(2)(ii). In addition, the United States alleges that a Golden Gate Pharmacy janitorial employee pilfered approximately 8,000 Oxycodone tablets during 2014-2015.

16. The United States alleges at least 384 violations by Ross Valley Pharmacy of the Act's recordkeeping requirements for the period in question – September 4, 2012 through

September 4, 2014. For example, the United States alleges that, in at least 151 instances between September 4, 2012 through September 4, 2014, Ross Valley Pharmacy filled improperly executed prescriptions in violation of 21 C.F.R. § 1306.05(f). The United States further alleges that, in at least 108 instances, Ross Valley Pharmacy failed to include reasons for expired controlled substances being maintained and whether substances could be used in manufacture in its biennial inventory, in violation of 21 C.F.R. § 1304.11(e)(1)(iv)(C). By way of further example, the United States alleges that Ross Valley Pharmacy, in at least 53 instances, failed to keep records documenting the manufacture of controlled substances, in violation of 21 C.F.R. § 1304.21(a).

17. For the purposes of this Agreement, "Covered Conduct" shall mean the violations alleged in paragraphs 13 through 16 above.

18. At all times relevant to the Covered Conduct, the Act authorizes the imposition of a civil penalty of as much as $10,000 or as much as $25,000 for each violation of 21 U.S.C. § 842(a), depending on the category of violation, and a civil penalty of as much as $25,000 for each violation of 21 U.S.C. § 842(b)(1).

19. This Agreement is neither an admission by any of the Lofholm Parties of liability for any allegations made by the United States nor a concession by the United States that its claims are not well founded.

20. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

TERMS AND CONDITIONS

In reliance on the recitals and representations contained herein, and in consideration of the mutual promises, covenants, and obligations set forth below, and intending to be legally bound hereby, the Parties agree as follows:

21. The Lofholm Parties shall pay to the United States Seven Hundred Seventeen Thousand Two Hundred Fifty Dollars ($717,250.00) (hereafter, the "Settlement Amount"), by electronic funds transfer, pursuant to written instructions to be provided by the Office of the United States Attorney for the Northern District of California upon execution of this Agreement, according to the schedule in Paragraph 22.

22. The Settlement Amount described in Paragraph 21 above shall be made by the Lofholm parties as follows:

a. the Lofholm Parties shall pay Three Hundred Thousand Dollars ($300,000.00) according to the terms of Paragraph 21 on or before May 31, 2017; and

b. the Lofholm Parties shall pay Four Hundred Seventeen Thousand Two Hundred Fifty Dollars ($417,250) according to the terms of Paragraph 21 on or before June 30, 2017.

23. In consideration of the payment of the Settlement Amount described in Paragraphs 21 and 22 above in full, the United States agrees to settle and relinquish all claims for civil penalties it may have against the Lofholm Parties, including Golden Gate Pharmacy Holdings, Inc., Golden Gate Pharmacy, Ross Valley Pharmacy and any officers, directors,

agents, and employees of either Golden Gate or Ross Valley Pharmacies for possible violations of the Act, and the regulations promulgated thereunder, based on the Covered Conduct.

24. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the United States' right to enforce compliance with any other requirements under the Act and regulations promulgated thereunder by commencing a civil or administrative action against one or more of the Lofholm Parties or any officers, directors, agents or employees of either Golden Gate or Ross Valley Pharmacies for violations of the Act that occurred or may occur subsequent to the period of the Covered Conduct described in this Agreement. In the event of such violations under the Act or the regulations promulgated thereunder, DEA will not be precluded from alleging and proving this Agreement and the evidence of the violations that led to this Agreement in any future actions taken against the Lofholm Parties, Golden Gate Pharmacy's DEA registrations, or Ross Valley Pharmacy's DEA registrations under 21 U.S.C. §§ 823 and 824.

25. The Lofholm Parties fully and finally release the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which have been asserted, could have been asserted, or may be asserted in the future against the United States, its agencies, employees, servants, and agents, related to the investigation, prosecution and settlement of this matter.

26. Notwithstanding any term of this Agreement, specifically reserved and excluded from its scope and intent as to any entity or person are the following:

a. Any potential criminal liability;

b. Any criminal, civil, or administrative claims arising under Title 26 of the United States Code (Internal Revenue Code);

c. Any liability to the United States for any conduct other than the Covered Conduct; and

d. Any claims based on such obligations as are created by this Agreement.

27. The Lofholm Parties and each of them waives and shall not assert any defenses any of the Lofholm Parties may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

28. This Agreement is not intended by the Parties, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

29. This Agreement shall be governed by the laws of the United States. Exclusive jurisdiction and venue for any dispute arising under this Agreement shall be the United States District Court for the Northern District of California.

30. This Agreement constitutes the entire agreement between the Parties, and cannot be amended, except in writing and signed by all the Parties to this Agreement.

31. Each of the signatories below represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever. For purposes of construction, this Agreement shall be deemed to have been drafted by all Parties to this

Agreement and shall not, therefore, be construed against any party for that reason in any subsequent dispute.

32. All parties to this Agreement understand that it will be a matter of public record and consent to the United States' disclosure of this Agreement and information about this Agreement to the public.

33. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so.

34. This Agreement is binding on the Lofholm Parties' successors, transferees, heirs, and assigns.

35. The parties agree that the Lofholm Parties are jointly and severally liable for any failure by any one of them to satisfy the terms and conditions of this settlement agreement, including but not limited to the payment of the Settlement Amount described in Paragraph 21 or the schedule of payments described in Paragraph 22.

