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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks 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 Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

- ☐ Publicly Traded Corporation – Pages 1,2,3,4
- ☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6
- ☐ Partnership - Pages 1,2,3,7,8
- ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Sheffield Pharmaceuticals LLC

Physical Address: 170 Broad St

City: New London State: CT Zip Code: 06320

Telephone Number: 860-442-4451 Fax Number: 860-442-0356

Toll Free Number: N/A

E-mail: anthony.solbrn@sheffieldpharma.com Website: www.sheffieldpharma.com

Facility Manager: Jeff Davis CEO and President

Professional qualifications and experience of facility manager: Jeff Davis has over 25 years of Pharmaceutical Manufacturing experience as well as company formation and Sales

Types of licensed outlets or authorized persons firm will serve:

☑ Pharmacies ☐ Practitioners ☑ Hospitals ☑ Wholesalers

☐ Other: Sheffield intends to sell product to third party distributor who is currently licensed in NV

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices

☐ Poisons or Chemicals

☐ Controlled Substances (include copy of DEA)

☐ Other: _____

☐ Hypodermic Devices

☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Zeta Pharmaceutical LLC.
Address: 120 Holmes Ave NE, Suite 116 Huntsville, AL 35801

Name: 3CI ~~Packag~~ Packaging Inc.
Address: 1000 CCC Dr Clayton, NC 27520

Name: AIBEA AMERICAS, INC
Address: 191 Route 31 North Washington, NJ 07882

Name: CAMPHOR TECHNOLOGIES CORP.
Address: 1584 Independence Blvd Sarasota FLA 34234

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

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 ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

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

Anthony D Sollima CSO and EVP of Regulatory Affairs — 3/25/2020

Print Name of Authorized Person — Date

Board Use Only	Date Processed:	Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Connecticut

Parent Company if any: Sheffield Pharmaceuticals LLC

Mailing Address: 170 Broad St

City: New London State: CT Zip: 06320

Telephone: 860-442-4451 Fax: 860-442-0356

Contact Person: Anthony Solhine

For any corporation non-publicly traded, disclose the following:

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

a) Sue Faria : Meadow Circle East Sandwich MA 02537-1041
Name Business Address

b) Thomas H Faria North Arena Las Vegas, NV 89178
Name Business Address

c) Nancy Faria West Main Road, Apt Middletown RI 0284
Name Business Address

d) Dana Faria Beach Dr SE, Unit St Petersburg FL 33701-3957
Name Business Address

2) Provide the number of shares issued by the corporation. Company ownership is set in percentage to each of 5 family members equally (100% 5 @ 20%)

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

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

Include with the application for a non-publicly traded corporation

List of officers and directors

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.

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

UNITED STATES OF AMERICA

CRIMINAL NO. 3:14CR 149 AWT

v.

VIOLATION:

THOMAS H. FARIA

33 U.S.C. § 1319(c)(2)(A)
(Clean Water Act)

INFORMATION

The United States Attorney charges:

COUNT ONE
(Knowing Violation of a Requirement Imposed in a Pretreatment Program Approved Under the Clean Water Act)

The Defendant – Thomas H. Faria

1. At all times relevant to this Information, the defendant, THOMAS H. FARIA, was a resident of Connecticut. In or about April 2003, the defendant became the president and chief executive officer of Faria Limited, LLC, d/b/a Sheffield Pharmaceuticals ("Faria Limited"), and assumed day-to-day management and control over the company. Since on or about April 30, 2008, until on or about May 13, 2014, the defendant held all of the company's voting shares.

Faria Limited, LLC, d/b/a Sheffield Pharmaceuticals

2. At all times relevant to this Information, Faria Limited was and remains a company operating a factory at 170 Broad Street in New London, Connecticut, that manufactures a wide range of over-the-counter pharmaceutical creams, ointments, and toothpastes. Faria Limited

purchased Sheffield Laboratories in 1986 and changed its operating name to Sheffield Pharmaceuticals.

The Clean Water Act and the NPDES Permit Program

3. The Clean Water Act ("CWA") at Title 33, United States Code, Section 1251 et seq., prohibits the discharge of pollutants to waters of the United States, except in a manner consistent with the National Pollutant Discharge Elimination System ("NPDES") permitting program set forth in Section 1342 of the CWA. Under the NPDES permitting program, all publicly owned sewage-treatment systems, commonly known as publicly owned treatment works ("POTWs"), that discharge to waters of the United States must obtain and comply with discharge permits. Because POTWs are designed to treat sewage, not industrial waste, such discharge permits often require the development and implementation of a POTW pretreatment program to treat industrial waste at the factory before the industrial waste reaches the POTW. The purpose of such pretreatment programs is to prevent introducing pollutants into a POTW that may pass through the POTW, may interfere with the POTW's operation, or may otherwise be incompatible with the POTW.

4. The CWA authorizes the Environmental Protection Agency ("EPA") to approve states to administer the NPDES permit program. To receive EPA approval, the state must develop a state pretreatment program that, among other things, incorporates POTW pretreatment program conditions into permits issued to POTWs; requires compliance by POTWs with these incorporated permit conditions; and requires compliance by industrial users with pretreatment standards. A state with an approved state pretreatment program may assume responsibility for implementing the POTW pretreatment program in lieu of requiring the POTW to develop a pretreatment program.

An Industrial Facility in Connecticut Must Have a Permit to Discharge Industrial Wastewater

5. In 1979, the State of Connecticut ("Connecticut") made a formal request to the EPA that Connecticut be approved to administer the NPDES program and to assume responsibility for implementing the POTW pretreatment program in lieu of requiring the POTW to develop a pretreatment program. In its application for pretreatment program approval dated March 27, 1979, the Connecticut Department of Environmental Protection ("CT DEP") stated, "The Department is committed to achievement of its own and the national goals of fishable swimmable waters and elimination of the discharge of pollutants. The treatment of industrial wastes prior to discharge to POTWs is a necessary and significant program element in achievement of those goals." In 1981, the EPA approved Connecticut's pretreatment program, including the request to operate a state-wide pretreatment program. The CT DEP is now named the Connecticut Department of Energy and Environmental Protection ("CT DEEP").

6. Connecticut's pretreatment program prohibits the discharge of industrial wastewater to POTWs without a CT DEEP permit. The failure to obtain a CT DEEP permit prior to discharging industrial wastewater to a POTW constitutes a violation of a requirement of a pretreatment program approved under Title 33, United States Code, Section 1342(b)(8).

7. The CT DEEP tailors wastewater permits for industrial users based on, among other things, the type and quantity of industrial wastewater being discharged by the facility. When applying for a wastewater permit from CT DEEP, an industrial facility must characterize and quantify the pollutants contained in its wastewater based on actual wastewater samples. A CT DEEP permit allows an industrial facility to discharge pollutants to the POTW only within the specific conditions and numeric limitations for pollutants mandated by the permit. Furthermore, CT DEEP permits impose on the industrial facility the obligation to sample and analyze its

wastewater regularly, and to report the results to the CT DEEP each month in a Discharge Monitoring Report ("DMR"). The CT DEEP relies upon the sampling data provided in these monthly DMRs to determine whether the industrial facility is complying with the discharge permit's parameters.

Faria Limited Did Not Have a CT DEEP Permit From 1986 to July 2011, But Still Discharged Industrial Wastewater to the New London POTW Throughout The Entire Period

8. At all times relevant to this matter, the City of New London Water Pollution Control Facility, together with its public sewer system, constituted a POTW ("New London POTW") within the meaning of the CWA and Connecticut's pretreatment program, and as approved by the EPA. The New London POTW discharges to the Thames River in southeastern Connecticut.

9. From in or about 1986 to July 2011, Faria Limited discharged industrial wastewater from its New London manufacturing operations to the New London POTW without a permit and in violation of Connecticut's approved pretreatment program. During this entire time period, Faria Limited lacked a pretreatment system at its factory to treat its industrial wastewater prior to discharge to the New London POTW, performed no regular monitoring of its discharges of industrial wastewater, and submitted no monthly DMRs to the CT DEEP.

The Defendant Knew for Several Years That Faria Limited Did Not Have a Permit From CT DEEP to Discharge Industrial Wastewater to the New London POTW

10. After becoming the company's president and chief executive officer in April 2003, the defendant learned through his own employees that Faria Limited was discharging pollutants in its industrial wastewater, including the toxic metal zinc, without the required permit. The defendant also learned that in order to obtain a permit from CT DEEP, Faria Limited would have to install, at significant expense, a wastewater pretreatment system that would pretreat its industrial wastewater prior to discharging it to the New London POTW.

a. On May 27, 2003, a manager on the Faria Limited production floor sent the following e-mail message, which was copied to the defendant and states in pertinent part:

> I strongly suggest we engage an environmental consultant to study this issue. There are several firms that specialize in just this type of permitting. In my experience I have never heard of an industry not needing a discharge permit to discharge into the sanitary sewer. This could potentially be very damaging to the company if it is discovered we are discharging to the sewer without the proper permits and monitoring.

b. Nearly two years later on April 5, 2005, the same manager sent directly to the defendant the following e-mail message and attached a proposal prepared by an environmental consultant to bring Faria Limited into compliance with the CWA and the CT DEEP:

> You need to understand a couple of things.
>
> 1) We are out of compliance with the Clean Water Act. We may continue on for years this way, however once it is recognized we are discharging to the New London POTW and not meeting the pretreatment standards it will mean an immediate shutdown of discharge due to the type of industry we are. Shutdown of our discharge will mean shutting down the factory unless we contract to have our discharge taken away to a disposal facility. This might never happen, or it could happen tomorrow. All it takes is one serious problem at the New London POTW after which the state starts taking a look upstream.
>
> 2) Criminal penalties could also be levied, and as officers of the company this burden will fall upon you. In my opinion this is probably a slim possibility, but the option exists to the state. But, remember that article I showed you in which [Company X] in Stafford Springs exceeded pretreatment standards when discharging to the local POTW. Multi million dollar fines and criminal prosecution did happen.
>
> I can't stress strongly enough that this should become the top priority in the project list. We need to take immediate action to get this treatment system set up and our permitting completed. To follow the letter of the law we should immediately discontinue all discharge to the New London POTW until this permitting is in place.

11. Under the defendant's leadership and with his knowledge, Faria Limited hired between 2004 and 2007 at least four environmental consulting firms to advise the company regarding its discharge of industrial wastewater to the New London POTW. The consultants of these firms informed Faria Limited that its discharge of industrial wastewater to the public sewage treatment system, without a pretreatment system or CT DEEP permit, was illegal.

a. In a report dated March 31, 2004, that was reviewed by the defendant, one environmental consultant stated: "A discharge permit from the CT DEP is required for cleaning-water discharge; therefore Sheffield is currently out of compliance."

b. In a report dated June 11, 2004, that was forwarded by e-mail to Faria, another environmental consultant stated, among other things: "We understand you are very concerned that going to CT DEP with permit applications, thereby acknowledging some level of noncompliance, might result in some business disruption." This consultant further stated: "It will take time and resources, but the alternative, which includes enforcement action [and] fines . . . will most certainly have a much larger impact on the bottom line."

c. Based on an analysis of samples taken from the factory's own wastewater, the consultant's report dated June 11, 2004, concluded that Faria Limited's industrial wastewater contained levels of zinc far in excess of any concentration permitted by CT DEEP.

12. On April 20, 2011, the CT DEEP conducted an unannounced inspection of Faria Limited. After finding that the company had no wastewater discharge permits, the CT DEEP inspector issued a Notice of Violation and cited Faria Limited for discharging manufacturing and laboratory wastewater without a permit.

13. On or about May 27, 2011, Faria Limited submitted a permit application to CT DEEP, so that Faria Limited could discharge industrial wastewater from its New London facility

into the New London POTW. By July 2011, Faria Limited had installed a wastewater pretreatment system at its factory to pretreat the pollutants contained in its industrial wastewater prior to its discharge to the New London POTW.

14. Based on the foregoing, from at least as early as April 2004 to May 2011, in the District of Connecticut, the defendant, as president and chief executive officer of Faria Limited, knowingly violated and caused to be violated a requirement imposed in a pretreatment program approved under section 1342(a)(3) and 1342(b)(8) of Title 33, United States Code—that is, the discharge of industrial wastewater into the New London publicly owned treatment works without a permit.

All in violation of Title 33, United States Code, Section 1319(c)(2)(A).

UNITED STATES OF AMERICA

DEIRDRE M. DALY
UNITED STATES ATTORNEY

HAROLD H. CHEN
ASSISTANT UNITED STATES ATTORNEY

PETER W. KENYON
SPECIAL ASST. UNITED STATES ATTORNEY

U.S. Department of Justice

United States Attorney
District of Connecticut

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July 8, 2014

Thomas J. Murphy, Esq.
James T. Cowdery, Esq.
Cowdery & Murphy, L.L.C.
280 Trumbull Street
Hartford, CT 06103

Re: United States v. Thomas H. Faria
Criminal No. 3:14CR149 AWT

Dear Attorneys Murphy and Cowdery:

This letter confirms the plea agreement between your client, Thomas H. Faria (the "defendant"), and the United States Attorney's Office for the District of Connecticut (the "Government" or "this Office") concerning the referenced criminal matter.

THE PLEA AND OFFENSE

The defendant agrees to waive his right to be indicted and to plead guilty to a one-count information charging him with knowingly violating the requirements imposed in a pretreatment program approved under the Clean Water Act. 33 U.S.C. § 1319(c)(2)(A). The defendant understands that to be guilty of this offense, the following essential elements of the offense must be satisfied:

1. From at least as early as April 2004 to May 2011, the defendant violated, or caused a violation of, a requirement imposed in a pretreatment program approved pursuant to 33 U.S.C. § 1342—that is, the discharge of industrial wastewater into the New London publicly owned treatment works without a permit; and

2. The defendant acted knowingly.

THE PENALTIES

This offense carries a maximum penalty of three years of imprisonment and a fine of not less than $5,000 but not more than $50,000 per day of the violation. In addition, under 18 U.S.C. § 3583, the Court may impose a term of supervised release of not more than one year to begin at

the expiration of any term of imprisonment. The defendant understands that should he violate any condition of the supervised release, he may be required to serve a further term of imprisonment of up to one year per violation with no credit for time already spent on supervised release.

The defendant also is subject to the alternative fine provision of 18 U.S.C. § 3571. Under this section, the maximum fine that may be imposed on the defendant is the greatest of the following amounts: (1) twice the gross gain to the defendant resulting from the offense; (2) twice the gross loss resulting from the offense; or (3) $250,000; or (4) the amount specified in the section defining the offense, which is a fine of not less than $5,000 but not more than $50,000 per day of the violation under 33 U.S.C. § 1319(c)(2).

In addition, the defendant is obligated by 18 U.S.C. § 3013 to pay a special assessment of $100 on each count of conviction. The defendant agrees to pay the special assessment to the Clerk of the Court on the day the guilty plea is accepted.

Unless otherwise ordered, should the Court impose a fine of more than $2,500 as part of the sentence, interest will be charged on the unpaid balance of the fine not paid within 15 days after the judgment date. 18 U.S.C. § 3612(f). Other penalties and fines may be assessed on the unpaid balance of a fine pursuant to 18 U.S.C. § 3572 (h), (i) and § 3612(g).

Agreement Regarding the Defendant's Involvement in Faria Limited, LLC, d/b/a Sheffield Pharmaceuticals

On March 7, 2014, the defendant resigned from his position as president and chief executive officer of Faria Limited, LLC, d/b/a Sheffield Pharmaceuticals ("Faria Limited"), and also relinquished his seat on the board of directors. On May 13, 2014, by written amendment to Faria Limited's corporate Operating Agreement, the defendant's 38% equity interest in Faria Limited was converted to Class B – Non Voting shares (or "membership units"). Pursuant to this conversion, the defendant no longer possesses any voting rights to exercise with respect to Faria Limited's operations and management, except that he is entitled to vote if Faria Limited's other equity owners are considering a sale in the future of all, or substantially all, of Faria Limited's membership units, assets, or business. The defendant hereby stipulates that subject to this sole limited exception for the exercise of his voting rights, he shall have no involvement in directing, managing, controlling, or working for Faria Limited in any manner until the Court determines that his term of supervised release has fully expired.

