NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy (non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

| New Outsourcing Facility | | | | |
|--|--|--|--|--|
| Ownership Change (Provide current license number if making changes:) OUT | | | | |
| □ 503a OR 🕱 503b Apply as retail pharmacy only. | | | | |
| Check <u>box</u> below for type of ownership and complete all required forms for type of ownership that | | | | |
| you have selected. If LLC use Non Publicly Corporation or Partnership | | | | |
| □ Publicly Traded Corporation – Pages 1-3 & 4 □ Partnership - Pages 1-3 & 6 | | | | |
| ☐ Publicly Traded Corporation – Pages 1-3 & 4 ☐ Partnership - Pages 1-3 & 6 ☐ Non Publicly Traded Corporation – Pages 1-3 & 5 ☐ Sole Owner – Pages 1-3 & 7 | | | | |
| GENERAL INFORMATION to be completed by all types of ownership | | | | |
| Facility Name: ATHENEX PHARMA SOLUTIONS, LLC | | | | |
| Physical Address: 11342 MAIN ST. | | | | |
| City: CLARENCE State: NEW YORK Zip Code: 14031 | | | | |
| Telephone: <u>7/6, 253, 6490</u> Fax: <u>7/6, 4/8, 7273</u> | | | | |
| Toll Free Number: 871. 413. 7823 (Required per NAC 639.708) | | | | |
| E-mail: RKEEM @ ATHENEX.com Website: ATHENEX PHARMA.Com | | | | |
| Supervising Pharmacist: SHARON STOYELL Nevada License #: 19877 | | | | |
| SERVICES PROVIDED | | | | |
| Yes/No | | | | |
| □ Ø Parenteral | | | | |
| ☑ □ Sterile Compounding | | | | |
| | | | | |
| □ 📈 Non Sterile Compounding | | | | |
| □ 🗗 Mail Service Sterile Compounding | | | | |
| □ Ø Other Services: | | | | |
| All boxes must be checked for the application to be complete | | | | |
| An appearance will be required at a board meeting before the license will be issued. | | | | |
| | | | | |
| Board Use Only Date Processed: Amount: \$500.00 | | | | |

| APPL | ICATION FOR OUT-OF STATE OUTSOURCING FACILITY | Page 2 |
|--------|--|-------------|
| FEI N | umber (From FDA application): 45-5250649 | |
| | e provide the name of the facility as registered with the FDA and the registra HENEX PHARMA SOLUTIONS, LLC 3008876196 | |
| Pleas | e provide a list of all DBA's used by outsourcing facility. A separate sheet is | acceptable. |
| | e provide the name and Nevada license number of the supervising pharmace: SHARON STOYELL Nevada License Number: / 9 | |
| | vada business license is not required, however if the Outsourcing Facility ha | s a Nevada |
| This p | page must be submitted for all types of ownership. | |
| Withir | n the last five (5) years: | |
| 1) | Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | Yes □ No 💢 |
| 2) | Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? | Yes □ No [X |
| 3) | Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? | Yes □ No 🔯 |
| 4) | Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | Yes □ No 🔀 |
| 5) | Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | Yes □ No 🗗 |
| Copie | answer to question 1 through 5 is "yes", a signed statement of explanation res of any documents that identify the circumstance or contain an order, agrees sition may be required. | |

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

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

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

| Does your outsourcing facility wholesale compounded medication for resale? | Yes 🗆 No 🔀 |
|--|------------|
| The Law prohibits the resale of compounded medication. By signing this applicattesting that your medications will be labeled with the statement "Not for Resauctsourcing facilities products will not be resold. | |
| Robert Klein | |
| Original Signature of Person Authorized to Submit Application, no copies or sta | amps |

ROBERT KEEM

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

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OWNERSHIP IS A PUBLICY TRADED COMPANY

| State of Incorporation: DELAWARE |
|---|
| Parent Company if any: <u>ATHENEX</u> , <u>INC</u> . |
| Corporation Name: <u>ATHENEX</u> , <u>TNC</u> . |
| Address: 1001 MAIN ST |
| City: <u>Buffaco</u> State: <u>N.Y.</u> Zip: <u>14203</u> |
| Telephone: 716.427.2950 Fax: 716.800.6816 |
| Contact Person: TERESA BAIR |
| If the corporation that holds an ownership interest in the applicant is a publicly traded corporation |

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

Include with the application for a publicly traded corporation

<u>Certificate of Corporate Status</u> (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. **PITACHED**.

List of officers and directors. ATTACHED.



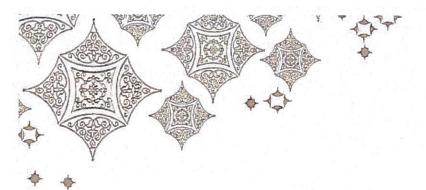
Athenex Pharma Solutions LLC is 100% wholly owned by Athenex, Inc., located at: 1001 Main Street, Suite 600, Buffalo, New York 14203. Phone: 716.427.2950.