36. The Parties agree that in the event the Lofholm Parties do not make the payments described in Paragraphs 21 and 22 in full, the United States shall have the option of (a) filing suit to enforce this Agreement, or (b) rescinding this Agreement and seeking any and all available remedies against the Lofholm Parties arising from the Scheduled Investigation, including but not limited to the imposition of civil fines and penalties in the full amounts provided by the Controlled Substances Act and the pertinent regulations. Should the United States choose to rescind the agreement and pursue remedies under subsection (b) of this Paragraph, the Lofholm Parties agree not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that are

filed by the United States by July 31, 2017, except to the extent such defenses were available on the Effective Date of this Agreement.

37. The Parties further agree that in the event the Lofholm Parties fail to make either payment described in Paragraph 22 as provided, the Lofholm Parties shall be liable for interest calculated from the Effective Date of this Agreement, at a rate of 1.0% per annum.

38. If the Lofholm Parties' obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against the Lofholm Parties for the claims that would otherwise be covered by the releases in this Agreement. The Lofholm Parties agree that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) and the Lofholm Parties shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) the Lofholm Parties shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within 30 calendar days of written notification to the Lofholm Parties that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of this Agreement; and (iii) the United States has valid claims against the Lofholm Parties for the full amount under relevant statutory and regulatory authority for each of the violations identified in the Scheduled Investigation.

39. This Agreement shall be effective on the date of signing by the last signatory to this Agreement ("Effective Date"). It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement. Facsimiles of signatures shall have the same effect as originals.

On behalf of the United States:

BRIAN J. STRETCH
United States Attorney
Northern District of California

DATED: April 3, 2017

JONATHAN U. LEE
Assistant U.S. Attorney
Attorneys for the United States

On behalf of the Lofholm Parties:

GOLDEN GATE PHARMACY HOLDINGS, INC.

DATED: 3-31-2017

REBECCA E. LOFHOLM
President

GOLDEN GATE PHARMACY SERVICES, INC.

DATED: 3-31-2017

REBECCA E. LOFHOLM
President

ROSS VALLEY COMPOUNDING
PHARMACY, INC.

DATED: 3-31-2017

REBECCA E. LOFHOLM
President

DATED: 3-31-2017

REBECCA E. LOFHOLM

DATED: 3-31-2017

PAUL W. LOFHOLM

CALIFORNIA PHARMACY LAWYERS

DATED: April 2, 2017

IVAN PETRZELKA, ESQ.
Attorneys for the Lofholm Parties

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

February 21, 2018

DATED MATERIAL ENCLOSED

GOLDEN GATE PHARMACY
1525 EAST FRANCISCO BLVD #2
SAN RAFAEL, CA 94901

GOLDEN GATE PHARMACY
C/O REBECCA LOFHOLM, PRES
9 MADRONE WAY
KENTFIELD, CA 94904

RE: CI 2015 67462
GOLDEN GATE PHARMACY
PHY 40742 (cancelled)

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- March 23, 2018: Unless the Citation is contested payment of fine(s) must be received by the Board.
- March 07, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- March 23, 2018: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No.
CI 2015 67462	GOLDEN GATE PHARMACY, PHY 40742 (cancelled)

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4300.1 Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMOUNT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	$2,500.00
Bus. & Prof. Code § 4081 subd. (a)/CCR, Title 16, § 1718	Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	$2,500.00

CONDUCT:

California Code of Regulations Section 1714 subdivision (b) states, in pertinent parts, each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, between 9/22/2014 and 9/14/2015, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 did not secure the controlled substance cabinet resulting in the following loss:

- 287 tablets of oxycodone 5mg
- 826 tablets of oxycodone 10mg
- 6453 tablets of oxycodone/apap 10/325mg
- 291 tablets of Oxycontin 10mg

Failure to secure the controlled substance cabinet which resulted in the loss of 7857 tablets of controlled substances is a violation of California Code of Regulations Section 1714 subdivision (b).

Business and Professions Code Section 4081 subdivision (a) states all records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 1200) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices. California Code of Regulations Section 1718 states "Current Inventory" as used in Section 4081 and 4332 of the

Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. Specifically, between 9/22/2014 and 9/14/2015, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 failed to maintain a current inventory resulting is the loss of 7,857 tablets of controlled substance.

Drug Name	Variance
Oxycodone 5mg	287
Oxycodone 10mg	826
Oxy/APAP10/325mg	6,453
Oxycontin 10mg	291
Total Tablets	**7,857**

Not maintaining a current inventory of controlled substances is a violation of Business and Professions Code Section 4081(a).

CITATION ISSUED ON: February 21, 2018 | **TOTAL AMOUNT OF FINE(S): $5,000.00**

PAYMENT OF FINE(S) DUE BY: March 23, 2018

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COL 7

CITATION AND FINE

Citation Number	Name, License No.
CI 2015 67462	GOLDEN GATE PHARMACY, PHY 40742 (cancelled)

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4300.1 Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMOUNT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	$2,500.00
Bus. & Prof. Code § 4081 subd. (a)/CCR, Title 16, § 1718	Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	$2,500.00

CONDUCT:

California Code of Regulations Section 1714 subdivision (b) states, in pertinent parts, each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, between 9/22/2014 and 9/14/2015, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 did not secure the controlled substance cabinet resulting in the following loss:

- 287 tablets of oxycodone 5mg
- 826 tablets of oxycodone 10mg
- 6453 tablets of oxycodone/apap 10/325mg
- 291 tablets of Oxycontin 10mg

Failure to secure the controlled substance cabinet which resulted in the loss of 7857 tablets of controlled substances is a violation of California Code of Regulations Section 1714 subdivision (b).