THE SENTENCING GUIDELINES

Applicability

The defendant understands that the Court is required to consider any applicable Sentencing Guidelines as well as other factors enumerated in 18 U.S.C. § 3553(a) to tailor an appropriate sentence in this case and is not bound by this plea agreement. The defendant agrees

that the Sentencing Guideline determinations will be made by the Court, by a preponderance of the evidence, based upon input from the defendant, the Government, and the United States Probation Office. The defendant further understands that he has no right to withdraw his guilty plea if his sentence or the Guideline application is other than he anticipated, including if the sentence is outside any of the ranges set forth in this agreement.

Acceptance of Responsibility

At this time, the Government agrees to recommend that the Court reduce by two levels the defendant's adjusted offense level under § 3E1.1(a) of the Sentencing Guidelines, based on the defendant's prompt recognition and affirmative acceptance of personal responsibility for the offense. Moreover, should the defendant qualify for a decrease under § 3E1.1(a) and his offense level determined prior to the operation of subsection (a) is level 16 or greater, the Government will file a motion with the Court pursuant to § 3E1.1(b) which recommends that the Court reduce the defendant's Adjusted Offense Level by one additional level based on his prompt notification of his intention to enter a plea of guilty. The defendant expressly understands that the Court is not obligated to accept the Government's recommendations on the reductions.

The above-listed recommendations are conditioned upon the defendant's affirmative demonstration of acceptance of responsibility, by (1) truthfully admitting the conduct comprising the offense(s) of conviction and truthfully admitting or not falsely denying any additional relevant conduct for which the defendant is accountable under Sentencing Guideline § 1B1.3, and (2) truthfully disclosing to the Probation Office personal information requested, including the submission of a complete and truthful financial statement detailing the defendant's financial condition.

In addition, the Government expressly reserves the right to seek denial of the adjustment for acceptance of responsibility if the defendant engages in any acts, unknown to the Government at the time of the signing of this agreement, which (1) indicate that the defendant has not terminated or withdrawn from criminal conduct or associations (Sentencing Guideline § 3E1.1); (2) could provide a basis for an adjustment for obstructing or impeding the administration of justice (Sentencing Guideline § 3C1.1); or (3) constitute a violation of any condition of release. Moreover, the Government reserves the right to seek denial of the adjustment for acceptance of responsibility if the defendant seeks to withdraw his plea of guilty or takes a position at sentencing, or otherwise, which, in the Government's assessment, is inconsistent with affirmative acceptance of personal responsibility. The defendant understands that he may not withdraw his plea of guilty if, for the reasons explained above, the Government does not make one or both of the recommendations or seeks denial of the adjustment for acceptance of responsibility.

Stipulation

Pursuant to § 6B1.4 of the Sentencing Guidelines, the defendant and the Government have entered into a stipulation, which is attached to and made a part of this plea agreement. The

defendant understands that this stipulation does not set forth all of the relevant conduct and characteristics that may be considered by the Court for purposes of sentencing. The defendant understands that this stipulation is not binding on the Court. The defendant also understands that the Government and the United States Probation Office are obligated to advise the Court of any additional relevant facts that subsequently come to their attention.

Guideline Stipulation

The parties agree that the Guidelines Manual in effect on the date of sentencing is used to determine the applicable Guidelines range.

The Government and the defendant disagree about the Guidelines calculation and the Guidelines range. Consequently, the parties stipulate that all Guidelines calculations, including the calculation of the defendant's total offense level and Guidelines range, shall be resolved at sentencing.

Based on the information currently available, the Government's position regarding the defendant's Guidelines calculation is as follows: The defendant's base offense level under U.S.S.G. § 2Q1.2(a) is 8. Six (6) levels are added because, under U.S.S.G. § 2Q1.2(b)(1)(A), the offense resulted in an ongoing, continuous, or repetitive discharge of a hazardous or toxic substance into the environment. Four (4) levels are added because, under U.S.S.G. § 2Q1.2(b)(4), the offense involved treatment, storage, or disposal without a permit. Two (2) more levels are added because, under U.S.S.G. § 3B1.1(c), the defendant was a leader of the offense. Assuming a three-level reduction under U.S.S.G. § 3E1.1 for acceptance of responsibility, the defendant's total offense level is 17. With a Criminal History Category I and a total offense level of 17, the defendant's Guidelines range would be 24 to 30 months of imprisonment (sentencing table). The fine range is governed by U.S.S.G. § 5E1.2(c)(4). The defendant is also subject to a supervised release term of one (1) year. U.S.S.G. § 5D1.2. The Government reserves its right to amend its position regarding the defendant's Guidelines calculation.

The defendant disagrees with the Government's Guidelines calculation and range, including the application of U.S.S.G. § 2Q1.2 (as opposed to U.S.S.G. § 2Q1.3) and of any aggravating role adjustment under U.S.S.G. § 3B1.1. The Government and the defendant reserve their rights to seek a departure or a non-Guidelines sentence, and both sides reserve their rights to object to a departure or a non-Guidelines sentence. Specifically, the defendant reserves his right to argue at sentencing pursuant to 18 U.S.C. § 3553(a) that the facts of this case provide significant mitigating grounds to support either a downward departure and/or the imposition of a non-Guidelines sentence.

The Government and the defendant reserve their respective rights to seek whatever sentence the parties deem appropriate.

The defendant expressly understands that the Court is not bound by this agreement on any of the Guidelines provisions specified above. The defendant further understands that he will

not be permitted to withdraw the plea of guilty in the event he disagrees with the Court's or the Probation Office's Guidelines calculations or Guidelines range.

In the event the Probation Office or the Court contemplates any sentencing calculations different from those argued for by the parties, the parties reserve the right to respond to any inquiries and make appropriate legal arguments regarding the proposed alternate calculations. Moreover, the parties expressly reserve the right to defend any sentencing determination, even if it differs from that argued for by the parties, in any post-sentencing proceeding.

Appeal Rights Regarding Sentencing

The parties reserve their respective rights to appeal and to oppose each other's appeal of the sentence imposed as permitted by 18 U.S.C. § 3742.

Information to the Court

The Government and the defendant reserve their rights to address the Court with respect to an appropriate sentence to be imposed in this case. Moreover, the Government and the defendant will discuss the facts of this case, including information regarding the defendant's background and character, 18 U.S.C. § 3661, with the United States Probation Office. The Government will provide the Probation Officer with access to material in its file, with the exception of grand jury material.

WAIVER OF RIGHTS

Waiver of Right to Indictment

The defendant understands that he has the right to have the facts of this case presented to a federal grand jury, consisting of between sixteen and twenty-three citizens, twelve of whom would have to find probable cause to believe that he committed the offense set forth in the information before an indictment could be returned. The defendant acknowledges that he is knowingly and intelligently waiving his right to be indicted.

Waiver of Trial Rights and Consequences of Guilty Plea

The defendant understands that he has the right to be represented by an attorney at every stage of the proceeding and, if necessary, one will be appointed to represent him.

The defendant understands that he has the right to plead not guilty or to persist in that plea if it has already been made, the right to a public trial, the right to be tried by a jury with the assistance of counsel, the right to confront and cross-examine the witnesses against him, the right not to be compelled to incriminate himself, the right to testify and present evidence, and the right to compel the attendance of witnesses to testify in his defense. The defendant understands that

by pleading guilty he waives and gives up those rights and that, if the plea of guilty is accepted by the Court, there will not be a further trial of any kind.

The defendant understands that, if he pleads guilty, the Court may ask him questions about each offense to which he pleads guilty, and if he answers those questions falsely under oath, on the record, and in the presence of counsel, his answers may later be used against him in a prosecution for perjury or making false statements.

Waiver of Statute of Limitations

The defendant agrees that, should the conviction following defendant's plea of guilty pursuant to this plea agreement be vacated for any reason, then any prosecution that is not time-barred by the applicable statute of limitations on the date of the signing of this plea agreement (including any indictment or counts the Government has agreed to dismiss at sentencing pursuant to this plea agreement) may be commenced or reinstated against defendant, notwithstanding the expiration of the statute of limitations between the signing of this plea agreement and the commencement or reinstatement of such prosecution. The defendant agrees to waive all defenses based on the statute of limitations with respect to any prosecution that is not time-barred on the date the plea agreement is signed.

ACKNOWLEDGMENT OF GUILT AND VOLUNTARINESS OF PLEA

The defendant acknowledges that he is entering into this agreement and is pleading guilty freely and voluntarily because he is guilty. The defendant further acknowledges that he is entering into this agreement without reliance upon any discussions between the Government and him (other than those described in the plea agreement letter), without promise of benefit of any kind (other than the concessions contained in the plea agreement letter), and without threats, force, intimidation, or coercion of any kind. The defendant further acknowledges his understanding of the nature of the offense to which he is pleading guilty, including the penalties provided by law. The defendant also acknowledges his complete satisfaction with the representation and advice received from his undersigned attorney. The defendant and his undersigned counsel are unaware of any conflict of interest concerning counsel's representation of the defendant in the case.

SCOPE OF THE AGREEMENT

The defendant acknowledges that this agreement is limited to the undersigned parties and cannot bind any other federal authority, or any state or local authority. The defendant acknowledges that no representations have been made to him with respect to any civil or administrative consequences that may result from this plea of guilty because such matters are solely within the province and discretion of the specific administrative or governmental entity involved. Finally, the defendant acknowledges that this agreement has been reached without regard to any civil tax matters that may be pending or which may arise involving him.

COLLATERAL CONSEQUENCES

The defendant understands that he will be adjudicated guilty of each offense to which he has pleaded guilty and will be deprived of certain rights, such as the right to hold public office, to serve on a jury, to possess firearms, and in some states, the right to vote. Further, the defendant understands that if he is not a citizen of the United States, a plea of guilty may result in removal from the United States, denial of citizenship, and denial of admission to the United States in the future. The defendant understands that pursuant to section 203(b) of the Justice For All Act, the Bureau of Prisons or the Probation Office will collect a DNA sample from the defendant for analysis and indexing. Finally, the defendant understands that the Government reserves the right to notify any state or federal agency by which he is licensed, or with which he does business, as well as any current or future employer of the fact of his conviction.

SATISFACTION OF FEDERAL CRIMINAL LIABILITY; BREACH

The defendant's guilty plea, if accepted by the Court, will satisfy the federal criminal liability of the defendant in the District of Connecticut as a result of his participation in violating a requirement imposed in a pretreatment program approved pursuant to the Clean Water Act—that is, the discharge of industrial wastewater into the New London publicly owned treatment works without a permit, which forms the basis of the information in this case. The defendant understands that if, before sentencing, he violates any term or condition of this agreement, engages in any criminal activity, or fails to appear for sentencing, the Government may void all or part of this agreement. If the agreement is voided in whole or in part, the defendant will not be permitted to withdraw his plea of guilty.

NO OTHER PROMISES

The defendant acknowledges that no other promises, agreements, or conditions have been entered into other than those set forth in this plea agreement, and none will be entered into unless set forth in writing, signed by all the parties.

This letter shall be presented to the Court, in open court, and filed in this case.

Very truly yours,

DEIRDRE M. DALY
UNITED STATES ATTORNEY

HAROLD H. CHEN
ASSISTANT UNITED STATES ATTORNEY

PETER W. KENYON
SPECIAL ASSISTANT U.S. ATTORNEY

The defendant certifies that he has read this plea agreement letter and its attachment(s) or has had it read or translated to him, that he has had ample time to discuss this agreement and its attachment(s) with counsel and that he fully understands and accepts its terms.

THOMAS H. FARIA
The Defendant

7/8/14
Date

I have thoroughly read, reviewed and explained this plea agreement and its attachment(s) to my client who advises me that he understands and accepts its terms.

THOMAS J. MURPHY, ESQ.
Attorney for the Defendant

7/8/14
Date

JAMES T. COWDERY, ESQ.
Attorney for the Defendant

7-8-14
Date

STIPULATION OF OFFENSE CONDUCT

The defendant, Thomas H. Faria ("Faria" or "the defendant"), and the Government stipulate to the following offense conduct that gives rise to the defendant's agreement to plead guilty to the information:

Faria Limited, LLC, d/b/a Sheffield Pharmaceuticals ("Faria Limited") was and is a company with a factory at 170 Broad Street in New London, Connecticut, that manufactures a wide range of over-the-counter pharmaceutical creams, ointments, and toothpastes. Faria Limited purchased Sheffield Laboratories in 1986 and changed its operating name to Sheffield Pharmaceuticals.

Faria, the company's president and chief executive officer, assumed control over the company in April 2003 after his father's death. As president and chief executive officer, Faria has been responsible for Faria Limited's operations since April 2003. In addition, Faria held all of the company's voting shares from April 30, 2008, until May 13, 2014.

The City of New London Water Pollution Control Facility, together with the New London public sewer system, constituted a publicly owned treatment works ("POTW") within the meaning of the Clean Water Act and Connecticut's pretreatment program as approved by the Environmental Protection Agency. Under the Clean Water Act, Connecticut's pretreatment program prohibits the discharge of industrial wastewater to POTWs without a permit issued by the Connecticut Department of Energy and Environmental Protection ("CT DEEP"). The failure to obtain a CT DEEP permit prior to discharging industrial wastewater to a POTW constitutes a violation of a requirement of a pretreatment program approved under Title 33, United States Code, Section 1342(b)(8).

From at least as early as April 2003 to July 2011, Faria Limited discharged industrial wastewater from its manufacturing operations to the New London POTW without a permit and in violation of Connecticut's approved pretreatment program. During this time period, Faria Limited lacked an approved wastewater treatment system and performed no regular monitoring of its discharges of industrial wastewater pursuant to a CT DEEP permit.

After becoming the company's president and chief executive officer in April 2003, Faria learned through his own employees that Faria Limited was discharging industrial wastewater without the permit required by the Clean Water Act. Despite knowing that Faria Limited needed to apply for and obtain a wastewater permit from CT DEEP, Faria continued to operate the factory and to discharge industrial wastewater to the New London POTW without a permit.

The parties stipulate that from at least as early as April 2004 to May 2011, the defendant, as president and chief executive officer of Faria Limited, knowingly violated and caused to be violated a requirement imposed in a pretreatment program approved under section 1342(a)(3) and 1342(b)(8) of Title 33, United States Code—that is, the discharge of industrial wastewater into the New London POTW without a permit.

The written stipulation above is incorporated into the preceding plea agreement. The defendant and the Government reserve their rights to present additional relevant offense conduct to the attention of the Court in connection with sentencing. Both parties agree that although this stipulation provides a sufficient factual basis for the guilty plea, both parties will provide the Court with additional relevant evidence for sentencing. Specifically, the defendant will submit materials that provide mitigating circumstances for the offense conduct, whereas the Government will submit materials that provide aggravating circumstances for the offense conduct.

THOMAS H. FARIA
The Defendant

HAROLD H. CHEN
ASSISTANT U.S. ATTORNEY

THOMAS J. MURPHY, ESQ.
Attorney for the Defendant

PETER W. KENYON
SPECIAL ASST. U.S. ATTORNEY

JAMES T. COWDERY, ESQ.
Attorney for the Defendant

AO245b (USDC-CT Rev. 9/07)

UNITED STATES DISTRICT COURT
District of Connecticut

UNITED STATES OF AMERICA

v.

THOMAS H. FARIA

JUDGMENT IN A CRIMINAL CASE

CASE NO. *3:14CR149 AWT*
USM NO: *22573-014*

Harold H. Chen
Peter West Kenyon
Assistant United States Attorneys

Thomas P. Murphy, Esquire
James T. Cowdery, Esquire
Defendant's Attorneys

THE DEFENDANT pled guilty to **Count 1 of an Information**. Accordingly, the defendant is adjudged guilty of the following offense:

Title & Section	Nature of Offense	Offense Concluded	Count
33:1319(c)(2)(A)	Knowing violation of a requirement imposed in a pretreatment program approved under the Clean Water Act	July 2011	1

The following sentence is imposed pursuant to the Sentencing Reform Act of 1984. The court concluded that a "non-Guidelines sentence," as opposed to a "Guidelines sentence," see United States v. Crosby, 397 F.3d 103, 112 n.6 (2d Cir. 2005), was appropriate in this case.

PROBATION

The defendant shall be placed on probation for a total term of 3 years. In determining the advisory Guidelines range, the court departed pursuant to Guidelines §2Q1.3(b)(4). The court then imposed a non-Guidelines sentence after concluding that such a sentence was necessary in order for the court to place proper weight on the fact that (i) the defendant's dominant motive for committing the offense and (ii) the defendant's post-offense acknowledgment of the wrongfulness of his conduct are mitigating factors that outweigh (iii) the need to impose a sentence that serves the purposes of general deterrence and promoting respect for the law.

