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13A

J-16

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.

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	6/3/2019 10:33:27 AM	Michelle Giovannucci - RP440876
Signature of Inspector	Date/Time	Signature of Owner/Representative

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

FACILITY

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

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

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

10000267.2/000743-1/1-0

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	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

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.

3724407 8300

SR# 20195824826

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

Authentication: 203160877

Date: 07-05-19

13B

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 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 ☐ 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

N930268

GRETCHEN WHITMER
GOVERNOR

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 Bersha
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 Direct Rx

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 L Berisha

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

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

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

13C

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: HOME Rx HEALTHCARE LLC

Physical Address: 707 FARRINGDON ST LUMBERTON NC 28358

Mailing Address: P.O. Box 1569

City: LUMBERTON State: NC Zip Code: 28359

Telephone: 910-802-4620 Fax: 910-802-4626

Toll Free Number: 844-725-2452 (Required per NAC 639.708)

E-mail: JASON@LUMBERTONDRUG.COM Website: N/A

Managing Pharmacist: JASON M. FOIL License Number: NC-14357

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: _____	☐	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 ☐

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

Jason M. Foil
Print Name of Authorized Person

10-3-19
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: NC

Parent Company if any: N/A

Mailing Address: P.O. Box 1569

City: Lumberton State: NC Zip: 28359

Telephone: 910-802-4620 Fax: 910-802-4626

Contact Person: JASON M. FOIL

For any corporation non publicly traded, disclose the following:

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

a) JASON M. FOIL (Name) TRINITY Drive Lumberton NC 28358 (Address) 50% of shares

b) SHELLEY P. FOIL (Name) TRINITY Drive Lumberton NC 28358 (Address) 50% of shares

c) _____ (Name) _____ (Address)

d) _____ (Name) _____ (Address)

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

3) What was the price paid per share? $10/share

4) What date did the corporation actually receive the cash assets? 10-30-13

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

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8:30 am 4:30 pm

Saturday CLOSED _____ am _____ pm

Sunday CLOSED _____ am _____ 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, JASON M. FOIL

Responsible Person of HOMEX HEALTHCARE

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

JASON M. FOIL

Print Name of Authorized Person

10-15-19

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF NC)
) ss.
Robeson COUNTY)

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

1. I am the Pharmacist in charge for HEMFAX HEALTH CARE (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, JASON M. FOIL, 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
3 day of December, 2019.

NOTARY PUBLIC

ELIZABETH MORIN
Notary Public, North Carolina
Cumberland County
My Commission Expires
9/29/20

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF EXISTENCE
(Limited Liability Company)

I, Elaine F. Marshall, Secretary of State of the State of North Carolina, do hereby certify that

HOMERX HEALTHCARE LLC

is a limited liability company duly formed, and existing under the laws of the State of North Carolina, having been formed on 30th day of October, 2013

I FURTHER certify that, as of the date of this certificate, (i) the said limited liability company is not dissolved under the terms of its articles of organization, (ii) the said limited liability company's articles of organization are not suspended for failure to comply with the Revenue Act of the State of North Carolina, (iii) that said limited liability company is not administratively dissolved for failure to comply with the provisions of the North Carolina Limited Liability Company Act, (iv) that this office has not filed any decree of judicial dissolution, articles of dissolution, articles of merger, or articles of conversion for said limited liability company.

Scan to verify online.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 23rd day of September, 2019.

Elaine F. Marshall

Secretary of State

Certification# 105601598-1 Reference# 15600915- Page: 1 of 1
Verify this certificate online at http://www.sosnc.gov/verification

Homerx Healthcare LLC List of Owners

Jason Foil R.Ph.

Home address: Trinity Drive Lumberton,NC 28358

DOB-

SSN-

Title- Owner/Pharmacy Manager

50% owner

Pharmacist license – NCBOP- 14357

Shelley Foil PharmD

Home Address: Trinity Drive Lumberton,NC 28358

DOB-

SSN-

Title- Owner/ Staff Pharmacist

50% Owner

Pharmacist license – NCBOP- 14892

NORTH CAROLINA BOARD OF PHARMACY

Facility: HomeRx Healthcare
Address: 707 Farringdom Street Lumberton, NC 28358
Permit Type: Pharmacy
Permit #: 11757
Re-Issue Date: 11/01/2019
Expiration Date: 12/31/2020
Pharmacy Manager: Jason Michael Foil (#14357)

NC Law requires notification of address change within 30 days.