Business and Professions Code Section 4081 subdivision (a) states all records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 1200) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices. California Code of Regulations Section 1718 states "Current Inventory" as used in Section 4081 and 4332 of the

Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. Specifically, between 9/22/2014 and 9/14/2015, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 failed to maintain a current inventory resulting is the loss of 7,857 tablets of controlled substance.

Drug Name	Variance
Oxycodone 5mg	287
Oxycodone 10mg	826
Oxy/APAP10/325mg	6,453
Oxycontin 10mg	291
Total Tablets	**7,857**

Not maintaining a current inventory of controlled substances is a violation of Business and Professions Code Section 4081(a).

CITATION ISSUED ON: February 21, 2018 | **TOTAL AMOUNT OF FINE(S): $5,000.00**

PAYMENT OF FINE(S) DUE BY: March 23, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: GOLDEN GATE PHARMACY, PHY 40742 (cancelled)
Citation and Fine CI 2015 67462

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On February 21, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
GOLDEN GATE PHARMACY 1525 EAST FRANCISCO BLVD #2 SAN RAFAEL, CA 94901	7017 0530 0001 1516 5934
GOLDEN GATE PHARMACY C/O REBECCA LOFHOLM, PRES 9 MADRONE WAY KENTFIELD, CA 94904	7017 0530 0001 1516 5941

I declare under penalty of perjury that the forgoing is true and correct.

Executed on February 21, 2018, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

February 21, 2018

DATED MATERIAL ENCLOSED

NICOLE MARIE LOFHOLM CLAUSEN
1525 E FRANCISCO BLVD SUITE 2
SAN RAFAEL, CA 94901

RE: CI 2017 78781
NICOLE MARIE LOFHOLM CLAUSEN
RPH 60056

The attached Citation and Fine, Order of Abatement ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation and indicates, within the Order of Abatement, information and/or material to be submitted to the Board.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- March 23, 2018: Unless the Citation is contested, Proof of Abatement and payment of fine(s) must be received by the Board.
- March 07, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- March 23, 2018: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), timely payment of any fine(s) and the submission of Proof of Abatement shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations title 16 section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

Citation Number	Name, License No.
CI 2017 78781	NICOLE MARIE LOFHOLM CLAUSEN, RPH 60056

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4113 subd. (c)		
VIOLATION CODE SECTION	OFFENSE	AMOUNT OF FINE
Bus. & Prof. Code § 4081 subd. (a)	Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	$2,500.00
Bus. & Prof. Code § 4113 subd. (c) /CCR, Title 16, § 1714 subd. (b)	Pharmacist in Charge shall be responsible for compliance with all state and federal laws pertaining to the practice of pharmacy/Operational Standards and Security; pharmacy responsible for pharmacy security	$2,500.00

CONDUCT:

Business and Professions Code Section 4113(c) states the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. California Code of Regulations Section 1714 subdivision (b) states, in pertinent parts, each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, between 9/22/2014 and 9/14/2015, Nicole Lofholm Clausen (RPH 60056), as pharmacist-in-charge, was responsible when Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 did not secure the controlled substance cabinet resulting in the following loss:

- 287 tablets of oxycodone 5mg
- 826 tablets of oxycodone 10mg
- 6453 tablets of oxycodone/apap 10/325mg
- 291 tablets of Oxycontin 10mg

Failure to secure the controlled substance cabinet which resulted in the loss of 7857 tablets of controlled substances is a violation of California Code of Regulations Section 1714 subdivision (b).

Business and Professions Code Section 4081 subdivision (a) states all records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept

by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 1200) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices. California Code of Regulations Section 1718 states "Current Inventory" as used in Section 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. Specifically, between 9/22/2014 and 9/14/2015, when Nicole Lofholm-Clausen, RPH 60056, was the pharmacist-in-charge, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 failed to maintain a current inventory resulting is the loss of 7,857 tablets of controlled substance.

Drug Name	Variance
Oxycodone 5mg	287
Oxycodone 10mg	826
Oxy/APAP10/325mg	6,453
Oxycontin 10mg	291
Total Tablets	7,857

Not maintaining a current inventory of controlled substances is a violation of Business and Professions Code Section 4081(a).

ORDER OF ABATEMENT

By the abatement date submit to the Board the following:

Either (1) full payment ($5,000.00) of the assessed fine(s), or (2) $4,000.00 and written notice to the Board of Pharmacy that you will be attending a Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training within the next 12 months.

If Nicole Lofholm-Clausen chooses option (2), Nicole Lofholm-Clausen shall submit proof of attendance at the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training within 12 months of the date of this citation. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If Nicole Lofholm-Clausen timely attends the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training within 12 months, the fine(s) levied by this citation shall be reduced to $4,000.00 and completion of the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training shall be considered satisfactory abatement of the citation. If Nicole Lofholm-Clausen fails to timely submit proof of attendance at the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training, the stay shall be lifted and the fine(s) shall be due and owing from Nicole Lofholm-Clausen within thirty (30) days of any such failure.

