DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802 ORAPHARM2_RESPONSES@fda.hhs.gov	5/3/2021-5/24/2021* FEI NUMBER 3005292119

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul J. D'Aunoy, Director of Pharmacy

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services Inc	1433 Sams, Units A and C
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Harahan, LA 70123	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 OBSERVED:

OBSERVATION 1

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically, on July 31, 2019, August 7, 2019, February 19, 2020 and May 27, 2020, the viable surface sample showed a recovery of at least 1 cfu in laminar flow hood (ISO 5). You did not evaluate the products manufactured on those days or take remedial action other than (b) (4) cleaning.

Additionally, employees had positive results for fingertip testing (which is performed (b) (4)) on November 18, 2019, November 4, 2020 and November 7, 2020. You did not evaluate the products manufactured on those days or take remedial action.

OBSERVATION 2

Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically, I observed the following:

a) During the (b) (4) cleaning of the clean room on May 6, 2021, the dwell time for (b) (4) solution made with (b) (4) does not stay wet for the recommended labeled time of (b) (4) on LFH (ISO 5), carts, cleaning buckets and other items located in the ISO 7 area when sprayed with the mixture. These items were immediately wiped with a sterile

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Claire M Minden, Investigator	X Claire M Minden Investigator Signed By: Claire M. Minden -S Date Signed: 05-24-2021 10:41:10	5/24/2021

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wipe after application of the (b) (4) allowing a dwell time of only (b) (4) for the LFH (ISO 5).

b) Carts used to introduce materials into the clean room are sprayed with (b) (4) are immediately wiped with a sterile wipe not allowing for the (b) (4) contact time as recommended on the (b) (4) label.

OBSERVATION 3

Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

Specifically, during operations on May 3, 2021, I observed the following:

a) When the final ingredient is added to TPN bags via a syringe, the ports of the TPN bag were not sprayed specifically nor were they wiped prior to insertion of needle to add the sterile ingredient. The TPN bag(s), just immediately to this step, are left outside the LFH (ISO 5) on a rack in the TPN room (ISO 7) and placed in a different LFH (ISO 5) for the final addition. This was observed to occur multiple times.

b) Employee grabbed multiple wrapped syringes in hand where not all surfaces were exposed in the TPN room (ISO 7), spray with (b) (4) inside the LFH (ISO 5) then place in the LFH (ISO 5).

c) Employee touched trash can, sprayed one glove and did not rub hands together (as common practice for all employees) to spread the sterile alcohol then picked up supplies in LFH (ISO 5) with unsprayed glove.

OBSERVATION 4

The ISO 5 classified aseptic processing areas had difficult to clean equipment or surface.

Specifically, on May 3, 2021, I observed the following:

a) Blue bin used to store multiple small vials for TPN production had white sticker residue and was

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inside LFH (ISO 5) for multiple preparations.

b) LFH #(b) (4) (ISO 5) in SVP room (ISO 7) had multiple scratches on sneeze guard portion.
c) Gouges in floor in front of LFH #(b) (4) in TPN room (ISO 7).
d) Bottom panel in SVP room (ISO 7) is chipped in corner.
e) Light fixture in SVP room (ISO 7) not flush and light fixture in TPN room (ISO 7) had crack.

***DATES OF INSPECTION**

5/03/2021(Mon), 5/06/2021(Thu), 5/07/2021(Fri), 5/10/2021(Mon), 5/24/2021(Mon)

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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 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."