Because the defendant is currently an Oregon resident, he will be supervised in the District of Oregon during his term of probation.

The mandatory and standard conditions of probation, as attached, are imposed. In addition, the following special conditions are imposed:

1. The defendant shall pay the fine that is being imposed in this case, at a rate of not less than $1,000 per month.

2. The defendant shall perform 300 hours of community service at the rate of 100 hours per year.

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments as follows.

Special Assessment:	$100.00, due immediately
Fine:	$30,000.00, to be paid at the rate of not less than $1,000 per month, during the defendant's period of probation, on the 10th day of each calendar month, commencing in April, 2015.
Restitution:	$0.00

It is further ordered that the defendant will notify the United States Attorney for this district within 30 days of any change of name, residence or mailing address until all fines, restitution, costs and special assessments imposed by this judgment are paid.

February 13, 2015
Date of Imposition of Sentence

____/s/ AWT
Alvin W. Thompson
United States District Judge
Date: February 17, 2015

Judgment received by U.S. Marshal at _____ on _____.

Print name _____

Signature _____
Deputy Marshal

CERTIFIED AS A TRUE COPY
ON THIS DATE _____
ROBERTA D. TABORA, Clerk
BY: _____
Deputy Clerk

CONDITIONS OF PROBATION

In addition to the Standard Conditions listed below, the following indicated (■) Mandatory Conditions are imposed:

MANDATORY CONDITIONS

■ (1) The defendant shall not commit another federal, state or local offense;

■ (2) For a felony, the defendant shall (A) make restitution, (B) give notice to victims of the offense pursuant to 18 U.S.C. section 3555, or (c) reside or refrain from residing, in a specified place or area, unless the court finds on the record that extraordinary circumstances exist that would make such a condition plainly unreasonable, in which event the court shall impose one or more of the discretionary conditions set forth under 18 U.S.C. section 3563(b);

■ (3) The defendant shall not unlawfully possess a controlled substance;

☐ (4) For a domestic violence crime as defined in 18 U.S.C. section 3561(b) by a defendant convicted of such an offense for the first time, the defendant shall attend a public, private, or non-profit offender rehabilitation program that has been approved by the court, in consultation with a State Coalition Against Domestic Violence or other appropriate experts, if an approved program is available within a 50-mile radius of the legal residence of the defendant;

■ (5) The defendant shall refrain from any unlawful use of a controlled substance and submit to one drug test within 15 days of release on probation and at least two periodic drug tests thereafter for use of a controlled substance;

■ (6) The defendant shall (A) make restitution in accordance with 18 U.S.C. sections 2248, 2259, 2264, 2327, 3663, 3663A, and 3664; and (B) pay the assessment imposed in accordance with 18 U.S.C. section 3013;

☐ (7) The defendant shall notify the court of any material change in the defendant's economic circumstances that might affect the defendant's ability to pay restitution, fines or special assessments;

■ (8) If the court has imposed a fine, the defendant shall pay the fine or adhere to a court-established payment schedule;

☐ (9) (A) In a state in which the requirements of the Sex Offender Registration and Notification Act (see 42 U.S.C. §§ 16911 and 16913) do not apply, a defendant convicted of a sexual offense as described in 18 U.S.C. § 4042(c)(4) (Pub. L. 105-119, § 115(a)(8), Nov. 26, 1997) shall report the address where the defendant will reside and any subsequent change of residence to the probation officer responsible for supervision, and shall register as a sex offender in any State where the person resides, is employed, carries on a vocation, or is a student; or

(B) In a state in which the requirements of Sex Offender Registration and Notification Act apply, a sex offender shall (i) register, and keep such registration current, where the offender resides, where the offender is an employee, and where the offender is a student, and for the initial registration, a sex offender also shall register in the jurisdiction in which convicted if such jurisdiction is different from the jurisdiction of residence; (ii) provide information required by 42 U.S.C. § 16914; and (iii) keep such registration current for the full registration period as set forth in 42 U.S.C. § 16915;

■ (10) The defendant shall cooperate in the collection of a DNA sample from the defendant.

While on probation, the defendant also shall comply with all of the following Standard Conditions:

STANDARD CONDITIONS

(1) The defendant shall not leave the judicial district or other specified geographic area without the permission of the court or probation officer;
(2) The defendant shall report to the probation officer in a manner and frequency directed by the court or probation officer;
(3) The defendant shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;
(4) The defendant shall support the defendant's dependents and meet other family responsibilities (including, but not limited to, complying with the terms of any court order or administrative process pursuant to the law of a state, the District of Columbia, or any other possession or territory of the United States requiring payments by the defendant for the support and maintenance of any child or of a child and the parent with whom the child is living);
(5) The defendant shall work regularly at a lawful occupation unless excused by the probation officer for schooling, training, or other acceptable reasons;
(6) The defendant shall notify the probation officer at least ten days prior to any change in residence or employment, or if such prior notification is not possible, then within five days after such change;
(7) The defendant shall refrain from excessive use of alcohol and shall not purchase, possess, use, distribute, or administer any controlled substance, or any paraphernalia related to any controlled substance, except as prescribed by a physician;
(8) The defendant shall not frequent places where controlled substances are illegally sold, used, distributed, or administered, or other places specified by the court;
(9) The defendant shall not associate with any persons engaged in criminal activity, and shall not associate with any person convicted of a felony unless granted permission to do so by the probation officer;
(10) The defendant shall permit a probation officer to visit the defendant at any time at home or elsewhere and shall permit confiscation of any contraband observed in plain view by the probation officer;
(11) The defendant shall notify the probation officer within seventy-two hours of being arrested or questioned by a law enforcement officer;
(12) The defendant shall not enter into any agreement to act as an informer or a special agent of a law enforcement agency without the permission of the court;
(13) The defendant shall pay the special assessment imposed or adhere to a court-ordered installment schedule for the payment of the special assessment.

Upon a finding of a violation of probation, I understand that the court may (1) revoke supervision and impose a term of imprisonment, (2) extend the term of supervision, and/or (3) modify the conditions of supervision.

These conditions have been read to me. I fully understand the conditions and have been provided a copy of them.

(Signed) _____ _____
Defendant **Date**

_____ _____
U.S. Probation Officer/Designated Witness **Date**

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Sheffield**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Sheffield Pharmaceuticals LLC	1210513	151177797	MANUFACTURE;	170 Broad Street, New London, Connecticut (CT) 06320, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries

Previous1Next

Data Current through: Thursday, Oct 17, 2019

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Verified 4/14/20 NB

SHEFFIELD PHARMACEUTICALS

Owners	% Ownership
Sue Faria –Voting member of LLC Marshview Circle East Sandwich, MA 02537-1041	16
Diane Faria- . Beach Drive SE, Unit 2003 St. Petersburg, FL 33701-3957	16
Gail Faria- .agoon Drive Fort Meyers, FL 33905-2500	14
Nancy Faria - West Main Road, Ap Middletown RI 02842	16
Thomas H. Faria - Neath Avenue Las Vegas, NV 89178	38

Sheffield Pharmaceutical Officers

Jeffrey Davis CEO and President	N/A
Anthony Sollima CSO and EVP of Regulatory Affairs	N/A

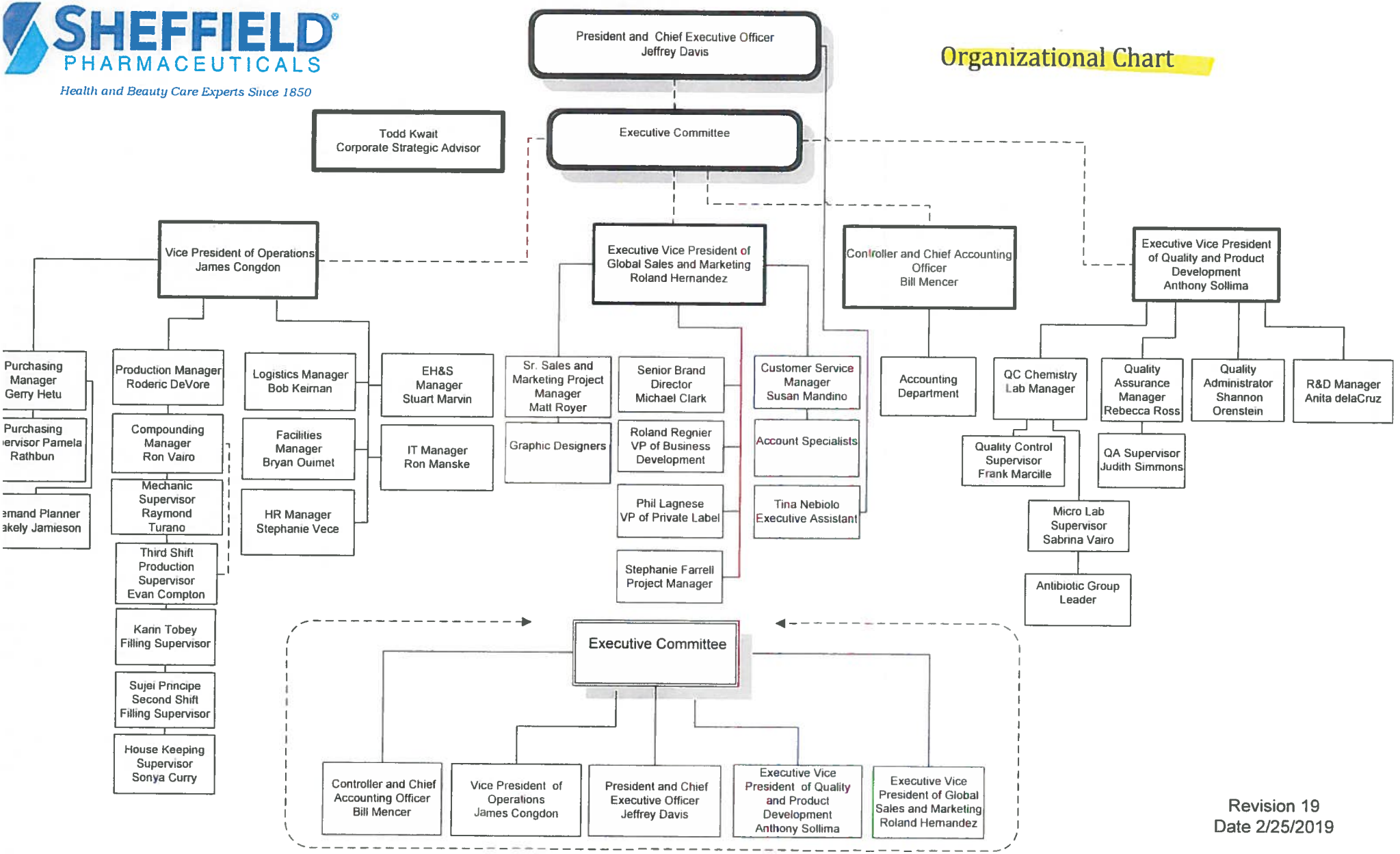
3/27/2020

1718

SHEFFIELD PHARMACEUTICALS

Health and Beauty Care Experts Since 1850

Organizational Chart



Revision 19
Date 2/25/2019

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. NV5212592

Application/License No. _____

Sheffield Pharmaceuticals, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 170 Broad Street New London, CT 06320 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 30, 2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 30th day of March, 2020.

APPLICANT/PRINCIPAL

COMPANY

Sheffield Pharmaceuticals, LLC

Authorized Representative

Jeffrey Davis, President & CEO

SIGNED and SEALED in the presence of:

Witness Anthony Sollima, Chief Scientific Officer

Witness William D. Mencer, Controller

SURETY

Merchants Bonding Company (Mutual)

Surety Company's Representative

Russell C Corner II, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Jessica Mendonca

Witness Denise Chianese

Countersigned by:

Nevada Resident Agent

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED - 0 - 1933

LP 2079 NV (7/19)

MERCHANTS BONDING COMPANY™

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Russell C Corner II

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and aut hority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 30th day of March , 2020 .

MERCHANTS NATIONAL BONDING, INC. -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.
On this 30th day of March , 2020 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA

POLLY MASON
Commission Number 750576
My Commission Expires
January 07, 2023

Polly Mason
Notary Public

(Expiration of notary's commission
does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 30th day of March , 2020 .

MERCHANTS NATIONAL BONDING, INC. -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) -o- 1933

William Warner Jr.
Secretary

MERCHANTS BONDING COMPANY

MERCHANTS BONDING COMPANY (MUTUAL) • P.O. BOX 14498 • DES MOINES, IOWA 50306-3498
PHONE: (800) 678-8171 • FAX: (515) 243-3854

ADDENDUM TO BOND

This Addendum is in reference to the bond(s) to which it is attached.

Merchants Bonding Company (Mutual) ("Merchants") deems the digital or electronic image of Merchants' corporate seal below affixed to the bond(s) to the same extent as if a raised corporate seal was physically stamped or impressed upon the bond(s). The digital or electronic seal below shall have the same force and effect as though manually fixed to the bond(s).

All terms of the bond(s) remain the same.

Signed and effective March 23, 2020.

MERCHANTS BONDING COMPANY (MUTUAL)

By: Larry Taylor

Larry Taylor, President

Office of the Secretary of the State of Connecticut

I, the Connecticut Secretary of the State, and keeper of the seal thereof, DO HEREBY CERTIFY, that articles of organization for

SHEFFIELD PHARMACEUTICALS, LLC

a domestic limited liability company, were filed in this office on September 29, 1999.

Articles of amendment for FARIA LIMITED LLC, changing its name to SHEFFIELD PHARMACEUTICALS, LLC, were filed on August 12, 2014.

Articles of dissolution have not been filed, and so far as indicated by the records of this office such limited liability company is in existence.

Secretary of the State

Date Issued: March 25, 2020

Business ID: 0631399 Standard Certificate Number: 2020159705001

Note: To verify this certificate, visit the web site http://www.concord.sots.ct.gov

Office of the Secretary of the State of Connecticut

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Business ID: 0631399 Standard Certificate Number: 2020159705001

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STATE OF CONNECTICUT
DEPARTMENT OF REVENUE SERVICES

03/25/2020

SHEFFIELD PHARMACEUTICALS, LLC
170 BROAD ST

NEW LONDON, CT 06320-5313

CT Tax Registration #: 9852971000

Status Letter

To Whom It May Concern,

Based on the information currently available, the State of Connecticut, Department of Revenue Services (DRS) records indicate that the entity listed above has filed all of its tax returns and paid all taxes that were reported due.

This status letter is valid until: **04/24/2020**

In providing this letter, DRS is **not** making any representations that it has conducted an audit examination or otherwise concluded that the information reported on the tax return(s) is correct. In the future, DRS may determine that additional tax returns were required or, to the extent allowed by law, make an assessment against the taxpayer and its successors or assigns.

This is not a Tax Clearance Certificate under Connecticut General Statutes §§12-294, 12-424, 12-546, or 12-707.

Sincerely,
Department of Revenue Services

DRS-033 (New 07/16)

STATE OF CONNECTICUT
DEPARTMENT OF CONSUMER PROTECTION

This is your registration certificate for your records. Such registration shall be shown to any properly interested person on request. Do not attempt to make any changes or alter this certificate in any way. This registration is not transferable. Questions regarding this registration can be emailed to the Drug Control Division at dcp.drugmanufacturers@ct.gov.

In an effort to be more efficient and Go Green, the department asks that you keep your email information current. The email on your account will be used for all correspondence from this office.

You can update your address and email address or print a duplicate certificate by logging into your account with your User Id and Password at www.elicense.ct.gov. If you need your User Id and/or Password, please email dcp.online@ct.gov.