CITATION ISSUED ON: February 21, 2018 **TOTAL AMOUNT OF FINE(S): $5,000.00**

PAYMENT OF FINE(S) DUE BY: March 23, 2018

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

Citation Number	Name, License No.
CI 2017 78781	NICOLE MARIE LOFHOLM CLAUSEN, RPH 60056

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4113 subd. (c)		
VIOLATION CODE SECTION	**OFFENSE**	**AMOUNT OF FINE**
Bus. & Prof. Code § 4081 subd. (a)	**Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory**	**$2,500.00**
Bus. & Prof. Code § 4113 subd. (c) /CCR, Title 16, § 1714 subd. (b)	**Pharmacist in Charge shall be responsible for compliance with all state and federal laws pertaining to the practice of pharmacy/Operational Standards and Security; pharmacy responsible for pharmacy security**	**$2,500.00**

CONDUCT:

Business and Professions Code Section 4113(c) states the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. California Code of Regulations Section 1714 subdivision (b) states, in pertinent parts, each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, between 9/22/2014 and 9/14/2015, Nicole Lofholm Clausen (RPH 60056), as pharmacist-in-charge, was responsible when Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 did not secure the controlled substance cabinet resulting in the following loss:

- 287 tablets of oxycodone 5mg
- 826 tablets of oxycodone 10mg
- 6453 tablets of oxycodone/apap 10/325mg
- 291 tablets of Oxycontin 10mg

Failure to secure the controlled substance cabinet which resulted in the loss of 7857 tablets of controlled substances is a violation of California Code of Regulations Section 1714 subdivision (b).

Business and Professions Code Section 4081 subdivision (a) states all records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept

by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 1200) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices. California Code of Regulations Section 1718 states "Current Inventory" as used in Section 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. Specifically, between 9/22/2014 and 9/14/2015, when Nicole Lofholm-Clausen, RPH 60056, was the pharmacist-in-charge, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 failed to maintain a current inventory resulting is the loss of 7,857 tablets of controlled substance.

Drug Name	Variance
Oxycodone 5mg	287
Oxycodone 10mg	826
Oxy/APAP10/325mg	6,453
Oxycontin 10mg	291
Total Tablets	7,857

Not maintaining a current inventory of controlled substances is a violation of Business and Professions Code Section 4081(a).

ORDER OF ABATEMENT

By the abatement date submit to the Board the following:

Either (1) full payment ($5,000.00) of the assessed fine(s), or (2) $4,000.00 and written notice to the Board of Pharmacy that you will be attending a Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training within the next 12 months.

If Nicole Lofholm-Clausen chooses option (2), Nicole Lofholm-Clausen shall submit proof of attendance at the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training within 12 months of the date of this citation. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If Nicole Lofholm-Clausen timely attends the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training within 12 months, the fine(s) levied by this citation shall be reduced to $4,000.00 and completion of the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training shall be considered satisfactory abatement of the citation. If Nicole Lofholm-Clausen fails to timely submit proof of attendance at the Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training, the stay shall be lifted and the fine(s) shall be due and owing from Nicole Lofholm-Clausen within thirty (30) days of any such failure.

CITATION ISSUED ON: February 21, 2018 | **TOTAL AMOUNT OF FINE(S): $5,000.00**

PAYMENT OF FINE(S) DUE BY: March 23, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: NICOLE MARIE LOFHOLM CLAUSEN , RPH 60056
Citation and Fine CI 2017 78781

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard Suite N219, Sacramento, California 95834-1924.

On February 21, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Order of Abatement, ~~Proof of Abatement~~, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
NICOLE MARIE LOFHOLM CLAUSEN 1525 E FRANCISCO BLVD SUITE 2 SAN RAFAEL, CA 94901	7017 0530 0001 1516 6382

I declare under penalty of perjury that the forgoing is true and correct.

Executed on February 21, 2018, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

February 21, 2018

DATED MATERIAL ENCLOSED

REBECCA ELLEN LOFHOLM
1525 E FRANCISCO BLVD #2
SAN RAFAEL, CA 94901

RE: CI 2017 78783
REBECCA ELLEN LOFHOLM
RPH 33497

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- March 23, 2018: Unless the Citation is contested payment of fine(s) must be received by the Board.
- March 07, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- March 23, 2018: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No.
CI 2017 78783	REBECCA ELLEN LOFHOLM, RPH 33497

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)		
VIOLATION CODE SECTION	**OFFENSE**	**AMOUNT OF FINE**
CCR, Title 16, § 1714 subd. (b)	**Operational Standards and Security; pharmacy responsible for pharmacy security**	**$2,500.00**
Bus. & Prof. Code § 4081 subd. (a) & (b)/CCR, Title 16, § 1718	**Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined**	**$2,500.00**

CONDUCT:

California Code of Regulations Section 1714 subdivision (b) states, in pertinent parts, each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, between 9/22/2014 and 9/14/2015, Rebecca Lofholm (RPH33497), as a pharmacist owner, was responsible when Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 did not secure the controlled substance cabinet resulting in the following loss:

- 287 tablets of oxycodone 5mg
- 826 tablets of oxycodone 10mg
- 6453 tablets of oxycodone/apap 10/325mg
- 291 tablets of Oxycontin 10mg

Failure to secure the controlled substance cabinet which resulted in the loss of 7857 tablets of controlled substances is a violation of California Code of Regulations Section 1714 subdivision (b).

