DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	12/5/2017-12/13/2017* FEI NUMBER 3008876196

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert F. Keem, General Manager

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 I OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

Specifically,

On 12/6/17, an operator was observed disinfecting Bay (b) (4) ISO 5 Horizontal Laminar Flow Hood ((b) (4)) with (b) (4) from (b) (4) , rather than (b) (4) , as outlined in the firm's procedure and performed in the firm's smoke studies. According to the firm's management and procedures, disinfection of the ISO 5 Horizontal Laminar Flow Hood should be conducted by starting in the area (b) (4) , in a manner that disinfects from the (b) (4) .

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

On 12/6/17, I observed no environmental monitoring sampling being performed in the ISO 5 area, in Bay (b) (4) Horizontal Laminar Flow Hood (b) (4)), where the operator is working, which is in front of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rachael A Moliver, Investigator	X Rachael A Moliver Investigator Signed By: Rachael Moliver -S Date Signed: 12-13-2017 12:54:21	12/13/2017

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Robert F. Keem, General Manager	
FIRM NAME Athenex Pharma Solutions, LLC	STREET ADDRESS 11342 Main St
CITY, STATE, ZIP CODE, COUNTRY Clarence, NY 14031-1718	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

the (b) (4) . Currently, the firm's media fill validations and environmental monitoring procedure state that (b) (4) ; however, viable monitoring is only performed in the (b) (4) .

OBSERVATION 3

Equipment for adequate control over temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically,

Your firm's monitored area is not where approved human finished drug products, which are used as the active ingredient in compounding operations, are stored. Currently, your firm only monitors the temperature in the warehouse in the (b) (4) ; however, approved human finished drug product (active ingredient) is located in the (b) (4) area of the warehouse across from the (b) (4) . The firm has not conducted temperature mapping studies in the worst-case conditions, including Summer and Winter, for the current warehouse configuration. Your firm has only done a temperature mapping study in the Spring of the warehouse's current configuration, which showed a broader temperature range for the location where the raw material product is stored than where the temperature probes reside.

OBSERVATION 4

The labels of your outsourcing facility's drug products are deficient.

Specifically,

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The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A), including:

(a) The dosage form.

(b) A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

The following list contains examples of labels for drug products which do not contain the required information:

- Epinephrine 2mg/250mL in 5% Dextrose
- Epinephrine 4mg/250mL in 5% Dextrose
- Phenylephrine 10mg/250mL in 0.9% Sodium Chloride
- Phenylephrine 20mg/250mL in 0.9% Sodium Chloride
- Phenylephrine 25mg/250mL in 0.9% Sodium Chloride
- Phenylephrine 40mg/250mL in 0.9% Sodium Chloride
- Phenylephrine 50mg/250mL in 0.9% Sodium Chloride
- Norepinephrine 8mg/250mL in 0.9% Sodium Chloride

***DATES OF INSPECTION**
12/05/2017(Tue), 12/06/2017(Wed), 12/07/2017(Thu), 12/08/2017(Fri), 12/11/2017(Mon), 12/12/2017(Tue), 12/13/2017(Wed)

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