Mailing address:

SHEFFIELD PHARMACEUTICALS
FARIA LIMITED, LLC D/B/A SHEFFIELD LABORATORIES
170 BROAD ST
NEW LONDON, CT 06320-5313

Email on file to be used for receiving all notices from this office:

anthony.sollima@sheffieldpharma.com

STATE OF CONNECTICUT ✦ DEPARTMENT OF CONSUMER PROTECTION

Be it known that

SHEFFIELD PHARMACEUTICALS
170 BROAD ST
NEW LONDON, CT 06320-5313

has satisfied the qualifications required by law and is hereby issued a

MANUFACTURER OF DRUGS, COSMETICS & MEDICAL DEVICES

Controlled Substances: No **Rx Legend Drugs: Yes** **Non Rx Legend Drugs: Yes** **Medical Devices: Yes** **Cosmetics: Yes**

Medical Gases/Oxygen: No **Durable Medical Equipment (DME): No** **Number of Chemists: 14**

Registration #: CSM.0000094
Effective Date: 08/05/2019
Expiration Date: 06/30/2020

verify online at www.elicense.ct.gov

Michelle Seagull

Michelle Seagull, Commissioner

JEFFREY S. DAVIS Harbor Rd. Colchester CT, 0641[illegible] et

ACCOMPLISHED OPERATIONS EXECUTIVE

- Highly accomplished executive leader with experience defining the strategic direction and growth of a cGMP compliant pharmaceutical company; responsible for shepherding the organization through a period of massive growth, from $6MM in annual revenue to over $43MM today.
- After becoming CEO in 2016, led and managed the debt restructure and recapitalization of Sheffield Pharmaceuticals and returned the company to profitability after multi-year losses,
- Maintains executive responsibility for all facets of operations, spanning Sales & Marketing , Finance, Regulatory affairs, Manufacturing, Supply Chain, Logistics, Environmental Health and Safety, Engineering, and Facilities; leverages competencies in Lean Manufacturing, Logistics, Global Sourcing, Corporate Strategy Development & Execution, Environmental Health & Safety, and regulatory requirements to achieve all corporate objectives.
- Experienced in the oversight of teams of Pharmaceutical professionals dedicated to product quality, safety and job ownership.
- Skilled in matters of corporate finance and the performance of due diligence in support of M&A transactions; assumes an active role in direct sales, as well as the management of quoting and bidding processes.
- Successfully leverages a winning combination of excellent management skills, team building expertise, and a "hands-on approach" to deliver results that exceed customer expectations.

Core Skills and Competencies

Corporate Executive Leadership – Sales and Marketing – Finance – Corporate Strategy - Operations Management
Training & Development – Inventory Management – Production Systems – OSHA Compliance – FDA compliance
Process Control Improvement – Equipment Procurement – Purchasing - cGMP Environments – EPA Regulations
Lean Manufacturing – Logistics – Environmental Health & Safety - Due Diligence – M&A Transactions

Career Achievements

- **SHEFFIELD PHARMACEUTICALS.** Led and managed a $16 million debt restructure and recapitalization in 2016, and returned the company to sustained profitability after Multiyear losses in 2016
- **SHEFFIELD PHARMACEUTICALS.** Led and managed Sheffield's first branded product launch, establishing a successful national CPG brand with distribution in over 25,000 retail doors
- **SHEFFIELD PHARMACEUTICALS.** Responsible for 600% growth and the transformation of the company from a small toiletries manufacturer to a cGMP compliant pharmaceutical manufacturer, building revenue from $6MM to over $43MM.
- **SHEFFIELD PHARMACEUTICALS**. Creates optimal strategies to achieve corporate goals using skills and knowledge in Lean Manufacturing, Finance, Sales and Marketing, Logistics, Global sourcing, Corporate Strategy Development & Execution, Environmental Health & Safety, and regulatory requirements
- **SHEFFIELD PHARMACEUTICALS**. Led the due diligence and execution of the acquisition of Lee Pharmaceuticals, a $7MM company, in California; managed the relocation and integration of a 100,000 square foot factory to Connecticut within 6 weeks.
- **PHOENIX ENVIRONMENTAL.** Gained invaluable expertise in the use of Gas Chromatograph and High Performance Liquid Chromatography techniques, as well as wet chemistry techniques.
- **DAVIS PHARMACEUTICALS**. Coordinated and led training for new employees to build competencies in materials handling and safety.

Relevant Professional Experience

SHEFFIELD PHARMACEUTICALS, New London, CT (1997-Present)

PRESIDENT & CHIEF EXECUTIVE OFFICER (2016 TO PRESENT)
A demonstrated record of success and achievement at this leading pharmaceutical company, marked by a promotion to a position of increased influence, authority, and accountability. Served as Operations Manager from 2004 to 2014 before promotion to an executive role as COO in 2014 and CEO in 2016.

- Designs and deploys corporate Vision, Mission, and Strategy, with the goal of maximizing sustainable business growth while overseeing a $40MM operating budget.
- Oversees all operations and business activities to ensure they produce the desired results and are consistent with the overall vision, strategy and mission
- Communicates with Board of Directors

CHIEF OPERATING OFFICER (2014 TO 2016)
As Chief Operating Officer, fulfills a key leadership role in a direct and indirect capacity over multiple functions, including Sales, Sales Support, Quality, Procurement, Logistics, HR, Engineering, and Finance. Advanced to this role to provide support to a new CEO and serve a major role in operations management and as a member of the executive leadership team.

- Leverages expertise in Lean Manufacturing, Logistics, Global sourcing, Corporate Strategy Development & Execution, Environmental Health & Safety, and regulatory requirements to build optimal strategies to achieve corporate goals.
- Led Multi-year effort to Automate all production operations
- Led the due diligence and acquisition of a $7MM company in California, managing the relocation and integration of a 100,000 square foot factory to Connecticut within 6 weeks.
- Eliminated 10% of freight costs through a strategic partnership with a 3PL to serve the needs of a key account.
- Reduced energy costs by 25% through the implementation of a $3MM consolidated heat and power system.
- Lowered Out of Stock incidents by 50% while simultaneously reducing obsolescence by 20% through a new sales forecasting and production planning system.

PRODUCTION MANAGER (1997 TO 2014)
Leads all vision, strategy, and execution for first and second shift production at this leading pharmaceutical company, with a focus on maintaining compliance with FDA, OSHA, EPA, and GMP requirements governing manufacturing operations. Leads the management of all inventory, while assuming a hands-on role hiring and training new employees.

- Serves as the architect of standard operating procedures governing production processes and maintenance.
- Serves an integral role addressing and resolving process control issues; works closely with production personnel to resolve production issues with the potential to impact productivity and output.
- Envisioned, developed, and deployed validation methods for new product processing and cleaning.
- Responsible for all purchasing and installation of production equipment.
- Contributed additional service and expertise facilitating the development of methods of manufacture and new product development.

PHOENIX ENVIRONMENTAL, Manchester, CT (1993-1997)
GC/HPLC ANALYST
Led a full spectrum of analysis responsibilities at this provider of high quality testing services for soils, water, sludge, and solids, gaining invaluable expertise in the operation and maintenance of a variety of laboratory equipment.

- Leveraged the use of Gas Chromatograph and High Performance Liquid Chromatography techniques, as well as wet chemistry techniques, to analyze soil and water samples.
- Analyzed metals using atomic absorption.

Early Career
Quality Control Analyst and Production Supervisor, DAVIS PHARMACEUTICALS, Plainfield, CT (1986-1994)

Education

Bachelor of Science Degree in Environmental Science – Eastern Connecticut State University
Cum Laude, GPA 3.69
Laboratory Assistant in the Geographic Information Systems Laboratory

Master of Science in Operations Management- Rensselaer Polytechnic Institute

Technical Proficiencies

Microsoft Office Suite, Various ERP software, Microsoft SharePoint, SAP B1,

14B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks 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 Wholesaler or ☒ Ownership Change (Provide current license number if making changes: WH 02274
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Sun Pharmaceutical Industries, Inc.

Physical Address: 29 Dunham Road

City: Billerica State: MA Zip Code: 01821

Telephone Number: 781-687-1219 Fax Number: 781-275-2634

Toll Free Number: 800-221-7554

E-mail: Susan.Tennent@sunpharma.com Website: www.sunpharma.com

Facility Manager: Daniel O'Brien

Professional qualifications and experience of facility manager: See Attached Resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☒ Practitioners ☒ Hospitals ☐ Wholesalers
☐ Other:

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other:
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: West Pharmaceutical Services
Address: 530 Herman O. West Drive, Exton, PA 19341

Name: Nipro PharmaPackaging
Address: 1200 North 10th Street, Millville, NJ 08332

Name: Alcami Carolins
Address: 4620 Creekstone Drive, Durham, NC 27703

Name: VWR Inc.
Address: 100 Matsonford Road, Radnor, PA 19087

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

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 ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

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

Daniel O'Brien
Print Name of Authorized Person

13 May 2020
Date

Board Use Only	Date Processed:_____	Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Sun Pharmaceutical Industries, Inc.

Mailing Address: 2 Independence Way

City: Princeton State: NJ Zip: 08540

Telephone: 609-720-9200 Fax: 609-514-1155

Contact Person: Zvi Albert, CFO

For any corporation non-publicly traded, disclose the following:

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

a) Not Applicable - 100% owned by Sun Pharmaceutical Industries, Inc.
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

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

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

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

Include with the application for a non-publicly traded corporation

List of officers and directors

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.

The attached summary document provides the explanation of disciplinary actions for Sun Pharmaceutical Industries, Inc. Please note that these actions pertain to the parent company, not this facility location.

C. J. Praveen June-08-2020

Praveen Devakadaksham, Director-Regulatory Affairs & Business Continuity

Sun Pharmaceutical Industries, Inc.

(predecessor company being Caraco Pharmaceutical Laboratories, Ltd)

(a) **FDA/2009**

On June 25, 2009, FDA, in conjunction with the Dept of Justice, issued a Warrant of Arrest in rem for the seizure of all product manufactured at the Detroit, MI manufacturing location, alleging that the product was adulterated as it was manufactured under conditions not meeting cGMP. Caraco entered in a Voluntary Consent Decree on Sept 29, 2009. This applied only to product manufactured at the 1150 Elijah McCoy, Detroit, MI 48202 facility and did not impact any product held for sale which was manufactured by a third party. No fines were imposed as a part of the Voluntary Consent Decree. Caraco proceeded to remediate the issues presented by the FDA with the aid of consultants. Caraco received permission from the FDA to re-start manufacturing operations at its 1150 Elijah McCoy, Detroit, MI 48202 facility in August of 2012 and has subsequently been classified as an acceptable manufacturing operation during FDA inspections conducted in 2013 and 2014. Post classified for operation by FDA, due to business consolidation, the site was closed and no more in operation and deregistered from USFDA facility established list in the fiscal year 2015-16.

(b) **Maine Pharmacy Board/2010**

On June 3, 2010, Maine Board of Pharmacy, during its board meeting, preliminarily denied Caraco Pharmaceutical Laboratories, Ltd in Wixom, MI an application for a wholesale distributor license. It was determined that Caraco Pharmaceutical Laboratories, Ltd had a restricted FDA permit. Pursuant to the board's Rule Chapter 12, section 4 (1), (3), (5), and (6), if the applicant had a license from any other jurisdiction suspended, revoked, cancelled, or otherwise restricted for any reason the board had the right to deny application. The matter was forwarded to the Maine Department of Attorney General. The Attorney General found that Caraco Pharmaceutical Laboratories, Ltd accurately responded to questions on its application and Caraco was not required by law or rule of the board to report the FDA warning since the FDA warning is different from the disciplinary action of a "warning" under Maine Pharmacy Laws and legally was not a matter that needed to be reported in response to license/ disciplinary questions in the application. At the end of the FDA's inspection of Caraco's facilities in Wixom, MI and Detroit, MI, it was noted that Caraco may resume manufacturing operation as reflected in a letter from the FDA to Caraco dated August 27, 2012. Maine Board of pharmacy granted a wholesale distributor license (WH70001485) to the Wixom, MI facility.

(c) **Florida/2012**

On August 28, 2012, the Florida Department of Business & Professional Regulation found Caraco Pharmaceutical Laboratories, Ltd located at wixom, MI (license# 26:213) in violation of Section 499.0121 of FL Statutes (2010) and Rule 61F-12.012 of the FL Administrative Code for failure to provide a complete audit trail of all transaction regarding the receipt and distribution of Prescription Drugs. Caraco Pharmaceutical Laboratories, Ltd failed to include the recipient's specific Florida license number on the packing slips. Enhancements were made to the internal data interface and implemented an enhanced packing slip which now accompanies the physical shipment. A fine of $10,000 was imposed and paid on September 6, 2012. The license was not encumbered.

(d) **Georgia/2014**
On June 10, 2014, the Georgia Board of Pharmacy cited Caraco Pharmaceutical Laboratories, Ltd (license #PHWH002689) at the facility in Wixom, Michigan for shipping without a valid permit. The license was not renewed and consequently lapsed in June 2013. The facility continued to ship into Georgia past expiration. A fine was paid for the violation (docket# 2014-0061} and the license was re-instated.

(e) **Alabama/2014**
On September 15, 2015 an order issued by the Alabama State Board of Pharmacy in response to Sun Pharmaceutical Industries, Inc.'s initial application for licensure with Alabama State for the facility located at 270 Prospect Plains Road, Cranbury, NJ 08512. The fine was paid and permit is granted. Please note that this order was issued due to a sister Sun site, located at 31060 Oak Creek Dr., Wixom, MI 48393, having received a violation from the state of Georgia in June 2014.

(f) Refer most recent settlement from ALABAMA (As separate attachment)

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
SUN PHARMACEUTICAL INDUSTRIES, INC.	)	**BOARD OF PHARMACY**
	)	
	)	**CASE NO: 19-L-0144**
Private Label Distributor Applicant	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Sun Pharmaceutical Industries, Inc. (hereinafter referred to as "Sun") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Sun through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows

1. The Board finds that Sun has violated Code of Alabama (1975) § 34-23-32(a) and/or (f) by distributing drug products in the State of Alabama during 2018 and/or 2019 without first having obtained your permit.

2. Sun's Application for a Private Label Distributor – Virtual shall be granted subject to compliance with the terms of this Consent Order.

3. Sun shall pay to the Board an administrative fine in the amount of Twenty-One Thousand dollars ($21,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of

payment to the Board shall not be dischargeable in bankruptcy and Sun shall not attempt to discharge the same in any bankruptcy proceeding.

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

5. By execution of this Consent Order, Sun 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.

6. That Sun 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.

7. That Sun acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Sun 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 had the right to seek advice of counsel before executing this Consent Order.

DONE this the 3rd day of October, 2019.

SUN PHARMACEUTICAL INDUSTRIES, INC.

BY: _____

ITS: Chief Executive Officer

_____

Luther Maxwell Dorr, Jr., attorney for Sun Pharmaceutical Industries, Inc.

DONE this the 8th day of October, 2019.

ALABAMA STATE BOARD OF PHARMACY

By: _____

Kenny Sanders, R.Ph , President

By: _____

James S. Ward
Its Attorney

WARD & COOPER, LLC.
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF OWNERSHIP, WHICH MERGES:

"PHARMALUCENCE, INC.", A DELAWARE CORPORATION,

"INSITE VISION INCORPORATED", A DELAWARE CORPORATION,

"MUTUAL PHARMACEUTICAL COMPANY, INC.", A DELAWARE CORPORATION,

WITH AND INTO "SUN PHARMACEUTICAL INDUSTRIES, INC." UNDER THE NAME OF "SUN PHARMACEUTICAL INDUSTRIES, INC.", A CORPORATION ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE, AS RECEIVED AND FILED IN THIS OFFICE ON THE THIRTIETH DAY OF MARCH, A.D. 2020, AT 4:26 O`CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF OWNERSHIP IS THE FIRST DAY OF APRIL, A.D. 2020 AT 12:01 O'CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

7893212 8100M
SR# 20202465390

Authentication: 202687150
Date: 03-31-20

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

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SUN PHARMACEUTICAL INDUSTRIES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF MARCH, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SUN PHARMACEUTICAL INDUSTRIES, INC." WAS INCORPORATED ON THE ELEVENTH DAY OF MARCH, A.D. 2020.