Our Corporate Officers for Athenex Pharma Solutions, LLC are as follows:

| Jeffrey M. Yordon | Jeffrey M. Yordon |
|---------------------------------------|---|
| President & COO | West Rue Paris Place |
| N. Martingale Road, Suite 230 | Inverness, IL 60067 |
| Schaumburg, IL 60173 | 7 |
| | Last four digits of Social Security Number: |
| <u>iyordon@athenex.com</u> | Date of birth: / |
| Teresa Brophy Bair | Teresa Brophy Bair |
| Vice President, Corporate Development | 380 Berryman Drive |
| 1001 Main Street, Suite 600 | Snyder, NY 14226 |
| Buffalo, NY 14203 | |
| | Last four digits of Social Security Number: |
| tbair@athenex.com | Date of birth: 1 |
| | |

General Manager for Athenex Pharma Solutions LLC, located at 11342 Main Street, Clarence, New York 14031, is as follows:

| Robert Keem | Robert Keem |
|--------------------------|---|
| General Manager | J Burroughs Drive |
| . ! Main Street | Snyder, New York 14226 |
| Clarence, New York 14031 | |
| V | Last four digits of Social Security Number: |
| rkeem@athenex.com | Date of birth: |
| 4 | |







ATHENEX PHARMA SOLUTIONS, LLC

FACILITY OPERATION OVERVIEW

Athenex Pharma Solutions, LLC is cGMP facility located in Clarence, NY. The facility is FDA registered and is designed to manufacture, test and release sterile drug products for the critical care hospital market. The facility consists of a fully integrated drug manufacturing operation with Warehousing, Quality Control, R&D, Manufacturing and Engineering all under the same roof. An overarching Quality Management System complying with the current GMP standards assures that all established policies and procedures are utilized and maintained appropriately. Our supply chain is supported by an organization wide Enterprise Resource Planning system and our policies and procedures are managed by a validated document and training platform.

Facility Details:

- -18,000 sqft
- -cGMP aseptic (ISO 5) compounding suites
- -Analytical and Microbiological testing services on-site
- -Product development team on-site
- -Hour of Operation (M-F, 8AM-5PM)
- -Pharmacist-in-Charge supervises all compounding activities
- -Distributing "direct to hospital" compounded products from Clarence manufacturing location
- -FDA Inspected Operation







Office of the Professions

Verification Searches

The information furnished at this web site is from the Office of Professions' official database and is updated daily, Monday through Friday. The Office of Professions considers this information to be a secure, primary source for license verification.

Pharmacy Establishment Information *

08/23/2018

Type: OUTSOURCE FACILITY

Legal Name: ATHENEX PHARMA SOLUTIONS, LLC

Trade Name: **Street Address:** 11342 MAIN ST.

14031-0000 CLARENCE, NY

Registration No: 035973 Date First Registered: 08/09/18

Registration Begins: 08/09/18 Registered through: 07/31/21

Supervisor: 044159 STOYELL SHARON P

Establishment Status: ACTIVE

Successor: NONE

Use your browser's back key to return to establishment list.

You may <u>search</u> to see if there has been recent disciplinary action against this registered establishment.



^{*} Use of this online verification service signifies that you have read and agree to the terms and conditions of use. See HELP glossary for further explanations of terms used on this page.



NEW YORK STATE BOARD OF PHARMACY, Kimberly Leonard, Executive Secretary 89 Washington Avenue, 2nd Floor, Albany, NY 12234-1000 Tel. (518) 474-3817, ext. 130; Fax (518) 473-6995 E-mail: pharmbd@nysed.gov ; Web: www.op.nysed.gov

August 22, 2017

Verification of an In State or Nonresident Pharmacy, Manufacturer/Repacker/Wholesaler or individuals Licensed in New York:

Online verification of the registration status of an in State or Nonresident pharmacy, and/or manufacturer/repacker/wholesaler, as well as the license and registration status of licensed professionals, can be performed free of charge at http://www.op.nysed.gov/opsearches.htm. An additional search can be performed on each verification screen to determine if an establishment or licensee has been disciplined by this Department.

Note: No other form of verification is available for pharmacy establishments. Please do not use "request for Written Confirmation of New York State Licensure" for verification of a registered establishment; that form is used only for certification or verification of licensed individuals.

Verification of Licensed Professionals (not establishments):

The Board Office cannot provide letters of good standing or license verification; however, the Certification/Verification Unit can provide documentation that will likely meet your needs.

A form must be submitted with the appropriate fee for either a certification or verification of a license. The difference between certification and verification is explained on the form which is available at http://www.op.nysed.gov/documents/confirmoflic.pdf.

I hope this information is helpful.

Thank you.

THE UNIVERSITY OF THE STATE OF NEW YORK EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

NAME OF SUPERVISOR SHARON P. STOYELL



2018-21

THIS IS TO CERTIFY

ATHENEX PHARMA SOLUTIONS, LLC 11342 MAIN ST. CLARENCE, NY 14031

is duly recorded as a

REGISTERED OUTSOURCING FACILITY

in conformity with the provisions of section 6808 of the Education Law

CERTIFICATE IS EFFECTIVE ON THE NINTH DAY OF AUGUST, 2018. CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF JULY, 2021.

a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER

035973



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