PLEASE NOTIFY BOARD OF NAME AND/OR ADDRESS CHANGE

REFER TO YOUR LICENSE NUMBER IN ANY COMMUNICATION

Permit #: 11757

NORTH CAROLINA BOARD OF PHARMACY

2020 Pharmacy

This is to certify that

Homerx Healthcare LLC

doing business as

HomeRx Healthcare

707 Farringdom Street Lumberton, NC 28358 Robeson

Has been renewed for the year ending December 31st 2020, as required by law and is issued to the pharmacist-manager pursuant to the representations made in application therefore. The issuance of this renewal permit is not complete and the permit is not valid until countersigned in the space indicated below by the pharmacist-manager as represented in the application. THIS PERMIT CERTIFICATE MUST BE CONSPICUOUSLY DISPLAYED IN THE PHARMACY TO WHICH IT APPLIES. Pharmacy permits are not transferable and may be revoked for the causes specified in the Law and the Rules and Regulations of the Board.

Jason Michael Foil (#14357)

PRESIDENT

11/01/2019
Re-Issued

EXECUTIVE DIRECTOR

10001730.2/000720-1/1-0

1:3
60/656

HOMERX HEALTHCARE
PO BOX 1569
LUMBERTON, NC 28359-0000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FH4291201	10-31-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	09-23-2019

HOMERX HEALTHCARE
707 FARRINGDOM ST
LUMBERTON, NC 28358-0007

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.

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

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FH4291201	10-31-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	09-23-2019

HOMERX HEALTHCARE
707 FARRINGDOM ST
LUMBERTON, NC 28358-0007

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Form DEA-223 (9/2016)

10/15/19

Re: Jason M. Foil Disciplinary action

To whom it may concern,

I entered into a consent order in April of 1999 that I did violate the NC patient counseling statute in relation to my practice of pharmacy. As a result of that admission I received an active 2 day suspension of my personal pharmacist license NC 14357 and a 2 year probation period. That time was served and my license has been in good standing ever since with no additional disciplinary actions. I have attached the Consent agreement to this notice.

Professionally

Jason M. Foil R.Ph
Pharmacist in Charge
Homerx Healthcare
Lumberton,NC 28358

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter Of:

DRUGS AMERICA (Permit No. 4945)	)	
JULIE DELLA- MEA (Licence No. 11332)	)	
JASON MICHAEL FOIL (License No. 14357)	)	CONSENT ORDER
BRIAN DOUGLAS MONROE (License No. 13972)	)	

On March 8, 1999, the North Carolina Board of Pharmacy issued notice to Drugs America, Julie Della-Mea, Jason Foil and Brian Monroe, pursuant to 21 North Carolina Administrative Code 46.2008, which scheduled a pre-hearing conference for March 25, 1999, at the Board office, 104-C Carrboro Plaza, Hwy. 54 Bypass, Carrboro, NC. The pre-hearing conference was scheduled in response to investigative findings suggesting that pharmacists at Drugs America had committed acts in violation of 21 NCAC 46.2504.

On March 25, 1999, the pre-hearing conference was conducted as scheduled. RPh. Della-Mea, Foil and Monroe were present without counsel. RPh. Dwight Ayscue was present for the permit. Present for the Board were Board member Robert Crocker, Director of Investigations Steve Hudson, and Board Investigators Josh Kohler and Lisa Dumire. Investigators Kohler and Dumire presented the investigative findings in this matter. After consideration of those findings and the pharmacist's response, Mr. Crocker proposed the following Finding of Fact, Conclusion of Law, and Disciplinary Action.

FINDING OF FACT

1. Jason Michael Foil (Respondent Foil) was issued license number 14357 by the Board on June 26, 1998. RPh. Brian Douglas Monroe (Respondent Monroe) was issued license number 13972 by the Board on July 1, 1997. Drugs America (Respondent permit) was issued permit number 4945 by the Board on April 5, 1988 and last renewed on December 11, 1998 with RPh. Julie Della-Mea as the RPh. Manager.