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

Jeffrey W. Bullock, Secretary of State

7893212 8300

SR# 20202087743

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

Authentication: 202570546

Date: 03-12-20

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0088410	04/25/2020	04/25/2021	Drug Manufacturers & Distributors

SCHEDULES VI

ISSUED TO

SUN PHARMACEUTICAL INDUSTRIES, INC.
29 DUNHAM ROAD
BILLERICA, MA 01821
ATTN: ABHAY GANDHI PRESIDENT AND CEO

COMMISSIONER OF PUBLIC HEALTH

RECIPIENT'S COPY

NEW

831014

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0088410	04/25/2020	04/25/2021	Drug Manufacturers & Distributors

SCHEDULES VI

ISSUED TO

SUN PHARMACEUTICAL INDUSTRIES, INC.
29 DUNHAM ROAD
BILLERICA, MA 01821
ATTN: ABHAY GANDHI PRESIDENT AND CEO

NEW

Dan O'Brien

Work Experience

Profile

Expertise

Education

BS Operations, Northeastern University

MS Operations, Worcester Polytechnic Institute

Post Graduate Study Aseptic Technology,
University of Tennessee

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Sun Pharmaceutical Industries, Inc.**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Sun Pharmaceutical Industries, Inc.	3009395771	139261648	ANALYSIS; LABEL; MANUFACTURE; PACK;	29 Dunham Rd, Billerica, Massachusetts (MA) 01821, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Wednesday, Apr 8, 2020

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Verified MS 6/9/20

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Sun Pharmaceutical Industries, Inc.**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Sun Pharmaceutical Industries, Inc.	3009395771	139261648	ANALYSIS; LABEL; MANUFACTURE; PACK;	29 Dunham Rd, Billerica, Massachusetts (MA) 01821, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries

Previous1Next

Data Current through: Tuesday, Jun 9, 2020

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Sun Phramceutical Industries, Inc.
29 Dunham Road Billerica, MA 01821

Corporate Officers

Abhay Gandhi
Chief Executive Officer, North America
2 Independence Way
Princeton, NJ 08540
Abhay.Gandhi@sunpharma.com

Zvi Albert
Vice President - Finance & Treasurer
2 Independence Way
Princeton, NJ 08540
Zvi.Albert@sunpharma.com

Michele Visosky
Vice President - Head of Human Resources, North America
3 Skyline Drive, Suite 120
Hawthorne, NY 10532
Michele.Visosky@sunpharma.com

Daryl LeSueur
Vice President - Head of Operations, North America Topicals, Liquids and Injectables
14 Terminal Road
New Brunswick, NJ 08901
Daryl.LeSueur@sunpharma.com

Jayesh Shah
Vice President - Procurement
1 Commerce Drive
Cranbury, NJ 08512
Jayesh.Shah@sunpharma.com

Please note that the updated home state (Massachusetts) license for Sun Pharmaceutical Industries, Inc. is expected to be received shortly. We have attached the current Pharmalucence, Inc. license and will forward the updated license showing the new company name as soon as it arrives.

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0088410	04/25/2020	04/25/2021	Drug Manufacturers & Distributors

SCHEDULES VI

ISSUED TO

PHARMALUCENCE, INC.
29 DUNHAM ROAD
BILLERICA, MA 01821
ATTN: ABHAY GANDHI PRESIDENT AND CEO

COMMISSIONER OF PUBLIC HEALTH

RECIPIENT'S COPY

RENEWAL

835913

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0088410	04/25/2020	04/25/2021	Drug Manufacturers & Distributors

SCHEDULES VI

ISSUED TO

PHARMALUCENCE, INC.
29 DUNHAM ROAD
BILLERICA, MA 01821
ATTN: ABHAY GANDHI PRESIDENT AND CEO

RENEWAL

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0088410	04/25/2020	04/25/2021	Drug Manufacturers & Distributors

SCHEDULES VI

ISSUED TO PHARMALUCENCE, INC.
29 DUNHAM ROAD
BILLERICA, MA 01821
ATTN: ABHAY GANDHI PRESIDENT AND CEO

COMMISSIONER OF PUBLIC HEALTH

FILE COPY

RENEWAL

835913

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0512872

Application/License No. _____

Sun Pharmaceutical Industries, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 29 Dunham Road, Billerica, MA 01821 (Address of Applicant/Principal), as PRINCIPAL, and Harco National Insurance Company (Surety Company), a corporation organized under the laws of the state of Illinois (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Newark Center, 20th Floor Newark, NJ 07102 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of Twenty Five Thousand and 00/100 Dollars (25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 7, 2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 7 day of May, 2020.

APPLICANT/PRINCIPAL
Sun Pharmaceutical Industries, Inc.

Authorized Representative

SURETY COMPANY
Harco National Insurance Company

Surety Company's Representative

Mary Y. Volmar, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Krystal Karnes

Witness Bonnie Rice

Countersigned by:

N/A
Nevada Resident Agent

POWER OF ATTORNEY

Bond # 0512872

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 702 Oberlin Road, Raleigh, North Carolina 27605

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

KATHY L. DELGRECO, RACHEL A. CHAVERIAT, MICHELLE LUTE-HEATHERLY, SANDRA KING, JESSICA FREDERICK, JULIE KARNES, REBECCA J. HOBBS, BONNIE L. RICE, MARIAH SMITH, MARY Y. VOLMAR, ANDREA ALLMAN, JOY M. WILLIAMS, CAROLYN E. WHEELER, VICKI NORINGER, LORETTA M. JONES, SANDY

Knoxville, TN

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2018

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2018, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

SHIRELLE A. OUTLEY NJ Comm. Exp. 04-04-2023 NOTARY PUBLIC No. 50079910 NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, May 07, 2020

A00795

Irene Martins, Assistant Secretary

SUN PHARMA

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

RE: Notification of Merger of Pharmalucence, Inc. License #WH02274 into Sun Pharmaceutical Industries, Inc.

Dear Sir/Madam:

This notification is to advise you that Pharmalucence, Inc., a SUN PHARMA Company, an FDA approved facility engaged in manufacturing and distribution of prescription drug products under license # WH02274 has merged into its parent company, Sun Pharmaceutical Industries, Inc., effective April 1, 2020.

Although Pharmalucence has changed its name to Sun Pharmaceutical Industries, Inc., the company's location, corporate officers, company management, designated representative, facility operations, and procedures & policies will not change. Pharmalucence was previously a wholly owned subsidiary of Sun Pharmaceutical Industries, Inc. Therefore, we kindly request that the current permit be transferred from Phamalucence to Sun Pharmaceutical Industries, Inc. at 29 Dunham Road, Billerica, MA 01821.

Enclosed is an application form, as required for this merger. If you have any questions or require additional information, you may contact me as the Designated Representative at 781-687-1242 (email: daniel.obrien@sunpharma.com), or contact my colleague Praveen Devakadaksham, Director-Regulatory Affairs & Business Continuity at 781-687-1232 (email: praveen.devakadaksham@sunpharma.com).

Sincerely,

05 June 2020

Daniel O'Brien
Site Head

14C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks 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 Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☒ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8

☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Zydus Pharmaceuticals (USA) Inc.

Physical Address: 73 Rate 31 North

City: Pennington State: NJ Zip Code: 08534

Telephone Number: 609-730-1900 Fax Number: 609-730-1998

Toll Free Number: _____

E-mail: lpastor@zydususa.com Website: www.zydususa.com

Facility Manager: Louis M. Pastor Jr.

Professional qualifications and experience of facility manager: A.V.P. Trade operations 16yrs experience in managing pharmaceutical operations for generic company

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☒ Wholesalers

☐ Other: Pharmacy wharehases, mail order facilities

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices

☐ Poisons or Chemicals ☐ Veterinary Legend Drugs

☒ Controlled Substances (include copy of DEA) (via a 3PL)

☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? 3PL is VAWD attached Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A
Address: _____

Name: N/A
Address: _____

Name: N/A
Address: _____

Name: N/A
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

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 ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

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

Michael Keenley, CEO + president — Print Name of Authorized Person

1/7/2020 — Date

Board Use Only	Date Processed:	Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: New Jersey

Parent Company if any: Cadila Healthcare Ltd.

Mailing Address: Zydus Corporate Park, No 63, Survey 536, Nr. Vaishnodevi

City: Ahmedabad State: India Zip: 382481

Telephone: 609-730-1900 x107 Fax: 609-730-1998

Contact Person: Ravi Yadavar

For any corporation non-publicly traded, disclose the following:

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

a) Cadila Healthcare Limited
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

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

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

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

Include with the application for a non-publicly traded corporation

List of officers and directors

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.

Establishment Inspection Report
Zydus Pharmaceuticals USA Inc
Pennington, NJ 08534-3601

FEI: **3008444937**
EI Start: 05/09/2014
EI End: 05/15/2014

REPORT LIMITED TO SUMMARY OF FINDINGS
This surveillance Establishment Inspection (EI) of Zydus Pharmaceuticals USA, Inc. was initiated pursuant to NWJ FY'14 workplan and the Memo dated 10/1/13 from CDER, Office of Compliance, Division of Safety Compliance (DSC), Office of Scientific Investigations and FACTS Assignment Identification #8711891, Operation Identification #7016138. It was conducted in accordance with Compliance Program (CP) 7353.001, Postmarketing Adverse Drug Experience (PADE) Reporting Inspections.

The previous EI from 2/10-22/11 was classified VAI (Voluntary Action Indicated) and resulted in a one point FDA Form 483 for not ensuring adverse drug experience information from foreign affiliates were received and reviewed for reporting to FDA.

On 5/9/14, I, Investigator Loretta Nemchik, presented my credentials and issued an FDA Form 482, Notice of Inspection, to Prashant J. Desai, Vice-President of Operations, at Zydus Pharmaceuticals USA, Inc. Mr. Desai stated he had the authority to receive the Notice and is responsible for business development and all technical operations including Regulatory Affairs (RA) and the supply chain in the United States. Joseph Renner, Chief Executive Officer (CEO), was not available at the initiation of the EI. Mr. Desai reports to Mr. Renner **(Exh 1, Organization chart)**. Mr. Renner reports to Pankaj Patel, the Chairman and Managing Director of the firm's parent company, Cadila Healthcare Ltd., headquartered in India (Zydus Tower, Satellite Cross Roads, Ahmedabad 380015, Gujarat, India). Also in attendance was Srinivas Gurram, Head of Regulatory Affairs at Zydus USA. Mr. Gurram is responsible for all RA and Pharmacovigilence (PV) activities in the U.S. and coordinates RA and PV activities between Cadila headquarters and FDA. Mr. Gurram administratively reports to Mr. Desai and has dotted line reporting responsibility to Mr. K. Anand, President of Global QA & RA for Cadila Healthcare. Mr. Anand reports to Mr. P. Patel **(Exh 2, Global Pharmacovigilance Organization Structure chart)**.

Zydus Pharmaceuticals USA continues to perform PV reporting of all 15-day ADE reports for drugs approved for market in the United States **(Exh 3, Total ANDA Filing and Approval Status for the US Market list)**. Periodic Adverse Drug Experience Reports (PADERs) and Annual Reports are compiled and submitted by the global headquarters **(Exh 4, Global PV contact information)**. The firm identified two major changes that occurred since the previous EI: 1) implementation of a global PV system on 2/28/11; and 2) a new subsidiary, Nesher Pharmaceuticals USA LLC (St. Louis, MO). The current EI covered ADE reporting from 5/1/12 to 5/1/14. Per assignment instructions, Warfarin Sodium Tablets USP [ANDA 40-663] and Metformin Hydrochloride [ANDA 77-064] were the primary focus of the review. Written procedures, 15-day reports, periodic reports, complaints, training records, vendor agreements, co-marketing safety agreements and ANDA annual reports were reviewed along with corrections to the previous FDA Form 483.

I observed the correction made in response to the previous FDA Form 483 appeared adequate. I identified no significant objectionable conditions during the current EI and issued no FDA Form 483. However, at close-out with Mr. Renner I discussed two examples of inaccurate awareness

dates, ten PADERs in 2012 submitted late, an unclear reporting responsibility in one Safety Agreement and one serious, unexpected literature case where the article submitted was not in English.

Written Procedures. I observed the firm has written procedures to cover the surveillance, receipt, evaluation and reporting of PADE reports to FDA. I collected copies of local and global procedures including: Adverse Drug Experience (ADE) Reporting Responsibilities Between The Medical Affairs Company (TMAC) and Zydus Pharmaceuticals USA Inc.; Pharmacovigilance Data Exchange Between Global PV Cell and Local Affiliates; and Case Processing on PvNET **(Exh 5, SOP-202-A-04; Exh 6, CHL/GPV/SOP/011 version 01; Exh 7 CHL/PV/WI-022 version 00)**. I also collected a list of procedures related to global PV **(Exh 8)**. The procedures collected appeared adequate.

Domestic PADEs. Standard Operating Procedure (SOP) 202-A-04 **(Exh 5)** outlines the ADE collection, processing, follow-up and reporting process. As identified during the previous EI, the firm contracts with The Medical Affairs Company (TMAC) located at 125 Town Park Drive, Suite 450, Kennesaw, GA to receive, evaluate, process, and follow-up on all domestic ADEs **(Exh 9, TMAC contact information)**. Upon receipt TMAC enters the information into the IRMS (Information Request Management System) database which assigns a unique identification number (firm [ZYD], year [14], AE and three digit sequential number). TMAC classifies the report as either a 15-day or periodic report and generates a MedWatch 3500A form which is sent via e-mail to Zydus USA's RA Department (Mr. Gurram or Dhaval Desai, RA Analyst). The RA Department submits a paper copy of the completed MedWatch form to FDA for 15-day reports or submits the periodic report information to the global headquarters for inclusion in the periodic report. Hardcopy source documents are maintained by TMAC. If Zydus USA directly receives a report of an adverse event the RA Department forwards the information to TMAC who processes it as described above. On a monthly basis TMAC prepares a report of all ADEs and forwards it to the RA Department for reconciliation.

Mr. Gurram provided lists of ADE cases from 5/1/12 to 5/1/14 for all products approved in the U.S. According to Mr. Gurram the list was generated from the information entered into the TMAC database. I estimated there were 160 ADEs from 5/1/12 to the end of 2012; 351 ADEs from 2013; and 135 ADEs thus far in 2014. Per assignment instructions, I focused on two products, Warfarin Sodium Tablets USP (ANDA 40-663) and Metformin Hydrochloride (ANDA 77-064). I also focused on serious and unexpected event reports for all products during this time period. I reviewed a total of 34 ADEs (8 metformin, 10 warfarin and all serious, unexpected ADEs from 2013). I observed no significant deficiencies. I observed two ADEs with inaccurate initial receipt dates but this did not cause any late reporting to FDA **(Exh 10, ZYD-13-AE-172 case documents; Exh 11, ZYD-13-AE-004 case documents)**.

Foreign PADE Reporting. SOP 202-A-04 **(Exh 5)** and global PV procedures CHL/GPV/SOP/011 version 01 **(Exh 6)** and CHL/PV/WI-022 version 00 **(Exh 7)** outline the ADE collection, processing,

follow-up and reporting process for ADEs from foreign sources. Non-U.S. ADEs are received by the parent company or its local affiliates (e.g., Zydus France, Zydus Healthcare Brazil, Zydus Pharma Japan) and are sent to global PV. Upon receipt global PV enters the information into the PvNET database which assigns a unique identification number (country of origin [FR], Zydus, six digit automatically generated number). Only global PV has entry access to the PvNET database. Global PV classifies the report and if serious and unexpected and the same active ingredient is approved for marketing in the U.S. global PV sends the report to the RA Department at Zydus USA. The RA Department then forwards the information to TMAC who processes it as described under the domestic PADE heading above. Source documents are scanned into the PvNET database. On a monthly basis global PV prepares and sends a reconciliation report to Zydus USA.

I asked Mr. Gurram if the firm had received any foreign spontaneous cases that were reportable in the United States from 5/1/12 to 5/1/14. He stated the firm had not received any. I requested global PV to perform a search of the PvNET database and generate a list of all serious and unexpected ADEs from foreign sources between 1/1/13 to 5/1/14 that were reportable in the United States. I observed the list provided contained only three literature cases from Zydus Spain **(Exh 12)**. I reviewed the three cases and observed that case ES-ZYDUS-002056-01 **(Exh 13)** did not contain a copy of the article translated to English. I informed Mr. Gurram at the time and Mr. Renner at close-out that the PADE Compliance Program states that literature articles should be submitted in English. I also observed that the other two cases ES-Zydus-002186 and ES-Zydus-001463 did not contain a copy of the articles. Mr. Gurram stated that the full articles are not always available.

Since I observed that the list contained no spontaneous foreign cases reportable in the U.S., I informed the firm that I was going to request that global PV perform a database search for all serious cases submitted from Zydus France from 1/1/13 to the present. Although I intended to watch the search process remotely via a computer link, upon my return to the firm the following day Mr. Gurram stated that due to the time difference global PV already performed the search and that there was one spontaneous, reportable case (FR-Zydus-003413, Mirtazapine) from Zydus France. This case was received by global PV on 5/12/14 and Zydus USA was in the process of submitting it to FDA. I requested that global PV perform another search of the database so I could observe the search process remotely via a computer link. I requested a source country of France and the same time period. I then requested and watched global PV filter the results to include only spontaneous (source = company) events. I selected four cases (FR-Zydus-002505, FR-Zydus-002517, FR-Zydus-002524, FR-Zydus-002526) involving drugs approved for marketing in the U.S. to review and observed no serious and unexpected events.

