DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Custom House, 200 Chestnut Street, Room 900 Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875 ORAPHARM1_RESPONSES@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	04/26/2022 - 05/04/2022* **FEI NUMBER** 3011755753

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Patrick T. Legal, Director of Pharmacy

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services, Inc.	410 Commerce Park Drive
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Cranberry Township, PA 16066	Producer of Sterile Drugs

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) (WE) OBSERVED:

OBSERVATION 1

Personnel conducted aseptic manipulations and placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically,

On 04/26/2022, during the preparation of (b) (4) additions into the (b)(4) IV bags, we observed an employee inserting the syringe into a product vial and removing product from the vial in a (b)(4) orientation that blocked the critical areas from receiving first pass air flow from the (b)(4) ISO 5 Laminar Air Flow (LAF) bench area. Operators were also observed making (b) (4) additions from (b)(4) into the (b)(4) bags in a (b)(4) orientation that blocked first pass ISO 5 air flow (i.e. Rx (b) (6) , requiring (b) (4) addition of (b) (4) Additionally, we observed employees reaching over open filled product vials and syringes of stock solution in the (b)(4) ISO 5 LAF bench area after disinfecting the units with non-sterile (b)(4) . Furthermore, we observed employees using a plastic bin to stack empty syringes used to hold sterile stock solution on top of each other, blocking first pass ISO 5 air.

OBSERVATION 2

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jazmine N. Brown	Jazmine N. Brown, Investigator Amy N. Chen, Investigator Elaine E. Gilfillan, Investigator	05/04/2022

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(Continuation of Observation 2)

From 4/26/2022 to 4/28/2022, we observed employees use non-sterile (b)(4) to clean and sanitize materials entering into the ISO 5 Laminar Air Flow Bench areas. Your firm's employees were observed spraying a sterile wipe with non-sterile (b)(4) and then cleaning the work surfaces and equipment inside of the ISO 5 Laminar Air Flow Bench areas.

OBSERVATION 3

The facility is designed and operated in a way that may permit the influx of lesser quality air into a higher quality air area.

Specifically,

During the walk-through of your facility, we observed an open slot along the North side of your ISO 7 (b)(4) production room that opens directly to the non-classified pharmacy area. This open slot is approximately (b)(4) in height and (b)(4) in length and is connected to a (b) (4) conveyor belt that leads to a (b)(4) bin to catch (b)(4) bags that are ready to be packaged for shipment. This activity was not conducted during any smoke study validation of the clean room.

OBSERVATION 4

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically,

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	Jazmine N. Brown Elaine E. Gilfillan	Jazmine N. Brown, Investigator Amy N. Chen, Investigator Elaine E. Gilfillan, Investigator	05/04/2022

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(Continuation of Observation 4)

The media fill program is deficient in that operator qualification of their media fills are performed in batch sizes of (b)(4) and (b)(4) in a (b)(4) bag using the (b)(4) compounder, however, the smallest (b)(4) batch size that is produced by your firm is (b)(4) for neonates and the largest batch size for other patients is (b)(4). Additionally, operator qualification media fills are performed using (b)(4) bag but your firm produces (b)(4) bags in sizes of (b)(4), and (b)(4) Filling of the batch sizes are not representative of the firm's worse-case scenario and have not been validated.

*Dates of the inspection: 04/26/2022 (Tues.), 04/27/2022(Wed.), 04/28/2022(Thurs.), 04/29/2022(Fri.), 05/02/2022(Mon.), and 05/04/2022(Wed.)

Add Continuation Page

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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."