2. On November 12, 1998, Respondent Foil dispensed Erythromycin to Investigator Dumire, who was working in an undercover capacity, without making an offer to counsel her about the product.

3. On November 30, 1998, Respondent Foil dispensed Erythromycin to Investigator Kohler, who was working in an undercover capacity, without making an offer to counsel him about the product.

4. On November 30, 1998, Respondent Monroe dispensed Doxycycline to Investigator Dumire, who was working in an undercover capacity, without making an offer to counsel her about the product.

5. Respondent permit and Respondents Foil and Monroe hereby waive any further Finding of Fact in this matter.

CONCLUSION OF LAW

Respondent permit and Respondents Foil and Monroe admit that they have violated 21 NCAC 46.2504 and that this conduct constitutes sufficient grounds for disciplinary action by the Board under GS 90-85.38 (a), (6), and (7).

Based on the foregoing, and with the consent of Respondents, IT IS THEREFORE THE

ORDER OF THE BOARD

1. That the permit issued to RPh. Julie Della-Mea and Mast Drug Company is hereby suspended for 7 days, which suspension is stayed for a period of two years upon the following conditions:

    I. The permit be actively suspended for a period of one (1) business day beginning no later than 90 days after the Board's acceptance of this Order.

II. That no laws governing the practice of pharmacy shall be violated at this location during the stay period.

III. That no violation of Board rules shall be violated at this location during the stayed period.

IV. That a sign be conspicuously displayed on the entrance to the pharmacy stating "This Pharmacy Closed By Order of the North Carolina Board of Pharmacy For One Day". Such sign will be furnished by the Board.

V. That Respondent permit shall notify the Board office at least 10 days in advance of the commencement date of the active suspension of the permit.

VI. That each technician employed at the pharmacy be trained in how to comply with 21 NCAC 46.2504.

VII. That a Policy & Procedures manual be constructed which effectively addresses the technician's role in complying with 21 NCAC 46.2504.

VIII. That each technician must indicate successful completion of the training in these Policies & Procedures by his/her signature in the manual.

2. That the license issued to Respondent Foil is hereby suspended for 7 days, which suspension is stayed for a period of two years upon the following conditions:

I. That the license be actively suspended for a period of three (3) business days beginning no later than 90 days of the Board's acceptance of this Order.

II. That during the stay period Respondent Foil shall violate no laws governing the practice of pharmacy.

III. That during the stay period Respondent Foil violate no rules of the Board of Pharmacy.

IV. That Respondent Foil shall notify the Board office at least 10 days in advance of the commencement date of the active suspension of his license. Such notification shall be in writing and directed to the North Carolina Board of Pharmacy, PO Box 459, Carrboro, NC 27510 or faxed to (919)967-5757. He shall surrender his license, the renewal certificate thereof, and his wallet card to the Board during the active suspension period.

3. That the license issued to Respondent RPh. Monroe is hereby suspended for 7 days, which suspension is stayed for a period of two years upon the following conditions:

I. That the license be actively suspended for a period of three (3) business days beginning no later than 90 days of the Board's acceptance of this Order.

II. That during the stay period Respondent Monroe shall violate no laws governing the practice of pharmacy during this stayed period.

III. That during the stay period Respondent Monroe violate no rules of the Board of Pharmacy during the stayed period.

IV. Respondent Monroe shall notify the Board office at least 10 days in advance of the commencement date of the active suspension of his license. Such notification shall be in writing and directed to the North Carolina Board of Pharmacy, PO Box 459, Carrboro, NC, 27510 or faxed to (919)967-5757. He shall surrender his license, the renewal certificate thereof, and his wallet card to the Board during the active suspension period.

By order of the North Carolina Board of Pharmacy this the 21st day of April, 1999.

By: Albert F. Lockamy, Jr.
Albert F. Lockamy, Jr.
President

ATTEST:

David R. Work
David R. Work
Executive Director

RPh. Jason M. Foil has full knowledge that he has the right to a hearing and to be represented by counsel in this matter, and freely, knowingly, and voluntarily waives such right by entering into this Consent Order. Jason M. Foil understands and agrees that by entering into this Consent Order, he voluntarily relinquished any right to judicial review of Board actions which may be taken concerning any related matters. Jason M. Foil understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Jason M. Foil admits there is a factual basis for the Finding of Fact set forth herein and that the Findings of Fact support the Conclusions of Law. Jason M. Foil consents to and accepts entry of this Consent Order for purposes of resolving this proceeding before the Board of Pharmacy. Jason M. Foil concurs with the foregoing Finding of Fact, Conclusion of Law, and Order of the Board and will not contest the Finding of Fact should further action be warranted in this matter.