Scientific Literature Reports. According to SOP 202-A-04 **(Exh 5, pg 12)**, Global PV performs literature searches on a weekly basis then enters any cases found into the PvNET database. Serious, unexpected cases for U.S. reporting are sent on a MedWatch form via e-mail to the Zydus USA RA Department who does the reporting to FDA by paper submission.

Mr. Gurram provided a copy of the search performed by Global PV for reportable literature cases from 1/1/13 to 5/1/14. I did not review any individual cases for reporting to FDA. However, I reviewed three literature cases from a previous search done to evaluate the receipt and reporting of ADEs from foreign sources and observed that the one case containing a copy of the literature article did not include an English translation of the article.

Postmarketing/IND Studies. Mr. Gurram stated the firm does not do any post-marketing studies. However, I observed that SOP 202-A-04 addresses how to handle adverse events pertaining to clinical trials **(Exh 5, pgs 12 & 13)**.

Periodic Safety Reports. SOP 202-A-04 addresses PADER preparation and submission **(Exh 5, pgs 16-18)**. I observed there is also a global PV procedure that addresses PADERs **(Exh 8)** but did not request it for review. Periodic reports are compiled and submitted electronically to FDA by global PV. The RA Department at Zydus USA composes a cover letter that is submitted with each PADER.

Mr. Desai provided a list that identifies the dates PADERS were filed in 2012, 2013 and 2014 for all products approved for marketing in the United States **(Exh 14, PADER list)**. I estimated there were 285 PADERs filed during this time period. I observed 10 of these were filed late and all 10 were in the May-June 2012 time period **(Exh 15, Cover letters corresponding to late PADERs)**. I brought this to the firm's attention. Mr. Gurram stated that the firm had a problem submitting the information electronically during that time period and global PV needed to scan all of the information onto a disc and send the disc to FDA. He attributed the delays to the increased time it took to scan the information. I suggested if a delay occurs in the future the cover letter submitted with the PADER should reflect the reason for the delay.

I reviewed the electronic versions of five randomly selected PADERs. I reviewed the contents and observed no deficiencies. I also selected 17 non-serious or expected ADE cases from the ADE case lists previously provided and verified they were reported in PADERs.

ANDA Annual Reports. The ANDA Annual Reports are also complied and submitted electronically to FDA by global PV. I reviewed the content and submission dates for the 2012 and 2013 ANDA Annual Reports for metformin and warfarin. I observed no deficiencies.

Waivers. Mr. Gurram stated the firm had no waivers from FDA.

PV Agreements. Zydus Pharmaceuticals USA Inc. is the distributor of multiple products for which it is not the marketing authorization (MHA) holder **(Exh 16, Distributor non-application holder product list)**. Mr. Gurram stated that the Zydus name is on the label for each of the distributed products. I reviewed the Quality Agreements the firm has with Emcure (acetazolamide), Abbvie/Abbott (clarithromycin, divalproex, fenobibrate, fenofibric acid, paricalcitol, potassium chloride), and Navinta (famotidine). I observed no deficiencies with the agreements made with

Emcure and Abbvie/Abbott. However, I informed Mr. Gurram at the time of my review and Mr. Renner at close-out that the agreement with Navinta did not directly state who was responsible for reporting ADEs to FDA **(Exh 17 pg 11, Navinta Quality Agreement dated 2/12/10)**. Mr. Renner stated the firm would review the agreement and update it for clarity if necessary. Mr. Gurram stated the firm has no PV/Quality Agreement with Nasur (oxycodone, potassium chloride) since it is a subsidiary of Zydus USA. Mr. Gurram stated that there is no agreement between Zydus USA and global PV at Cadila. However, there is an SOP that governs PV data exchange **(Exh 6)**.

I also reviewed the Master Services Agreement between TMAC and Zydus USA **(Exh 18)**. I observed no deficiencies.

Complaint Files. Standard Operating Procedure (SOP) 203-A-03 **(Exh 19)** outlines the complaint receipt, review, processing, follow-up, investigation and reporting process. The firm contracts with TMAC to handle receive and categorize complaints as a complaint and/or an ADE. Investigating and reporting the results is the responsibility of the RA Department at Zydus USA in association with Cadila Healthcare Ltd., the manufacturer of Zydus USA's marketed drug products. If a complaint claims ineffectiveness of the drug product TMAC processes it as both an ADE and a complaint. All complaints are investigated. TMAC typically requests return of the product. If the complainant returns the product and the quantity returned is sufficient the manufacturing facility tests the product to ensure it meets release specifications. If the product is not returned or the quantity returned is not sufficient but the lot number is known the manufacturing site tests a retain. If the lot number is not known no testing is performed by the manufacturing site. The manufacturing site sends the results of the complaint investigation to the RA Department of Zydus USA who communicates the results to the complainant.

I requested and reviewed the list of open product complaints. I observed that any complaint on the list that claimed ineffectiveness also had an ADE number. I correlated the ADE numbers on the open complaint list to the ADE lists provided by the firm. I observed no deficiencies. I observed three complaints since the previous EI in the FACTS database flagged as follow-up at the next EI. None involved unlisted (unexpected) events and therefore did not require a 15-day report.

ADMINISTRATIVE DATA

Inspected firm:	Zydus Pharmaceuticals USA Inc
Location:	73 Route 31 N Pennington, NJ 08534-3601
Phone:	609-730-1900
FAX:	609-730-1999
Mailing address:	73 Route 31 N Pennington, NJ 08534-3601

Establishment Inspection Report	FEI:	**3008444937**
Zydus Pharmaceuticals USA Inc	EI Start:	05/09/2014
Pennington, NJ 08534-3601	EI End:	05/15/2014

Dates of inspection:	5/9/2014, 5/12/2014, 5/13/2014, 5/14/2014, 5/15/2014
Days in the facility:	5
Participants:	Loretta Nemchik, Investigator

EXHIBITS COLLECTED

1. Zydus Pharmaceuticals USA Inc. Organizational Chart, 1 pg
2. Global PV Organization Chart, 1 pg
3. Product list, 22 pgs
4. Global PV contact information, 1 pg
5. Adverse Drug Experience (ADE) Reporting Responsibilities between the Medical Affairs Company (TMAC) and Zydus Pharmaceuticals USA Inc. SOP 202-A-04 effective 12/20/13, 74 pgs
6. Pharmacovigilance Data Exchange Between Global PV Cell and Local Affiliates, SOP CHL/GPV/SOP/011 version 01, 9 pgs
7. Case Processing on PvNET, SOP CHL/PV/WI-022 version 00, 39 pgs
8. List of global PV procedures, 2 pgs
9. TMAC contact information, 2 pgs
10. ADE case ZYD-13-AE-172 selected pages, 4 pgs
11. ADE case ZYD-13-AE-004 selected pages, 7 pgs
12. ADEs from foreign affiliates 1/1/13-4/30/14, 1 pg
13. ADE case ES-Zydus-002056-01 selected pages, 10 pgs
14. 2012-2014 PADER submission list, 16 pgs
15. Submission cover letters of late PADERs, 11 pgs
16. List of distributed non-MHA products, 4 pgs
17. Quality Agreement between Zydus USA and Navinta, 17 pgs
18. Master Services Agreement between Zydus USA and TMAC, 10 pgs
19. Product Complaint Handling Responsibilities Between the Medical Affairs Company (TMAC) and Zydus Pharmaceuticals USA Inc. SOP 203-A-03 effective 12/20/13, 45 pgs

ATTACHMENTS

FDA Form 482, Notice of Inspection, dated 5/9/14 issued to Prashant J. Desai, 3 pgs

CDER, Office of Compliance Assignment Memo dated 10/1/13, 3 pgs

Establishment Inspection Report
Zydus Pharmaceuticals USA Inc
Pennington, NJ 08534-3601

FEI: **3008444937**
EI Start: 05/09/2014
EI End: 05/15/2014

Loretta Nemchik

Loretta Nemchik, Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Jersey District Office
Central Region
Voorhees Resident Post
1020 Laurel Oak Road – Suite 203
Voorhees, NJ 08043
Telephone: 856-783-1398

Prashant
Shah
Mice
FYI
file

June 19, 2014

Mr. Joseph Renner, CEO
Zydus Pharmaceuticals USA Inc.
73 Route 31 N.
Pennington, NJ 08534-3601

Dear Mr. Renner,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at the above address on May 9th, 2014 through May 15th, 2014 by Investigator Loretta Nemchick on behalf of the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under 21 C.F.R. 20.64 (d) (3), it will release a copy of the EIR to the inspected establishment. This new procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and 21CFR Part 20. This, however, does not preclude you from requesting and, possibly, obtaining any additional information under FOIA.

If there is any question about the released information, feel free to contact:

Louise Miranda
U.S. Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, New Jersey 07054
Telephone: 973-331-4903

Sincerely,

Nerizza B. Guerin
Supervisory Consumer Safety Officer

NBG/gjp
Attachment

WARNING LETTER

Cadila Healthcare Limited

MARCS-CMS 584856 – OCTOBER 29, 2019

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Mr. Pankaj R. Patel

Chairman

Cadila Healthcare Limited

Zydus Tower, Satellite Cross Roads
Ahmedabad 380015 Gujarat
India

Issuing Office:

Center for Drug Evaluation and Research

10903 New Hampshire Avenue,
Silver Spring, MD 20993
United States

Warning Letter 320-20-05

October 29, 2019

Dear Mr. Patel:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Cadila Healthcare Limited, FEI 3002984011, at 419 & 420 8a Village-Moraiya, Ahmedabad, from April 22 to May 3, 2019.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP,

your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your May 24, 2019 response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigators observed specific violations including, but not limited to, the following.

1. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a))

Your cleaning procedure for non-dedicated equipment, including your (b)(4), is inadequate. Our investigators observed multiple (b)(4), used in the production of potent and non-potent compounds, marked as clean and containing residues of what appeared to be different products. The residues were observed on the back of the (b)(4), after product change-over cleaning. The (b)(4) system of your equipment interacts with the interior of the equipment in which products are processed.

Significant equipment flaws and cleaning deficiencies resulted in cross-contamination between your drug products. For example, you lacked provisions for inspecting or cleaning the area behind the (b)(4).

After our inspection, your firm observed residues in additional non-dedicated equipment and confirmed the recovery of multiple active ingredients through swab samples and visible (b)(4) residues collected from product-contact surfaces. For example:

- Equipment ID #CH/PM/013 – (b)(4) active ingredients were identified in swab and (b)(4) residues out of (b)(4) products processed in the equipment.
- Equipment ID #CH/PP/028 – (b)(4) active ingredients were identified in swab and (b)(4) residues out of (b)(4) products processed in the equipment.
- Equipment ID #CH/TS/013 - (b)(4) active ingredients were identified in swab and (b)(4) residues out of (b)(4) products processed in the equipment.
- Equipment ID #CH/MC/TAB/1999/19 - (b)(4) active ingredients were identified in swab and (b)(4) residues out of (b)(4) products processed in the equipment.
- Equipment ID #CH/MC/TAB/2004/176 - (b)(4) active ingredients were identified in swab and (b)(4) residues out of (b)(4) products processed in the equipment.

After our inspection, your firm also tested reserve samples of selected batches to assess the potential for cross contamination. Your testing confirmed the presence of active ingredients manufactured in numerous samples tested, including but not limited to:

- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets

- Appropriate improvements to your cleaning validation program with special emphasis on incorporating conditions identified as worst case in your drug manufacturing operation. This should include but not be limited to identification and evaluation of all worst-case:

  - drugs with higher toxicities
  - drugs with higher drug potencies
  - drugs of lower solubility in their cleaning solvents
  - drugs with characteristics that make them difficult to clean
  - swabbing locations for areas that are most difficult to clean
  - maximum hold times before cleaning

  In addition, describe the steps that must be taken in your change management system before introduction of new manufacturing equipment or a new product.

- A summary of updated SOPs that ensure an appropriate program is in place for verification and validation of cleaning procedures for products, processes, and equipment. Also, include a copy of your cleaning validation report once completed.

2. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

Your investigations into failures during periodic qualification of the (b)(4) cycles are inadequate. For example, investigation DC/2018/381 was initiated on June 9, 2018 for a failure during periodic requalification of the (b)(4) used for (b)(4) Injection (b)(4) ml in (b)(4) ml vial. The required F_0 was not achieved and there was significant (b)(4) variation for at least (b)(4). You concluded that the root cause was improper (b)(4). As part of the impact assessment, you evaluated the qualification reports for other products that utilize the same (b)(4) and concluded that there was no impact on other (b)(4) products. Therefore, you did not extend the CAPA to other products.

However, in March 2019, you initiated investigation DC/2019/190 and DC/2019/195 because of another failure during the periodic requalification of the same (b)(4) used for the (b)(4) of (b)(4) Injection (b)(4) ml in (b)(4) ml vial. Again, several sensors did not achieve the required F_0, and one did not reach the (b)(4) temperature. In addition, at the end of the incubation, the biological indicators at multiple locations in the (b)(4) showed microbiological growth. This resulted in the recall of (b)(4) batch of (b)(4) Injection, USP, (b)(4) mg per (b)(4) ml ((b)(4) mg per ml), due to lack of (b)(4) assurance.

In this instance you also concluded that the root cause was improper (b)(4). There was no assurance that your assessment of other (b)(4) products using this (b)(4) was thorough and that adequate CAPA were identified and implemented. In addition, your investigation did not sufficiently address why your originally validated cycle parameters were not met and why the process fell out of a state of control.

Your response adds that there has been some drift in the calibration of the built-in (b)(4) that control the (b)(4) cycle since 2017. However, your response lacks an assessment of the adequacy of the (b)(4) calibration standards, as you acknowledge in the response that the variation observed is within your established acceptance criteria. Also, calibration of (b)(4) was verified as part of your original investigation.

According to your firm's investigation report there have been seven deviations during the periodic requalification of this (b)(4) in the past two years. Recurrent failures suggest that you have not adequately identified the root cause and lack

- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets
- Residues of (b)(4) active ingredients in (b)(4) tablets

As a result of these inspectional findings your firm initiated a recall of numerous batches manufactured in your (b)(4) #CH/TS/013 (dedicated to potent compounds).

In your response, you committed to corrective and preventive actions (CAPA) for non-dedicated equipment, including revisions to cleaning procedures, mechanical changes to equipment to prevent (b)(4), cleaning validation for all processing equipment, and further testing to analyze reserve samples of batches manufactured using (b)(4) to quantify the potential carryover of previous products.

Your firm's review concluded that the significant cross-contamination identified by your firm does not represent a risk to patients.

Your response is insufficient. Your response stated that any potential residue that enters the (b)(4) and contaminates the next drug product can produce a nearly uniform distribution in the (b)(4) and that (b)(4) steps minimize localization of carryover residue. Your rationale is not scientifically sound in that cross-contamination cannot be assumed to be uniformly distributed.

In addition, your response described failure modes that may have contributed to the accumulation of residues in the (b)(4). But you failed to explain when the cross-contamination involving numerous products started and why it had not been detected. Your response also stated that testing for cross-contamination in the products provides good assurance that any carryover is detected. However, reserve sample testing alone is insufficient to mitigate associated risks. The extent of the cross-contamination found suggests a lack of assurance that products meet appropriate standards for identity, quality, purity and safety.

In response to this letter provide the following:

- Your CAPA plan to implement routine, vigilant operations management oversight of facilities and equipment. This plan should ensure, among other things, prompt detection of equipment/facilities performance issues, effective execution of repairs, adherence to appropriate preventive maintenance schedules, timely technological upgrades to the equipment/facility infrastructure, and improved systems for ongoing management review.
- A comprehensive, independent retrospective assessment of your cleaning effectiveness to evaluate the scope of cross-contamination hazards and recalls initiated to determine if additional batches were affected. This should include, but not be limited to:
    - Identification of any inadequacies of cleaning procedures and practices for each piece of manufacturing equipment used to manufacture more than one product.
    - Any updates to your investigation regarding the identity of residues, other manufacturing equipment that may have been improperly cleaned, and an assessment whether additional cross-contaminated products may have been released for distribution.
- A CAPA plan based on the retrospective assessment, that includes appropriate remediations to your cleaning processes and practices, and timelines for completion. Provide a detailed summary of vulnerabilities in your process for lifecycle management of equipment cleaning. Describe improvements to your cleaning program, including enhancements to cleaning effectiveness; improved ongoing verification of proper cleaning execution for all products and equipment; and all other needed remediations.

conditions.