Business and Professions Code Section 4081 subdivision (a) states all records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 1200) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices. California Code of Regulations Section 1718 states "Current Inventory" as used in Section 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all

dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. Business and Professions Code Section 4081(b) states the owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section. Specifically, between 9/22/2014 and 9/14/2015, when Rebecca Lofholm, RPH 33497, was the pharmacist owner, Golden Gate Pharmacy (PHY 40742) located at 1525 E. Francisco Blvd Suite#2, San Rafael, CA 94901 failed to maintain a current inventory resulting is the loss of 7,857 tablets of controlled substance.

Drug Name	Variance
Oxycodone 5mg	287
Oxycodone 10mg	826
Oxy/APAP10/325mg	6,453
Oxycontin 10mg	291
Total Tablets	7,857

Not maintaining a current inventory of controlled substances is a violation of Business and Professions Code Section 4081(a).

CITATION ISSUED ON: February 21, 2018 **TOTAL AMOUNT OF FINE(S): $5,000.00**

PAYMENT OF FINE(S) DUE BY: March 23, 2018

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 26, 2018

CERTIFIED MAIL

NICOLE MARIE LOFHOLM CLAUSEN
1525 E FRANCISCO BLVD SUITE 2
SAN RAFAEL, CA 94901

California Pharmacy Lawyers
Ivan Petrzelka, Attorney at Law
49 Discovery, Suite 240
Irvine, CA 92618-6713

RE: CI 2017 78781
NICOLE MARIE LOFHOLM CLAUSEN
RPH 60056

This is to acknowledge your request for an office conference regarding the above-referenced citation, as allowed by California Code of Regulations, title 16, section 1775.4, subdivision (b).

Please be advised that the office conference is not a hearing. It is an opportunity for you to discuss the events that took place, and to present new information and mitigating factors pertaining to the citation that you would like considered. There is no discovery available in this process. The conference is not open to the public. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant. Legal counsel or an authorized representative may accompany you to the meeting.

After your office conference, the citation and/or fine may be affirmed, modified or dismissed. You will be advised of the outcome within 14 calendar days from the date of the conference. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. This modified decision shall be deemed to be a final order including any administrative fine levied and/or an order of abatement. You may appeal this decision pursuant to California Code of Regulations title 16, section 1775.4, subdivision (d).

The office conference you requested is scheduled for **Thursday, April 26, 2018.** **Please arrive at 9:00 A.M.** The meeting will be held at:

Department of Consumer Affairs
Board of Pharmacy
1625 N. Market Boulevard
Santa Cruz Room, Suite N 214
Sacramento, CA 95834-1924

CI 2017 78781
NICOLE MARIE LOFHOLM CLAUSEN
RPH 60056

Page Two

Important

When you arrive to the Office Conference Location, please sign in (for the Sacramento Office) at the First Floor Guard Station AND at the Board of Pharmacy's (Reception Desk in Suite N-219) OR (for the Van Nuys Office) sign in at Meeting Location outside the Auditorium / OR outside of Suite #315) OR (for the San Diego Office) sign in at the meeting location outside of Suite #101.

Your meeting will be heard on a first-come basis, according to the order of sign in. Upon receipt of this letter, please contact Jennifer Sevilla at (916) 574-7925, to confirm your attendance for this meeting. For good cause, you may request that the office conference be rescheduled. The board will allow only one request for a postponement. Once a matter has been rescheduled it will be heard and a decision will be made. Thank you for your cooperation in this matter.

Virginia Herold
Executive Officer
Board of Pharmacy

by

Jennifer Sevilla
Associate Enforcement Analyst

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: CONTESTED CITATION OFFICE CONFERENCE Ci 2017 78781

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On March 26, 2018, I served the attached:

Letter of Acknowledgement and Notice of Office Conference

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO
NICOLE MARIE LOFHOLM CLAUSEN 1525 E FRANCISCO BLVD SUITE 2 SAN RAFAEL, CA 94901	7017 0530 0001 1516 4449
California Pharmacy Lawyers Ivan Petrzelka, Attorney at Law 49 Discovery, Suite 240 Irvine, CA 92618-6713	7017 0530 0001 1516 4456

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 26, 2018, at Sacramento, California.

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 26, 2018

CERTIFIED MAIL

GOLDEN GATE PHARMACY
ATTN: C/O REBECCA LOFHOLM, PRS
1525 EAST FRANCISCO BLVD #2
SAN RAFAEL, CA 94901

California Pharmacy Lawyers
Ivan Petrzelka, Attorney at Law
49 Discovery, Suite 240
Irvine, CA 92618-6713

RE: CI 2015 67462
GOLDEN GATE PHARMACY
PHY 40742 (cancelled)

This is to acknowledge your request for an office conference regarding the above-referenced citation, as allowed by California Code of Regulations, title 16, section 1775.4, subdivision (b).

Please be advised that the office conference is not a hearing. It is an opportunity for you to discuss the events that took place, and to present new information and mitigating factors pertaining to the citation that you would like considered. There is no discovery available in this process. The conference is not open to the public. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant. Legal counsel or an authorized representative may accompany you to the meeting.

After your office conference, the citation and/or fine may be affirmed, modified or dismissed. You will be advised of the outcome within 14 calendar days from the date of the conference. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. This modified decision shall be deemed to be a final order including any administrative fine levied and/or an order of abatement. You may appeal this decision pursuant to California Code of Regulations title 16, section 1775.4, subdivision (d).