CONSENTED TO BY Jason M Foil 4/7/99
Jason M. Foil Date

State of NC

VANCE County

I, N. M. Edwards, a Notary Public for the above named County and State, do hereby certify that Jason M. Foil personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witnessed my hand and official seal

This the 7th day of April, 1999.

N. M. Edwards
Notary Public

My Commission Expires: 02/04/2003

Jason M. Foil does not accept the proposed Consent Order in this matter.

Jason M. Foil Date

13D

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** 02311
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: Promesa Health Pharmacy

Physical Address: 10815 Old Mill Road

Mailing Address: same

City: Omaha State: NE Zip Code: 68154

Telephone: 877-234-4409 Fax: 877-234-4429

Toll Free Number: 877-234-4409 (Required per NAC 639.708)

E-mail: mlwhite@promesahealth.com Website: NA

Managing Pharmacist: Margie White License Number: 10750-NE

TYPE OF PHARMACY AND **SERVICES PROVIDED**

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☒ Retail	☐	☒
☐	☒ 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.

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

Jeffrey Silver

Print Name of Authorized Person

11-19-2019

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: Nebraska

Parent Company if any: Applied Underwriters, Inc.

Mailing Address: 10805 Old Mill Road

City: Omaha State: NE Zip: 68154

Telephone: 402-342-4900 Fax: 402-393-8558

Contact Person: Jeffrey Silver

For any corporation non publicly traded, disclose the following:

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

a) none
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 1,000

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

4) What date did the corporation actually receive the cash assets? 6-7-2006

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 8 am 5 pm Saturday 10 am 12 pm

Sunday closed am _____ pm 24 Hours _____

(TUESDAY 8am -3pm)

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: PH02311

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Jeffrey Silver

Responsible Person of Promesa Health 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

Jeffrey Silver
Print Name of Authorized Person

11-19-2019
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Nebraska)
) ss.
Douglas COUNTY)

I, Margie White, 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 PIC for Promesa Health 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, Margie White, 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
19 day of November, 2019.

NOTARY PUBLIC

State of Nebraska – General Notary
NICOLE MINZEL
My Commission Expires
August 17, 2022

STATE OF NEBRASKA

United States of America, } ss.
State of Nebraska }

Secretary of State
State Capitol
Lincoln, Nebraska

I, Robert B. Evnen, Secretary of State of the State of Nebraska, do hereby certify that

PROMESA HEALTH, INC.

incorporated on May 31, 2006 and is duly incorporated under the law of Nebraska;

that no occupation taxes due from and assessable against the Corporation are unpaid and have become delinquent;

that no annual or biennial report required to be forwarded by the Corporation to the Secretary of State has become delinquent;

that Articles of Dissolution have not been filed.

This certificate is not to be construed as an endorsement, recommendation, or notice of approval of the entity's financial condition or business activities and practices.

In Testimony Whereof,

I have hereunto set my hand and affixed the Great Seal of the State of Nebraska on this date of

November 20, 2019

Secretary of State

Verification ID a8273f3 has been assigned to this document. Go to ne.gov/go/validate to validate authenticity for up to 12 months.

STATE OF NEBRASKA

United States of America, } ss.
State of Nebraska }

Secretary of State
State Capitol
Lincoln, Nebraska

I, Robert B. Evnen, Secretary of State of the State of Nebraska, do hereby certify that

APPLIED UNDERWRITERS, INC.

incorporated on March 30, 2001 and is duly incorporated under the law of Nebraska;

that no occupation taxes due from and assessable against the Corporation are unpaid and have become delinquent;

that no annual or biennial report required to be forwarded by the Corporation to the Secretary of State has become delinquent;

that Articles of Dissolution have not been filed.

This certificate is not to be construed as an endorsement, recommendation, or notice of approval of the entity's financial condition or business activities and practices.