In response to this letter, provide the following:

- A risk assessment of all contamination hazards with respect to your aseptic processes, equipment, and facilities, including an independent assessment that includes, but is not limited to:
  - All human interactions within the (b)(4) area
  - Equipment placement and ergonomics
  - Air quality in the (b)(4) area and surrounding room
  - Facility layout
  - Personnel Flows and Material Flows (throughout all rooms used to conduct and support sterile operations)
- A comprehensive, independent retrospective review of all batches that remain within expiry in the U.S. market, which incorporates the knowledge of hazards gained from your risk assessment. Include any additional actions you intend to initiate because of the retrospective review.

4. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

Your environmental and personnel monitoring program is deficient. For example, your procedures allowed personnel performing aseptic interventions (e.g., (b)(4)) in the (b)(4) area to have (b)(4) colony-forming units (CFU) on their (b)(4) without triggering an appropriate investigation. During our inspection, a firm official indicated that your firm does not consider the (b)(4) to be an (b)(4) intervention and operators are only held to ISO 7 limits.

The (b)(4) step in your operation is a critical aseptic intervention, and it is manually intensive. Our inspection noted significant aseptic technique breaches during performance of this intervention.

Your firm's response is inadequate. We acknowledge your commitment to conduct a protocol-based assessment to evaluate the adequacy of limits of viable monitoring based on the classification of the area and the criticality of the operation. However, your response did not include a retrospective review of your personnel monitoring data to identify the instances in which operators held to ISO 7 limits conducted activities in the (b)(4) area, and if the (b)(4) limits were exceeded. Growth observed on (b)(4) samples taken from personnel performing any activities within the (b)(4) area should, at a minimum, lead to trending and assessment, and could trigger further actions and investigation.

In response to this letter, provide the following for products that remain within expiry in the U.S. market:

- A risk assessment of personnel and environmental monitoring data since April 2017, including but not limited to identification of adverse trends or acute findings, and any potential impact on marketed products. Place special emphasis on data from your aseptic processing rooms, as well as any adverse trends that indicate any loss of environmental control in your facility's overall suite of cleanrooms.
- A detailed update to the CAPAs implemented and their current status in light of your decision to permanently close down the injectable manufacturing lines that serve the U.S. market.
- Describe how your firm will ensure continued accountability and responsibility for all products remaining in distribution from this facility (e.g. complaint evaluation, stability testing, handling of reserve samples, post-marketing reporting activities, OOS investigations and document retention). State who will be performing these duties and procedures that will be followed for all marketed products.

Cessation of Sterile Drug Manufacturing for U.S. Marketed Products

(b)(4) assurance.

In response to this letter provide the following:

- A comprehensive retrospective, independent review of all batches (b)(4) with this (b)(4) that were distributed in the U.S. market and remain within expiry. This review should include, but not be limited, to:
  - Review of your (b)(4) parameters, including time and (b)(4) settings to ensure a (b)(4) assurance level of (b)(4) or more.
  - Evaluations of F-value and Z-value data and any related assumptions; (b)(4); D-value determinations and population enumerations for each biological indicator lot; and commercial batch data to determine whether (b)(4) cycles used for your products were complete/adequate.
- A comprehensive and independent assessment of your system for investigating deviations, and failures. Your CAPA plan should include, but not be limited to, improvements in investigations, root cause analysis, written procedures, staff competencies (e.g., evaluating potential root causes), and quality unit oversight. Also, include your process for evaluating CAPA plan effectiveness.

3. Your firm failed to follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).

Poor Aseptic Behavior

Operators displayed poor aseptic practices during aseptic set-up and filling operations. For example:

- Operators leaned over the open bag of sterilized stoppers. These bags are subsequently introduced into the stopper chute. Also, the operator's hands passed over the sterile stopper chute and over sterilized stoppers already added into the chute. Notably, your procedures specifically prohibit personnel leaning over the product or sterilized containers and closures.
- Operators used (b)(4) Restricted Access Barrier Systems ((b)(4)RABS) (b)(4) to pick up sterile forceps and remove fallen vials. During that intervention, the (b)(4) extend over open vials without clearing them. According to your procedures, (b)(4)RABS (b)(4) are sterilized only (b)(4). Your firm's staff confirmed that these (b)(4) cannot be considered sterile during this extended use period.

Inadequate Cleanroom Design and Smoke Study Deficiencies

Your stopper chute leans (b)(4) of the filling line during stopper loading operations thereby creating turbulence as the air flows (b)(4) filters (b)(4) the chute.

In addition to this inadequate design, your smoke studies performed for your (b)(4) areas also lacked simulation of multiple critical interventions that occur during aseptic manufacturing operations.

Thorough smoke studies are essential to evaluate the effects of such interventions on unidirectional airflow and to ensure design modifications are made wherever necessary.

The (b)(4) area is critical because sterile product is exposed and therefore vulnerable to contamination. Your aseptic filling process should be designed, and operations executed, to prevent contamination hazards to your sterile product. The flawed design of the filling line and execution of the aseptic operations promoted influx of contamination into the critical filling areas.

Your firm's response is inadequate. You did not provide a thorough evaluation of all batches produced under inadequate

In your October 2, 2019 communication, you informed the FDA that you would permanently cease production of injectable drug products for the United States. It is important to note that full remediation of the related CGMP violations cited will be necessary if you decide to resume the manufacturing of injectable drug products at this site, or if any successor firm assumes responsibility over the site's operation in the future. In your response include your action plan for transferring any of your injectable drug products to other facilities. Notify this office in writing if you decide to revisit your decision and resume manufacturing injectable drugs for the U.S. in the future.

Additional Guidance on Aseptic Processing

See FDA's guidance document *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice* to help you meet the CGMP requirements when manufacturing sterile drugs using aseptic processing at https://www.fda.gov/media/71026/download (https://www.fda.gov/media/71026/download).

Repeat Violations at Facility

In previous warning letters (WL 320-11-015 and 320-16-05), FDA cited similar CGMP violations. You proposed specific remediation for these violations in your response. Repeated failures demonstrate that executive management oversight and control over the manufacture of drugs is inadequate.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence or the occurrence of other violations.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b). This also allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Until you correct all violations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new drug applications or supplements listing your firm as a drug manufacturer.

Failure to correct these violations may also result in the FDA refusing admission of articles manufactured at Cadila Healthcare Limited, 3002984011, at 419 & 420 8a Village-Moraiya, Ahmedabad, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Articles under this authority may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov (mailto:CDER-OC-OMQ-Communications@fda.hhs.gov) or mail your reply to:

Rebecca Parrilla, M.S.

Compliance Officer

U.S. Food and Drug Administration

White Oak Building 51, Room 4235

10903 New Hampshire Avenue

Silver Spring, MD 20993

Please identify your response with FEI 3002984011.

Sincerely,

/S/

Francis Godwin

Director

Office of Manufacturing Quality

Office of Compliance

Center for Drug Evaluation and Research

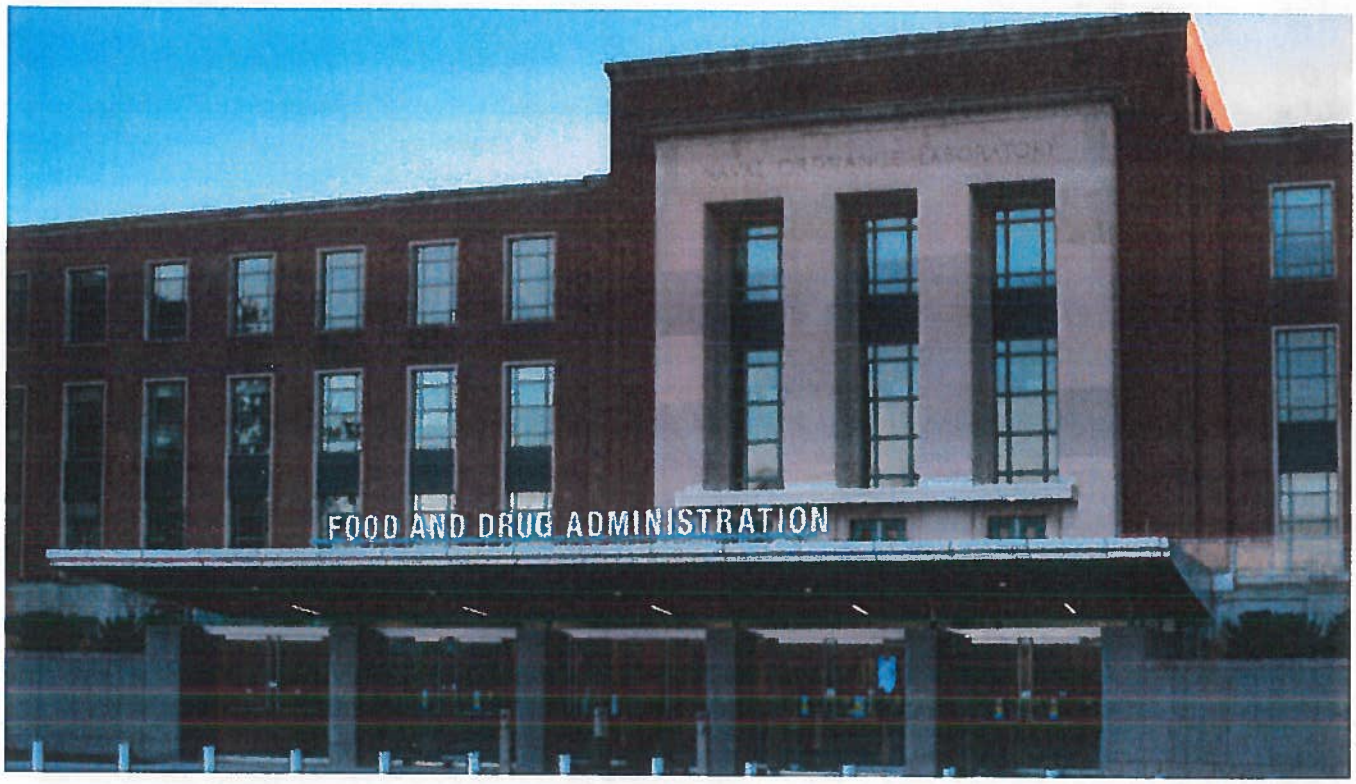
More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

STAT[1]

FDA slams another Indian drug maker for serious quality problems

By Ed Silverman[2] @Pharmalot[3]

January 6, 2016



India's Cadila Healthcare has run into trouble with the FDA. *FDA*

If there is a surefire way to arouse the concerns of Food and Drug Administration inspectors, try this: take a notebook listing manufacturing problems, place it in plastic bags along with other paperwork, and toss them in a nearby scrap yard where the inspectors can find them.

Here's another approach: leave "unofficial notebooks," which are used to track manufacturing activities, lying around an office so the inspectors can read how bacteria is present in the water system, but become puzzled when the problem is not cited in official company records.

These were just two of several "serious breaches" of good manufacturing practices the FDA cited in a Dec. 23, 2015, warning letter[4] sent to Cadila Healthcare, one of India's largest drug makers. The letter followed agency inspections of two manufacturing plants in India between August and December 2014.

Related: [5]

Review of FDA oversight of Asian drug plants requested by lawmakers [5]

What else concerned the FDA?

There were problems with the potency of warfarin made at one plant and Cadila agreed to temporarily suspend production. But after running tests, the company resumed production in November 2014. Yet in June 2015, Cadila acknowledged to the FDA that problems with some lots of warfarin were subsequently found, but had been shipped anyway.

Meanwhile, nine consumer complaints were lodged by way of pharmacies and distributors over potential product mix-ups. But while Cadila conceded some drugs were made on adjacent production lines, the company never completed its investigation. Were mix-ups caused by inadequate cleaning, unsuitable equipment, material flow, or something else? Cadila didn't know, which made it hard to fix the problem.

There's more. Several batches of active pharmaceutical ingredients failed an analysis, but Cadila never explored why this occurred. The drug maker also failed to prevent unauthorized access or changes to data. FDA inspectors noted a lab manager could delete data from software and, in fact, one file was deleted. But an audit trail function was never activated and Cadila did not have records of any changes.

For its part, Cadila issued a statement[6] to the Bombay Stock Exchange last week to maintain that it takes "quality and compliance matters very seriously

… and is working hard to ensure that the commitments made to the FDA are fully completed." The drug maker also insisted its products are safe and effective and that no products shipped to the United States are made with ingredients from the plant where the analyses failed.

"This has a theme found in a lot of warning letters, especially warning letters issued to Indian companies," said Vince Suneja, chief executive of TwoFour Insight Group[7], a consulting firm that works with Indian drug makers. "There's a failure to properly investigate problems and a lack of adequate controls for data."

Indeed, as we have noted previously, this is only the latest instance in which the FDA has scolded an Indian drug maker or ingredients supplier for quality control problems. Over the past several years, in fact, there has been mounting concern over the safety of the pharmaceutical supply chain after the agency cited several companies for production failures.

The most notable example was Ranbaxy Laboratories, which is now owned by Sun Pharmaceutical. The drug maker has been a poster child for manufacturing problems. Last year, Ranbaxy paid a $500 million fine to US authorities as part of a settlement that included pleading guilty to two charges of violating drug safety laws that, for example, involved manipulating data.

Related:[8]

French proposal for 'Made in EU' labels threatens to divide drug industry[8]

Several companies have also been hit with so-called import alerts in which the FDA bans products made at a specific facility. The crackdown, however, has alarmed Indian drug makers. They have complained the FDA has singled them out for especially tough inspections, which occur too frequently and haphazardly, depriving them of the opportunity to make substantive changes.

The ongoing problems prompted several congressional lawmakers last month

to ask[5] the US Government Accountability Office to review FDA oversight of foreign manufacturing plants.

Last year, the FDA began considering a new approach to inspecting manufacturing facilities in India. The plan is to "allow our inspectors to document where a firm's quality management system exceeds what would be required to meet regulatory compliance," FDA officials wrote in a blog post[9]. "To put it simply: the inspections can yield also carrots, and not just sticks."

The FDA has also begun working with the Indian government to bolster domestic oversight. Right now, the agency has three inspectors who work in the country, but others regularly travel there as well, so the total number varies. India's drug makers, however, are angry over the FDA scrutiny, which has led to a series of import alerts[10] that ban products from being shipped to the US.

