**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax:(718)662-5661<br>ORAPHARM1_RESPONSES@fda.hhs.gov | 9/8/2022-9/16/2022*<br>FEI NUMBER<br>3008876196 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Timothy Call, Senior Director of Manufacturing

| FIRM NAME | STREET ADDRESS |
|---|---|
| Athenex Pharma Solutions, LLC | 11342 Main St |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Clarence, NY 14031-1718 | Outsourcing Facility |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**
**OBSERVATION 1**
There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your investigations into sterility failures were not conducted thoroughly to evaluate potential root causes in the production facility and to implement robust corrective and preventative action plans to mitigate sterility risks to products. During Oct 2021 to Dec 2021, two sterility failures were observed on the finished product sterility testing, identified to be Gram Positive Rods (*Bacillus licheniformis* and *Niallia circulans)*, belonging to Bacillus species of family. Sterility failures were investigated under #OOS-OOT-2021-0044 on 20Oct2021 for 8mg Norepinephrine in 0.9% Sodium Chloride (250mL IV Bag), Lot# (b) (4) ; and #OOS-OOT-2021-0054 on 02Dec2021for 1 Unit/mL Vasopressin 0.9% Sodium Chloride (50mL), Lot (b) (4) . Investigations into sterility failures did not include comprehensive evaluations of environmental monitoring results from the compounding area and personnel; and the review of the environmental excursions were not extended to all excursions from all sources during this time period. Your failure to identify elevated environmental excursions in the aseptic compounding areas (with spore forming microorganisms) as a potential contamination source, insufficient corrective actions were implemented to mitigate spore forming microorganisms in the environment and to protect product sterility during aseptic operations.

During our review of the environmental trend report for (b) (4) , we observed increased environmental excursion levels from compounding personnel gloves/gowns during October 2021 with at least 13 out of 18 microorganisms identified to be Gram Positive Rods, belonging to

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Junho Pak, Investigator<br>Syeda N Mahazabin, Investigator | X Junho Pak Investigator Signed By 2000578589 Date Signed 09-16-2022 12 08 42 | 9/16/2022 |

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Bacillus species family.

***DATES OF INSPECTION**

9/08/2022(Thu), 9/09/2022(Fri), 9/12/2022(Mon), 9/13/2022(Tue), 9/14/2022(Wed), 9/15/2022(Thu), 9/16/2022(Fri)

X Syeda N Mahazabin
Investigator
Signed By: Syeda N. Mahazabin -S
Date Signed: 09-16-2022 12:09:24

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Junho Pak, Investigator
Syeda N Mahazabin, Investigator

X Junho Pak
Investigator
Signed By: 2000578589
Date Signed: 09-16-2022
12:08:42

DATE ISSUED
9/16/2022

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

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

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

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