In Testimony Whereof,

I have hereunto set my hand and affixed the Great Seal of the State of Nebraska on this date of

November 20, 2019

Secretary of State

Verification ID 0488166 has been assigned to this document. Go to ne.gov/go/validate to validate authenticity for up to 12 months.

Affidavit

Promesa Health Pharmacy remains wholly owned by Promesa Health, Inc. Promesa Health, Inc. remains a wholly owned subsidiary of Applied Underwriters Inc.

The officers have changed from Steven Menzies, President; Sidney Ferenc, Vice President/Treasurer; Jeffrey Silver, Vice President/Secretary to Steven Menzies, President and Treasurer; Jeffrey Silver, Vice President/Secretary.

Affidavit A below, must be completed by the owner, partner or by the principal officer. If the person executing Affidavit "A" is not also the pharmacist-in-charge of the pharmacy, then the pharmacist-in-charge must complete Affidavit "B."

I do solemnly swear and affirm that the foregoing statements on this form or those on any attachment(s) to this form are to the best of my knowledge true and correct.

Affidavit "A"

Jeffrey Silver
Print Name of Owner, Partner or Officer

Signature of above

Subscribed and sworn to before me
this 5th day of November
in the year 2019

Print Notary's name:

Shari Michaelson
Notary's signature:

Shari Michaelson

My commission expires:

August 8, 2023

Affix Seal Here:

GENERAL NOTARY - State of Nebraska
SHARI MICHAELSON
My Comm. Exp. August 8, 2023

Affidavit "B"

Margie White
Print Name of Owner, Partner or Officer

Signature of above

Subscribed and sworn to before me
this 5th day of November
in the year 2019

Print Notary's name:

Shari Michaelson
Notary's signature:

Shari Michaelson

My commission expires:

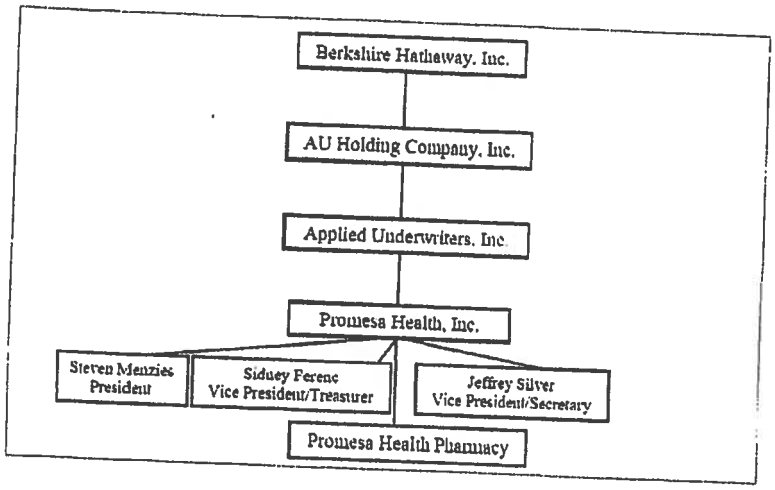
August 8, 2023

Affix Seal Here:

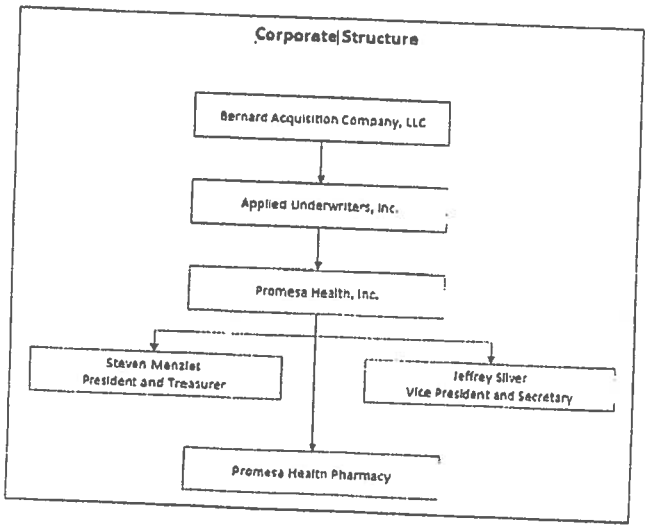
GENERAL NOTARY - State of Nebraska
SHARI MICHAELSON
My Comm. Exp. August 8, 2023