The office conference you requested is scheduled for **Thursday, April 26, 2018.** **Please arrive at 9:00 A.M.** The meeting will be held at:

Department of Consumer Affairs
Board of Pharmacy
1625 N. Market Boulevard
Santa Cruz Room, Suite N 214
Sacramento, CA 95834-1924

CI 2015 67462
GOLDEN GATE PHARMACY
PHY 40742 (cancelled)

Page Two

Important

When you arrive to the Office Conference Location, please sign in (for the Sacramento Office) at the First Floor Guard Station AND at the Board of Pharmacy's (Reception Desk in Suite N-219) OR (for the Van Nuys Office) sign in at Meeting Location outside the Auditorium / OR outside of Suite #315) OR (for the San Diego Office) sign in at the meeting location outside of Suite #101.

Your meeting will be heard on a first-come basis, according to the order of sign in. Upon receipt of this letter, please contact Jennifer Sevilla at (916) 574-7925, to confirm your attendance for this meeting. For good cause, you may request that the office conference be rescheduled. The board will allow only one request for a postponement. Once a matter has been rescheduled it will be heard and a decision will be made. Thank you for your cooperation in this matter.

Virginia Herold
Executive Officer
Board of Pharmacy

by

Jennifer Sevilla
Associate Enforcement Analyst

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: CONTESTED CITATION OFFICE CONFERENCE CI 2015 67462

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On March 26, 2018, I served the attached:

Letter of Acknowledgement and Notice of Office Conference

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO
GOLDEN GATE PHARMACY ATTN: C/O REBECCA LOFHOLM, PRS 1525 EAST FRANCISCO BLVD #2 SAN RAFAEL, CA 94901	7017 0530 0001 1516 4401
California Pharmacy Lawyers Ivan Petrzelka, Attorney at Law 49 Discovery, Suite 240 Irvine, CA 92618-6713	7017 0530 0001 1516 4418

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 26, 2018, at Sacramento, California.

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 26, 2018

CERTIFIED MAIL

REBECCA ELLEN LOFHOLM
1525 E FRANCISCO BLVD #2
SAN RAFAEL, CA 94901

California Pharmacy Lawyers
Ivan Petrzelka, Attorney at Law
49 Discovery, Suite 240
Irvine, CA 92618-6713

RE: CI 2017 78783
REBECCA ELLEN LOFHOLM
RPH 33497

This is to acknowledge your request for an office conference regarding the above-referenced citation, as allowed by California Code of Regulations, title 16, section 1775.4, subdivision (b).

Please be advised that the office conference is not a hearing. It is an opportunity for you to discuss the events that took place, and to present new information and mitigating factors pertaining to the citation that you would like considered. There is no discovery available in this process. The conference is not open to the public. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant. Legal counsel or an authorized representative may accompany you to the meeting.

After your office conference, the citation and/or fine may be affirmed, modified or dismissed. You will be advised of the outcome within 14 calendar days from the date of the conference. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. This modified decision shall be deemed to be a final order including any administrative fine levied and/or an order of abatement. You may appeal this decision pursuant to California Code of Regulations title 16, section 1775.4, subdivision (d).

The office conference you requested is scheduled for **Thursday, April 26, 2018.** **Please arrive at 9:00 A.M.** The meeting will be held at:

Department of Consumer Affairs
Board of Pharmacy
1625 N. Market Boulevard
Santa Cruz Room, Suite N 214
Sacramento, CA 95834-1924

CI 2017 78783
REBECCA ELLEN LOFHOLM
RPH 33497

Page Two

Important

When you arrive to the Office Conference Location, please sign in (for the Sacramento Office) at the First Floor Guard Station AND at the Board of Pharmacy's (Reception Desk in Suite N-219) OR (for the Van Nuys Office) sign in at Meeting Location outside the Auditorium / OR outside of Suite #315) OR (for the San Diego Office) sign in at the meeting location outside of Suite #101.

Your meeting will be heard on a first-come basis, according to the order of sign in. Upon receipt of this letter, please contact Jennifer Sevilla at (916) 574-7925, to confirm your attendance for this meeting. For good cause, you may request that the office conference be rescheduled. The board will allow only one request for a postponement. Once a matter has been rescheduled it will be heard and a decision will be made. Thank you for your cooperation in this matter.

Virginia Herold
Executive Officer
Board of Pharmacy

by

Jennifer Sevilla
Associate Enforcement Analyst

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: CONTESTED CITATION OFFICE CONFERENCE CI 2017 78783

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On March 26, 2018, I served the attached:

Letter of Acknowledgement and Notice of Office Conference

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO
REBECCA ELLEN LOFHOLM 1525 E FRANCISCO BLVD #2 SAN RAFAEL, CA 94901	7017 0530 0001 1516 4425
California Pharmacy Lawyers Ivan Petrzelka, Attorney at Law 49 Discovery, Suite 240 Irvine, CA 92618-6713	7017 0530 0001 1516 4432

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 26, 2018, at Sacramento, California.

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR

October 03, 2018

NICOLE MARIE LOFHOLM CLAUSEN
1525 E FRANCISCO BLVD #2
SAN RAFAEL, CA 94901

California Pharmacy Lawyers
Ivan Petrzelka, Attorney at Law
49 Discovery, Suite 240
Irvine, CA 92618-6713

RE: CI 2017 78781
NICOLE MARIE LOFHOLM CLAUSEN
RPH 60056

The Board is in receipt of the Statement of Continuing Education Credit, indicating you attended a Board of Pharmacy/Drug Enforcement Agency Rx Drug Abuse training course.

