DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	11/09/2015 - 11/20/2015* FEI NUMBER 1000307034

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Peter F. McGarvey, Director of Pharmacy Operations

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services, Inc.	253 Gibraltar Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Horsham, PA 19044-2305	Producer of Sterile Drug Products

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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,
In sterile drug production rooms (b) (4) and (b) (4) classified as ISO7 and ISO 5 the following was observed:

a. During production of drug products in the ISO 5 sterile drug production work stations eye brows and facial skin were exposed on multiple employees.

b. Dirt and grime was observed on the handles of the (b) (4) located under the ISO 5 hood and during production.

OBSERVATION 2

Clothing of personnel engaged in the manufacturing, processing, and packing of drug products is not appropriate for the duties they perform.

Specifically, in accordance with SOP 40000171, titled "Gowning Requirements" your firm allows employees to (b) (4) (b) (4) Employees de- gown and exit the cleanroom suite for breaks, by (b) (4) (b) (4) in the gowning room classified ISO 8. Employees return to the cleanroom suite after their breaks (b) (4) (b) (4)

OBSERVATION 3

The flow of components, drug product containers, closures, and drug products though the building is not designed to prevent contamination.

Specifically,

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a. (b) (4) was left hanging on the trash can. The (b) (4) is used to (b) (4) in accordance with SOP-CAPS 4000158 titled "Clean room Compounding area -(b) (4) (b) (4) (b) (4) to entering the ISO 7 areas. The (b) (4) times are not recorded in logs.

b. In the ISO 7 area in the sterile drug production room (b) (4) the ISO 5 sterile drug production work station a (b) (4) with uncontrolled (b) (4) and other components were stored in the corner. The (b) (4) contained the following components: (b) (4)

OBSERVATION 4

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,

1. In accordance with SOP 4000183, Cleaning Procedure, the clean-room suite which includes ISO 5 area hoods are cleaned with (b) (4) and (b) (4) (b) (4)
Paint chips and dark rust can be seen on white hooks in ISO 5 sterile drug production work stations (b) (4) and near the following sterile drug components and TPN product:

a. Heparin Sodium (b) (4)
b. (b) (4)
c.

2. Throughout the ceilings in the non-classified component staging areas where (b) (4) (b) (4) and near or adjacent to the HVAC systems multiple holes with exposed insulation in multiple areas was observed. Some of the holes with exposed insulation were (b) (4) Also, products were being stored on the floors under the holes and exposed insulation.

OBSERVATION 5

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, mops were stored in buckets in front of the vents in the ISO 7 areas adjacent to the ISO 5 hoods in the sterile production room.

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OBSERVATION 6

Each lot of a component, drug product container, and closure that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically, for all incoming sterile active pharmaceutical ingredients (API) no certificate of Analysis (COA) are obtained or reviewed by Quality. The firm does not receive COAs for their APIs or final product containers.

OBSERVATION 7

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, no final product testing is performed for sterility, endotoxin or potency on finished drug products.

OBSERVATION 8

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,
a. From January 2015 to September 2015 no deviations reports, investigations or CAPA's were initiated for rejected sterile drug products for the following:
25 Leaky Bags
24 Wrong Bag Size
16 Cloudy Bags
12 Compounding Errors
5 Expired Materials
28 Core Particles

b. Complaint# 10-140530-010 was received for a baby girl patient for elevated calcium levels on 05/29/14. The investigation covered time period of 05/14-18/14. No medical assessment was documented, as required of CAPS on a Product Complaint Form Product Complaint Form FRM-CAPS-4000054 version 1.

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OBSERVATION 9

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

Specifically, for bioburden testing regarding the ISO 5 areas, the firm requires (b) (4) for an action and for an investigation to be initiated. Additionally, the ISO 5 areas are monitored (b) (4) and not daily. In addition, employee gloves and gowns are sampled (b) (4) not daily. For example, (b) (4) and employee finger tips and gowning sleeves are sampled (b) (4) and not daily. (b) (4)
(b) (4)

*** DATES OF INSPECTION:**
11/09/2015(Mon), 11/10/2015(Tue), 11/12/2015(Thu), 11/13/2015(Fri), 11/16/2015(Mon), 11/17/2015(Tue), 11/18/2015(Wed), 11/20/2015(Fri)

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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 judgement, 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."

Weeks
ARM 11/20/15