In reference to N.J.A.C. 13:39-4.20, the following change in corporate officers has occurred:

Previous Corporate Structure:



Current Corporate Structure:



Previous List of Corporate Officers:

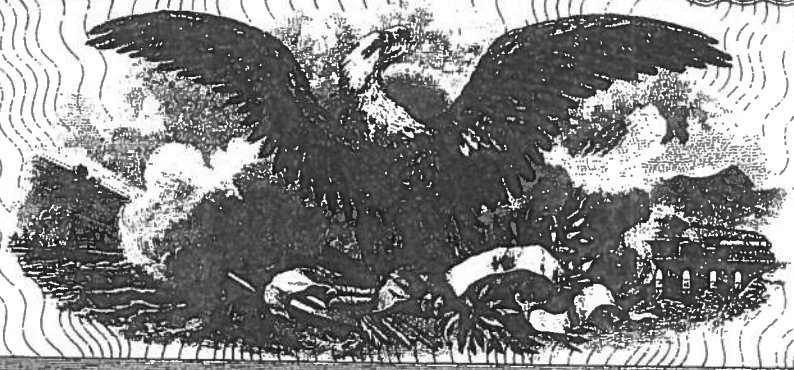
Name	Address	Title
Steven Menzies	10805 Old Mill Road Omaha. NE 68154	President/ Treasurer
Jeffrey Silver	10805 Old Mill Road Omaha. NE 68154	Vice President/Secretary
Sidney Ferenc	10805 Old Mill Road Omaha. NE 68154	Chairman Emeritus

New List of Corporate Officers:

Name	Address	Title
Steven Menzies	10805 Old Mill Road Omaha. NE 68154	President/ Treasurer
Jeffrey Silver	10805 Old Mill Road Omaha. NE 68154	Vice President/Secretary

INCORPORATED UNDER THE LAWS OF THE

STATE OF NEBRASKA



NUMBER

1

1,000

SHARES

PROMESA HEALTH, INC.

A Nebraska Corporation

This Certifies that APPLIED UNDERWRITERS, INC. is the owner of

ONE THOUSAND (1,000) Shares of the Capital Stock of

transferable only on the Books of the Corporation by the holder hereof in person or by duly authorized Attorney on surrender of this Certificate properly endorsed.

In Witness Whereof the said Corporation has caused this Certificate to be signed by its duly authorized officers and its Corporate Seal to be hereunto affixed at Omaha, Nebraska

this 7th day of June A.D. 2006.

Sidney R. Berens, President

Jeffrey A. Silver, Secretary

Shares $1.00 Each.

NEBRASKA

Good Life. Great Mission.

DEPT. OF HEALTH AND HUMAN SERVICES

Pete Ricketts, Governor

CERTIFICATION OF LICENSE

Nevada Board of Pharmacy
431 W Plumb Ln
Reno, NV 89509

PROFESSION NAME:	Community Pharmacy License		
Number:	2748	Status:	Active
Issuance Date:	04/05/2007	Expiration Date:	07/01/2020
Name:	Promesa Health Pharmacy		
Address:	10815 Old Mill Rd Omaha NE 68154		
Credential Obtained by:	Application		
Disciplinary Action:			

To expedite the certification process, the Licensure Unit is using the above format. There is no derogatory information in the professional's records if the Disciplinary Action section above is left blank.

Jesse Cushman, Program Manager
Office of Medical & Specialized Health
Licensure Unit

November 25, 2019

You may verify licenses under the following Internet Web Site Address: http://www.nebraska.gov/LISSearch/search.cgi

(SEAL)

STOCK REGISTER
OF
PROMESA HEALTH, INC.

As of June 7, 2006

Cert. #	Name	Issue Date	# of Shares	Cancel Date
1	Applied Underwriters, Inc.	06/07/06	1,000	

State of Nebraska

Department of Health and Human Services
Division of Public Health

Community Pharmacy License

This is to certify that **Promesa Health Pharmacy**
Is issued License No. **2748** to operate a Pharmacy at:
10815 Old Mill Rd Omaha NE 68154
Promesa Health, Inc
Margie Lynn White, RP In Charge

Issued under the name and Seal of the Department of Health and Human Services Division of Public Health, State of Nebraska, on **04/05/2007.**
Expiration Date: 07/01/2020

DEPARTMENT OF HEALTH AND HUMAN SERVICES
STATE OF
SEAL
NEBRASKA
EST. JULY 1, 2007

Dear Pharmacy Board,

Promesa Health Pharmacy was issued a reprimand and fine of $500 from the Illinois Pharmacy Board in response to the Maine complaint reported on our previous renewal form. Please let me know if you need any further information.