Since you successfully completed the required training, the fine levied by this citation has been reduced to zero.

The documentation has been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Associate Enforcement Analyst, Jennifer Sevilla at (916) 574-7925.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

October 9, 2019

To: Whom it May Concern

Response to Affirmative Answers on Arrest History Question:

The incident occurred in November of 1999 in Bozeman, Montana. I was 20 years old at the time. I was a passenger in a car that was pulled over. All passengers were given a breathalyzer test, of which I failed. I was charged with Minor in Possession of Alcohol, which is a misdemeanor. I plead guilty to the charge and was assessed a fine of $80.

If The Board needs any further details of the incident, or has any questions, I can be contacted on my cell phone, which is , or by email at erik.clausen@ggprx.com.

Regards,

Erik Matthew Clausen
Chief Operating Officer
Golden Gate Pharmacy Services
8 Digital Drive, Suite 200
Novato, CA 94949

Date: 6/13/2019
Time: 11:11 AM
Page 1 of 1

Bozeman Municipal Court
Party Detail Summary
Criminal and Civil Cases

User: JNELSON

Clausen, Erik M

Balance due court: 0.00

Case: TK-115-1999-35918 **Defendant** **Closed**
Judge: Karl P Seel
Filing Date: 11/21/1999

Charge	Degree	Disposed	Plea	Finding	Citation
Possessing Beer Or Liquor While Under Age (		11/22/1999	Guilty	Guilty	145222
Issued: 11/21/1999	Fines/Fees:	80.00	Paid:	80.00	Balance: 0.00
	Case Total:	**80.00**	**Paid:**	**80.00**	**Balance: 0.00**

I, Jamie Nelson, hereby certify that this is a true and correct copy of the original as the same appears in the files and records of the office of the Municipal Court of the City of Bozeman, County of Gallatin, State of Montana.

Dated the 14th day of June, 2019

Jamie Nelson
Bozeman Municipal Court Clerk

NOTICE TO APPEAR AND COMPLAINT ISSUED BY BOZEMAN POLICE DEPARTMENT 012A 145222

TE OF MONTANA / CITY OF BOZEMAN } VS

DEFENDANT NAME: FIRST ERIK MIDDLE M. LAST CLAUSEN

STREET 5 6TH

CITY Bozoman STATE MT ZIP 59715

SEX M WT 170 HT 603 EYES BLU HAIR BRO DOB MONTH DAY YEAR

D/L NO. D/L STATE MT D/L EXP YEAR 00

HOME PHONE 1 EMPLOYER MSU STUD BUSINESS PHONE

VEHICLE LICENSE NO. LIC STATE MONTH YEAR

VEHICLE YEAR VEHICLE COLOR

VEHICLE MAKE

VEHICLE TYPE ☐ CAR ☐ TRUCK ☐ PICKUP ☐ TRK/TRLR ☐ MOTORCYCLE ☐

UNIFORM VIOLATION CODE 0021-0

DOCKET NUMBER (9) 3598

E DEFENDANT IS HEREBY GIVEN NOTICE TO APPEAR IN

☐ JUSTICE Rm 168 ☑ CITY Rm 123 ☐ YOUTH Rm 100

RT OF CARLSON DEPT#

NTY OF GALLATIN

ATED AT 615 SOUTH 16TH (DOWNSTAIRS)

OZEMAN MONTANA ON OR BEFORE

I AM MONDAY, WEDNESDAY OR THURSDAY

22 DAY OF NOV 99

NSWER THIS CHARGE.

IIS 22 DAY OF NOV 99

OMPLAINT WAS PRESENTED TO ME AND THE OFFICER OATH SWORE THAT THE CHARGES ARE TRUE.

Signature of Judge or Notary

TARY FOR THE STATE OF MONTANA SIDING AT BOZEMAN, MONTANA COMMISSION EXPIRES Sept 23-2000

FAILURE TO APPEAR MAY RESULT IN A SUSPENSION OF YOUR DRIVER'S LICENSE OR PRIVILEGE TO DRIVE

THE ABOVE NAMED DEFENDANT IS CHARGED WITH VIOLATING

☑ MONTANA CODE ☐ CITY CODE ☐ COUNTY ORDINANCE SECTION # 45-5-624

ON THE 21 DAY OF NOV 99 AT 0335 MILITARY TIME

IN THAT SAID DEFENDANT DID PURPOSELY OR KNOWINGLY OR NEGLIGENTLY

MINOR IN POSSESSION OF ALCOHOL (2ND)

PBT #10 .020 B.A.C

NAMELY AT (LOCATION) 0 W. COLLEGE

IF CHECKED ☐ PERSONAL APPEARANCE IN COURT REQUIRED ☐ BRING A PARENT

☑ B.A. TEST GIVEN ☐ ACCIDENT RADAR UNIT NO. 24

BADGE NO 152

BADGE NO 157

SIGNATURE OF OFFICER

RECEIVED $ NONE AS APPEARANCE BOND

I, Jamie Nelson, hereby certify that this is a true and correct copy of the original as the same appears in the files and records of the office of the Municipal Court of the City of Bozeman, County of Gallatin, State of Montana.