About the Author

Ed Silverman[2]

Pharmalot Columnist, Senior Writer

Ed covers the pharmaceutical industry.

ed.silverman@statnews.com [11]
@Pharmalot [3]

Links

1. https://www.statnews.com/category/the-regulars/pharmalot/
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5. https://www.statnews.com/pharmalot/2015/12/21/drugs-fda-congress/
6. http://zyduscadila.com/wp-content/uploads/2015/12/Warning_Letter_US_FDA.pdf
7. http://twofourinsight.com/

8. https://www.statnews.com/pharmalot/2015/11/19/pharmalot-drug-labels-france-sanofi/
9. http://blogs.fda.gov/fdavoice/index.php/2015/03/from-new-jersey-to-new-delhi-a-global-focus-on-quality/
10. http://www.accessdata.fda.gov/cms_ia/countrylist.html
11. https://www.statnews.com/pharmalot/2016/01/06/fda-warning-letter-cadila /mailto:ed.silverman@statnews.com
12. https://www.statnews.com/tag/drug-makers/
13. https://www.statnews.com/tag/fda/
14. https://www.statnews.com/tag/warning-letter/
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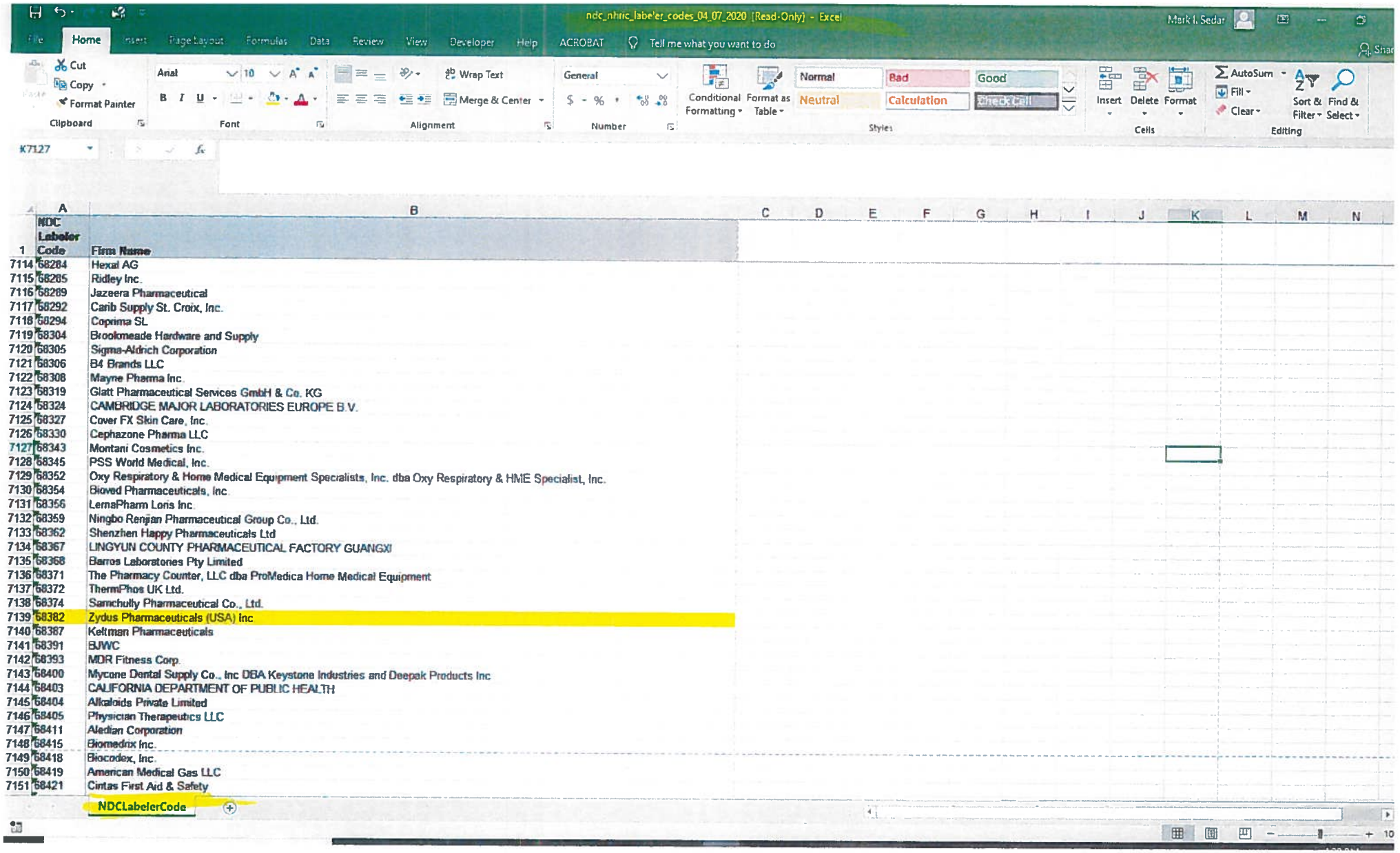

Verified MS 4/7/2020

73 Route 31 North • Pennington, NJ 08534
Phone: 609-730-1900
Fax: 609-730-1998

January 7th, 2020

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

To whom it may concern:

Zydus Pharmaceuticals USA Inc. imports controlled (CIV) and non-controlled prescription drugs from our FDA approved manufacturing facilities in India for distribution in the USA. The finished dosages imported are stored at our 3PL warehouse, Eversana Life Sciences Services, LLC, 4580 Mendenhall Road, Memphis, TN 38141. Zydus markets and sells these products to Pharmacy warehouses, Distributors and wholesalers.

The State of New Jersey does not require inspection of our corporate headquarters location in Pennington, NJ.

Sincerely,

Louis Pastor
AVP, Trade Operations

Corporate Officers	Title	DOB	Address
Michael Keenley	CEO, President		Route N., Pennington, NJ 08534
Ravi Yadavar	CFO, Treasurer		Route N., Pennington, NJ 08534
Crystal Fisher	Treasurer		Route N., Pennington, NJ 08534

1782

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0739049

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

73 ROUTE 31 NORTH PENNINGTON, NJ 08534-

Reg. No.
5003171

ZYDUS PHARMACEUTICALS USA INC
ATTN: STUART D. GROW, SR EXE.
73 ROUTE 31 NORTH
PENNINGTON, NJ 08534-

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

EXPIRES: January 31, 2021

Establishment Copy

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

ZYDUS PHARMACEUTICALS (USA) INC.
0100915422

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on November 18, 2003.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

JOSEPH D RENNER
73, ROUTE 31 NORTH
PENNINGTON, NJ 08534

THE GREAT SEAL OF THE STATE OF NEW JERSEY
LIBERTY AND PROSPERITY
1776

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 18th day of December, 2019

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6103368802

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 13BSBIH8903

Application/License No. _____

Zydus Pharmaceuticals USA, Inc., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
73 NJ-31, Pennington, NJ, 08534, as
Address of Applicant/Principal
PRINCIPAL, and Hartford Fire Insurance Company, a
Surety Company
corporation organized under the laws of the state of Connecticut
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Hartford Plaza, Hartford, CT 06155 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 4/1/20.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of March, 2020.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Surety Company's Representative

James S. Hickey, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

n/a
Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: LINK INSURANCE SERVICES
Agency Code: 13-651708

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint James S. Hickey

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 13BSBIH8903
Naming Zydus Pharmaceuticals USA, Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA }
COUNTY OF SEMINOLE } ss. Lake Mary

On this 13th day of February, 2020, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

NOTARY PUBLIC STATE OF FLORIDA

Jessica Ciccone

Jessica Noelle Ciccone
My Commission #FF029702
Expires June 20, 2021

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of March 26, 2020.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois

Keith D. Dozois, Assistant Vice President

The National Association of Boards of Pharmacy®

hereby awards

Verified-Accredited Wholesale Distributors®

Accreditation

to

Eversana Life Science Services, LLC

located at

4580 Mendenhall Road, Memphis, TN 38141

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

Carmen A. Catizone, Executive Director/Secretary

October 17, 2018 - October 16, 2021

Period of Accreditation

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

1787

Louis M. Pastor Jr.
3 Lower Mountain Rd
Furlong, PA 18925

PROFESSIONAL EXPERIENCE

Zydus Pharmaceuticals USA Inc, Pennington, NJ **December 2013-Present**

A.V.P. Trade Operations

- Manage day to day interactions with Third Party Logistics provider handing warehousing and distribution activities
- Manage chargebacks department
- Manage day to day sales operations including product allocation, inventory management, reporting and forecasting
- Take a lead role in government contracting and negotiations
- Participate in Business Development activities including contract review and negotiation
- Manage state licensing compliance

CorePharma, LLC, Middlesex NJ **March 2009-December 2013**
Amedra Pharmaceuticals LLC, Horsham PA

Director, Sales Administration

- Create product launch plans to meet and exceed market share and profitability targets
- Identify market and pricing opportunities to grow current products
- Manage all day to day sales operations functions including contracts, returns, rebates, customer service, forecasting, chargebacks and Medicaid
- Work closely with Finance to develop and adjust accrual method for rebates, Medicaid, returns and chargebacks
- Develop sales strategies and growth incentive programs to grow market share on current products
- Participate in contract negations to acquire mature brands and other generic product opportunities
- Responsible for developing and executing the strategy to bring Sales, Marketing and Distribution functions from 3rd party logistics provider back to CorePharma.
- Set-up all internal operations to support new warehousing and distribution functions
- Work with contract manufacturers and Supply Planning on new launches and forecasting

Cadista Pharmaceuticals, Horsham PA **February 2006-March 2009**

Sr. Manager, Sales Administration

- Manage strategic customer contract negotiations, proposal developments and pricing
- Lead weekly production planning and monthly Sales and Operations Planning meetings
- Spearheaded seamless transition from third party distribution to internal distribution resulting in annual savings of over $500k
- Maintain superior service levels with all customers through accurate forecasts and production schedules
- Responsible for gathering and reporting monthly sales data to Global Management Team
- Work closely with CFO to ensure adequate accruals are maintained and rebates are accounted for accurately
- Federal Government liaison for Veterans Administration Contract and Federal Supply Schedule

Sandoz Inc, Princeton NJ **October 2003-February 2006**

Pricing Analyst

- Performed profitability analysis on proposals
- Partnered with Rebates, Chargebacks and Collections to resolve contract and pricing disputes
- Monitored Siebel approval process of contracts and pricing to ensure timely customer responses
- Coordinated data analysis for contract renewals
- Determined contractual and financial impact of price increases
- Performed business reviews for RFP's ensuring competitive pricing among classes of trade and adherence to the Robinson-Patman Act
- Managed the implementation of price changes and new product offers in response to customer requests

Business Systems Analyst

- Business Warehouse and SAP liaison for Sales and Marketing-*Recognized with a Galaxy Award*
- Created ad hoc sales reports for various functional areas
- Identified areas of improvement within SAP and partnered with IT to implement the changes
- Developed and analyzed reports to improve customer service levels
- Worked with various areas to enhance and develop current systems

Corporate Account Representative

- Maintained and developed relationships with strategic clients by managing day to day activities- *Recognized with a Galaxy Award for outstanding customer focus and performance*
- Supported internal and external auditors
- Ensured SOX compliance with regard to order processing

Commerce Bank, NA, Flemington, NJ **April 1999-October 2003**

Assistant Branch Manager, Certified Consumer Lender

- Supervised operation of the branch to ensure the highest level of customer service
- Responsible for employee development and retention
- Performed daily and monthly audits
- Lead monthly meetings
- Responsible for employee performance reviews
- Oversaw the loan process to ensure timely completion of loan applications

SKILLS

- Microsoft Word, Excel, PowerPoint and Access, Lotus Notes, SAP, Business Warehouse, Siebel, Baan, Outlook

EDUCATION

Rider University, Lawrenceville NJ
Bachelor of Science in Marketing
Major- Marketing
Cum Laude

14D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks 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 Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☑ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: APNAR PHARMA LP

Physical Address: 4820 LANIER RD

City: CHINO State: CA Zip Code: 91710

Telephone Number: 844-283-9825 Fax Number: 909-525-4142

Toll Free Number: _____

E-mail: dharmesh.patel@apnarpharma.com Website: www.apnarpharma.com

Facility Manager: DHARMESH PATEL

Professional qualifications and experience of facility manager: Pharmacist

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☑ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☐ No ☑
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: KAISER PERMANENTE
Address: 300 PULLMAN STREET, LIVERMORE, CA, 94551

Name: MCKESSON CORPORATION
Address: 6555 STATE HIGHWAY 161, IRVING, TX 75037

Name: CARDINAL HEALTH
Address: 7000 CARDINAL PLACE, DUBLIN, OH, 43017

Name: AMERISOURCE BERGEN
Address: 500 INNOVATION DRIVE, MN, 55379

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

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 ☑

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

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

DHARMESH PATEL
Print Name of Authorized Person

03/24/2020
Date

Board Use Only	Date Processed:_____	Amount: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PARTNERSHIP. All persons listed as a partner must accurately complete a personal history record form.

Type of Partnership: General _____ Limited X

List names of 4 largest partners and percentage of ownership:

Name: DHARMESH PATEL %: 70

Name: UMESH PATEL %: 24

Name: DIPAK SURESH PATEL %: 6

Name: _____ %: _____

Partnership Name: APNAR PHARMA LP

Mailing Address: LANIER ROAD

City, State Zip Code: CHINO, CA, 91710

Telephone Number: _____ Fax Number: 909-525-4142

Contact Person: DHARMESH PATEL

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

Include with the application for a partnership

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of $25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

***If you are a FDA registered manufacturer, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of $25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers only".

State of California
Secretary of State
CERTIFICATE OF STATUS

ENTITY NAME: APNAR PHARMA, LP

FILE NUMBER:	201400800012
FORMATION DATE:	01/02/2014
TYPE:	DOMESTIC LIMITED PARTNERSHIP
JURISDICTION:	CALIFORNIA
STATUS:	ACTIVE (GOOD STANDING)

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

The entity is authorized to exercise all of its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records and does not reflect documents that are pending review or other events that may affect status.

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

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of June 24, 2020.

ALEX PADILLA
Secretary of State

FSB

State of California
Secretary of State

CERTIFICATE OF STATUS

ENTITY NAME: APNAR PHARMA, LP

FILE NUMBER:	201400800012
FORMATION DATE:	01/02/2014
TYPE:	DOMESTIC LIMITED PARTNERSHIP
JURISDICTION:	CALIFORNIA
STATUS:	ACTIVE (GOOD STANDING)

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

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

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

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of December 31, 2019.

ALEX PADILLA
Secretary of State

CFG

NP-25 (REV 02/2019)

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

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

April 9, 2020

APNAR PHARMA LP
4820 LANIER RD
CHINO CA 91710

California State Board of Pharmacy License Verification

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

Licensee Name: APNAR PHARMA LP

License Type: WHOLESALER

License Number: WLS 7576

Status: ACTIVE

Issue Date: 05/06/2019

Expiration Date: 01/01/2021

Address of Record: 4820 LANIER RD CHINO CA 91710

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

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

Renewal License

Wholesale Drug Permit

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

LICENSE NO. WLS 7576
RECEIPT NO. 00700181

VALID UNTIL MAY 01, 2021

APNAR PHARMA LP
4820 LANIER RD
CHINO CA 91710

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

03/12/20

03/12/20 The official status of this license can be verified at www.pharmacy.ca.gov

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

FORM WPHWLS (09/30/19) WLS

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 10105323

Application/License No. _____

Apnar Pharma LP DBA Apnar Pharma LP (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4820 LANIER RD CHINO, CA 91710 (Address of Applicant/Principal), as PRINCIPAL, and Hudson Insurance Company (Surety Company), a corporation organized under the laws of the state of Delaware (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1035 Greenwood Blvd, Suite 265 Lake Mary, FL 32746 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 3/30/2020 12:00:00 AM (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this _____ day of _____, 20____.

APPLICANT/PRINCIPAL

_____
Authorized Representative

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SURETY COMPANY

_____
Surety Company's Representative

Matt Bocklage, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

Countersigned by:

_____
Nevada Resident Agent

10105323

HUDSON INSURANCE GROUP

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Matt Bocklage

of the State of MO

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

One Hundred Thousand Dollars ($100,000.00)

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly authorized on this 6th day of February, 20 20 at New York, New York.

SEAL (Corporate seal)

HUDSON INSURANCE COMPANY

Attest.....
Dina Daskalakis
Corporate Secretary

By.....
Michael P. Cifone
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

On the 6th day of February, 20 20 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of **HUDSON INSURANCE COMPANY**, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

CAMERON GOURLAY NOTARY PUBLIC STATE OF NEW YORK

.....
CAMERON GOURLAY
Notary Public, State of New York
No. 01GO6372305
Qualified in New York County
Commission Expires June 4, 2022

CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

The undersigned **Dina Daskalakis** hereby certifies

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

In Witness the hand of the undersigned and the seal of said Corporation this 30th day of March, 20 20.

SEAL (Corporate seal) 1918

By.....
Dina Daskalakis, Corporate Secretary

DHARMESH PATEL

Rice Ave ,Chino Ca

Work Experience

- **1999 to 2002** Rite Aid Pharmacy, Newport Beach, California
  Pharmacy Technician

2002 to 2004 Rite aid, Newport Beach, California
Intern Pharmacist

2004 to 2006 Family Pharmacy, Long Beach, California
Pharmacist in Charge

2006 to 2010 Community Pharmacy, Bakersfield, California
Pharmacist in Charge

2010 to 07/2011 Caring Pharmacy, Riverside, California
Pharmacist in charge

2015//03/24 to 01/01/2012 – Parkview medical plaza pharmacy, Riverside, California
pharmacist in charge.

2015/03/25/ to current -Pharmacist and CEO at APNAR PHARMA, chino, California

Responsibilities

-Responsible for pharmacy operations which included ordering and inventory control of pharmaceutical drugs.

-Supervised seven employees including their workflows.

-Responsible to increase company's production

- Build strong pipeline of drugs .and monitoring all small to big projects.

Certification: Certified in immunization. Certified in compounding medicines by PCCA.

PHARMA LP 4820 LANIER RD ,CHINO CA 91710

Date :04/02/2020

To: Nevada Board Of Pharmacy

RE: List of employees handling the drugs on a daily basis

Employee Names;
Sandy Samperio
Agustin Hernandez
Neel Patel

Sincerely,

Signature _____ Date 04/2/2020
Dharmesh Patel
President/Pharmacist

0 www.apnarpharma.com Q dharmesh.patel@apnarpharma.com @ 844-283-9825
Corporate Office: Apnar Pharma LP 4820 LANIER RD, Chino, CA, 91710, USA.