Respectfully,

Margie White, RPh

877-234-4409

mlwhite@promesahealth.com

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION OF THE ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION,	)	
Complainant,	)	Case No. 2016-08443
v.	)	
Promesa Health Pharmacy, License No. 054.016217, Respondent.	)	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by its attorney Bonita Canavan and Respondent Promesa Health Pharmacy, by its authorized representative Vice President and Secretary Jeffrey Silver ("Respondent"), hereby agree to the following:

STIPULATIONS

Pursuant to the Illinois Pharmacy Practice Act ("Act") 85/et seq., Promesa Health Pharmacy holds non resident pharmacy license no. 054.016217, which is currently in active status.

The Department received a self report from Respondent's incoming pharmacist in charge ("PIC") Margie White that the Respondent non-resident pharmacy, whose home state is Nebraska, entered into a Consent Order with the Board of Pharmacy of the State of Maine in Case No. 2015-PHA-11742 for failing to timely file its application of change in PIC within seven (7) days of April 23, 2015. Respondent filed the Maine application on May 26, 2015, twenty-six (26) days after it was due on April 30, 2015. The Maine Consent Order "imposed a warning, and civil penalty of one thousand dollars ($1,000.00)" on Respondent.

The Respondent's acts and/or omissions constitute grounds for disciplinary action against Respondent's license as a pharmacy on the authority of 225 ILCS 85/30(a)(8).

Pursuant to 68 IAC 1130.200(b), the following factors are considered in mitigation: (1) Respondent promptly self-reported the Maine discipline; and (2) has fully cooperated with the Department.

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and the parties herein. Respondent has been advised of the right to have any allegation(s) reduced to written charges, to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, the right to counsel, the right to contest any charges brought and present mitigating evidence, and the right to administrative review of any order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either the Board of Pharmacy ("Board") or Director. Respondent acknowledges that Respondent has entered into this Consent Order freely and of Respondent's own will without threat or coercion by the Department or any person, and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Respondent acknowledges that the Department attorney may be requested to communicate with the Board or Director in furtherance of the approval of this Consent Order. Respondent has been informed that this Consent Order will be presented to the Director. If this Consent Order is not approved, Respondent waives any right to raise any prejudice resulting from the Director's consideration of this Consent Order. Respondent understands that this Consent Order is not effective unless and until it is adopted by the Director. A copy of any original signature(s) affixed to this Consent Order shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Respondent and the Department have agreed, in order to resolve this matter, that Respondent be permitted to enter into a Consent Order with the Department, providing for the imposition of Consent measures which are fair and equitable under the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by its attorney Bonita Canavan and Respondent hereby agree to the following:

A. Respondent's pharmacy license no. 054.016217 is reprimanded.

B. Respondent shall pay a fine of five hundred dollars ($500.00) within sixty (60) days of the effective date of this Order. The fine is to be paid by personal check, cashier's check, or personal money order. Said check shall be made payable to:

Illinois Department of Financial and Professional Regulation
SSC – Accounts Receivable Section – Fines
PO Box 7086
Springfield, Illinois 62791-7086

In the notation portion of the check, Respondent shall write case no. 2016-08443 and license no. 054-016217.

C. If Respondent fails to pay the five hundred dollar ($500.00) fine, or any portion of the fine, and the Department initiates a collection effort to retrieve all or any portion of the fine, Respondent shall be responsible for all costs and fees incurred by the Department in said collection effort.

D. Respondent agrees that any violation this Consent Order permits the Director of the Division of Professional Regulation to issue an Order forthwith mandating the automatic, indefinite and immediate suspension of Respondent's pharmacy license. This suspension shall not preclude the Department from taking any other disciplinary or other action it deems appropriate. In the event Respondent contests in writing by the filing of a petition with the Department that complies with the Department's Rules of Practice in Administrative Hearings, and contests the factual basis underlying the suspension within thirty (30) days of

the effective date of the suspension, then Respondent shall be afforded a hearing on the merits.