Dated the 14th day of June, 2019

Jamie Nelson

Bozeman Municipal Court Clerk

STATE OF MONTANA,

Plaintiff,

v.

Erik Clausen Defendant.

CITY COURT OF THE CITY OF BOZEMAN
COUNTY OF GALLATIN, STATE OF MONTANA

SENTENCING ORDER/ORDER OF COMMITMENT

WHEREAS, on 11-22, 199 9 the above Defendant was (✓) arraigned in open Court ( ) video arraignment (✓) pled guilty ( ) convicted by jury ( ) convicted by judge, as set forth below, it is ORDERED that you, said Sheriff of Gallatin County take and receive the Defendant:

Cause No: 99-35918- MIP 2nd 1st

Bond: $ _____ cash / surety ☐ Defendant not to be released until bond paid ☐ Release immediately.

Sentence imposed:

☑ _____ months / year suspended/deferred sentence all but _____ hours / days incarceration to be served:

☐ Ineligible Work Program -- Unless indicated, defendant eligible for consideration for Work Program
☐ Credit for time served
☐ Incarceration immediate ☐ Incarceration in lieu of fines/costs/assessments of _____ days to serve in detention
☑ Fine of $ 50 + $5 and $15 administrative fees ☐ "No contact" Order entered by Court
☐ Witness/administrative fees/other court costs 70+10=80
☐ Community Service: Week hours, must complete by _____ ☐ Time Pay
☐ ACT (alcohol) 1st 2nd 3rd ☐ ACT (drugs) 1st 2nd 3rd ☐ MIP (alcohol) 1st 2nd 3rd
☐ Probationary Driver's License is recommended by the Court.
☑ Other Book + release

****

AS A PART OF YOUR SENTENCE, YOU SHALL:

☑ Obey all laws. ☐ Complete MIP Program. ☑ Notify Court of change of address/telephone number.
☒ Complete the Act/Drug Counseling Program & comply with recommendations of counselors.
☐ Complete minimum 25 hours Domestic Abuse Couseling within 6 months.
☐ Not drive until legally licensed to do so.
☐ Driver's license: ○ Surrendered ○ Lost per defendant ○ taken at Detention Center.
☐ License plates & registration suspended _____ Days.
☐ Surrender license plates & registration by _____.
☐ Re-enroll ACT/MIP/DRUG/Domestic Abuse/Additional Treatment/Community Service by _____.
☐ SHALL NOT consume alcohol or frequent any place whose primary purpose is to serve alcoholic beverages.
☐ SHALL NOT enter or be on the grounds of _____ for a period of _____ Months.
☑ COMPLY WITH COURT ORDERS. FAILURE TO APPEAR/PAY FINES/COMPLY MAY RESULT IN THE ISSUANCE OF A SUMMONS, ARREST WARRANT AND/OR SUSPENSION OF YOUR DRIVER'S LICENSE.

DONE AND ORDERED 11-22, 199 9.

PATRICIA KYLE CARLSON, Bozeman City Court Judge

I acknowledge that I will report to Detention Center by 4:00 pm on day of sentencing to make arrangements for jail sentence, and that I am to serve my time on 11-22, 199 9. I may not report while under the influence of alcohol.

Defendant's signature & date: _____ 11-22, 199 9.

cc: ☐ Detention Center (original) ☐ Court ☐ Defendant ☐ Assistant City Attorney ☐ CONTINUED ON PAGE 2

NOTICE TO APPEAR AND COMPLAINT

ISSUED BY BOZEMAN POLICE DEPARTMENT

…E OF MONTANA / CITY OF BOZEMAN VS

DEFENDANT NAME — FIRST: ERIK — MIDDLE: M. — LAST: CLAUSEN

STREET: S 6TH

CITY: Bozeman — STATE: MT — ZIP: 59715

SEX: M — WT: 176 — HT: 603 — EYES: BLU — HAIR: BRD — DOB

D/L STATE: MT — D/L EXP: 00

EMPLOYER: MSU-STUD

…E DEFENDANT IS HEREBY GIVEN NOTICE TO APPEAR IN

JUSTICE ☒ CITY ☐ YOUTH

…RT OF CARLSON DEPT#

…NTY OF GALLATIN

…ZEMAN, MONTANA ON OR BEFORE …AM MONDAY, WEDNESDAY OR THURSDAY

22 DAY OF NOV 99

…NSWER THIS CHARGE

…IS 22 DAY OF NOV 99

…OMPLAINT WAS PRESENTED TO ME AND THE OFFICER …OATH SWORE THAT THE CHARGES ARE TRUE.

Signature of Judge or Notary

…ARY FOR THE STATE OF MONTANA …IDING AT BOZEMAN, MONTANA …COMMISSION EXPIRES Sept 23 2000

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IF CHECKED ☒ PERSONAL APPEARANCE IN COURT REQUIRED ☐ BRING A PARENT

☒ B.A. TEST GIVEN ☐ ACCIDENT

RADAR UNIT NO. 24

BADGE NO. 152

BADGE NO. 151

SIGNATURE OF OFFICER

UNIFORM VIOLATION CODE 0021-0

DOCKET NUMBER (99) 3591?

RECEIVED $ NONE AS APPEARANCE BOND

22nd November 1999

Guilty 1st offense

Fine - 40+5+5+10+10+10 = 80

Waived C/S

Def Booked + release

35+5+10+10

38689 11-22-99