E. This Consent Order is a public disciplinary action and will be available to the public. It shall be reported to the National Practitioners Data Bank and other applicable reporting services.

F. This Consent Order shall become effective upon approval by the Director, as signed and below.

Signatures on the following page.

9/14/2018
Date

Department attorney Bonita Canavan

8/25/2018
Date

Promesa Health Pharmacy by its Vice President and Secretary Jeffrey Silver

9/14/18
Date

Illinois Board of Pharmacy Member

This Consent Order is hereby approved in full:

Dated this 15 day of October, 2018.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY BRYAN A. SCHNEIDER

Jessica A. Baer
Director of Professional Regulation

Case No. 2016-08443
License No. 054.016217

Dear Board of Pharmacy,

Promesa Health Pharmacy was issued a warning and $1000 fine for not submitting the change of PIC application within 7 days for change of PIC in Maine. I have attached the Final Consent Agreement. Please let me know if I can provide any further information.

Respectfully,

Margie White, Rph

877-234-4409

mlwhite@promesahealth.com

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
PROMESA HEALTH PHARMACY	)	CONSENT AGREEMENT
	)	
Complaint No. 2015-PHA-11742	)	
	)	

PARTIES

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

FACTS

1. At all times relevant to this matter, Promesa was licensed by the Board as a mail order pharmacy, license no. MO40001072, located at 10815 Old Mill Road in Omaha, Nebraska.
2. On April 23, 2015, Margie L. White replaced Nichole R. Wilson as the pharmacist in charge ("PIC") of Promesa, thereby requiring Promesa to submit a Change of PIC application to the Board within 7 days after the PIC change.
3. Promesa, however, did not file a change of PIC application with the Board until May 26, 2015.
4. On November 24, 2015, Board Investigator Thomas Avery filed a complaint with the Board alleging that Promesa had failed to file a timely Change of PIC application.

5. The Board docketed this complaint as complaint no. 2015-PHA-11742.

6. Under Board Rules Chapter 11, § 3, upon a change of PIC, a mail order pharmacy must file a new application with the Board by registered mail no later than seven (7) days after the change.

7. On August 4, 2016, following a presentation of the complaint, the Board voted to offer Promesa this Consent Agreement in order to finally resolve Complaint No. 2015-PHA-11742.

8. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Mary A. Lord, Paralegal, Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333-0035 by September 12, 2016, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

9. Promesa admits to the facts as stated above and admits that such conduct constitutes grounds for discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(5) for violating a rule of the Board, specifically Board Rules Chapter 11, § 3, by failing to file a new application with the Board by registered mail no later than 7 days after a change of PIC.

10. As DISCIPLINE for the conduct admitted to in paragraph 9 above, Promesa agrees to accept the imposition of:

    a. A WARNING; and

    b. A CIVIL PENALTY in the amount of one thousand dollars ($1,000.00). Payment of the civil penalty shall be made by certified check or money order payable to the "Treasurer, State of Maine" and delivered to Mary A. Lord, Paralegal, Department of Professional and Financial Regulation, 35 State House Station,

Augusta, Maine 04333, within thirty (30) days of the execution of this Consent Agreement.

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

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

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

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

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

16. The Board and Promesa agree that no further agency or legal action will be initiated against Promesa by the Board based upon the specific violations admitted to herein, except or unless Promesa fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct in the event that other allegations are brought against Promesa. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining discipline in any further complaints against Promesa.

17. Promesa acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement.

that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

PROMESA HEALTH PHARMACY

DATED: 9/1/16

BY: _____
Authorized Representative

I Jeffrey Silver
Printed Name

DATED: 9/9/2016

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

DATED: 9/13/2016

_____
ANDREW L. BLACK
Assistant Attorney General

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP0138087	03-31-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	02-11-2019

PROMESA HEALTH PHARMACY
PROMESA HEALTH INC
10815 OLD MILL RD
OMAHA, NE 68154-2607

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
FP0138087	03-31-2022	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	02-11-2019

PROMESA HEALTH PHARMACY
PROMESA HEALTH INC
10815 OLD MILL RD
OMAHA, NE 68154-2607

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)