DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food and Drug Administration 404 BNA Drive, Bldg 200, Suite 500 Nashville, TN 37217 615-366-7801 FDA-483 Responses: ORAPHARMA2_RESPONSES@FDA.HHS.GOV	02/03-12/2020 FEI NUMBER 3013236711

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Richard L. Crockett, Medical Center Director

FIRM NAME	STREET ADDRESS
Overton Brooks VA Medical Center	510 E Stoner Ave
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Shreveport, LA 71101-4243	Producer of Sterile and Non-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.

OBSERVATION 1

The ISO 5 classified aseptic processing area was located within a non-classified room (segregated production area).

Specifically, your firm's ISO-5 classified (b) (4) located in the Hazardous Area (Room (b) (4)) and the ISO-5 classified (b) (4) located in the Non-Hazardous Area (Room (b) (4)), are in unclassified rooms. These (b) (4) contain a (b) (4) antechamber. The (b) (4) chamber is under (b) (4) pressure. According to your firm's Inpatient Pharmacy Manager, the antechambers do not supply a continuous flow of HEPA filtered air.

On 3 February 2020, we observed your pharmacist open the (b) (4) ISO-5 classified antechamber exposing the inside of the antechamber to the unclassified air in the surrounding room, during the transfer of materials from the "segregated compounding area" (SCA) into the antechamber. In addition, prior to the movement of these materials, the antechamber's interior surfaces were not disinfected.

Your firm performs aseptic operations within the (b) (4) and (b) (4) to produce sterile hazardous and non-hazardous drug products. The (b) (4) and (b) (4) have been operational in their current locations (rooms (b) (4) and (b) (4) respectively) since May 2017.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	June P. Page, Investigator Brandon C. Heitmeier, Regulatory Officer	2/12/2020

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OBSERVATION 2

Equipment in close enough proximity to the ISO 5 area that could compromise the air in the ISO 5 area.

Specifically, on 3 February 2020, we observed a portable air conditioner in your firm's non-hazardous "segregated compounding area" (SCA) (Rm (b) (4)), which contains a condenser water tank. According to your Chief of Pharmacy, the portable air conditioner is located approximately 97 inches from your firm's (b) (4) (ISO-5 Classified), where aseptic operations are performed for non-hazardous sterile drug products. According to your firm's Inpatient Pharmacy Manager, the antechambers do not supply a continuous flow of HEPA filtered air.

According to your firm's Chief of Pharmacy, the portable air conditioner has been in your firm's non-hazardous SCA from June 2017 – 4 February 2020. Per your firm's (b) (4) prescription log, your firm has approximately produced (b) (4) sterile drug products in the (b) (4) from (b) (4) (b) (4)

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June P. Page - S3 Digitally signed by June P Page S3 DN: c US o U S Government ou HHS ou FDA ou People cn June P Page S3 0 9 2342 19200300 100 1 1 2000405709 Date: 2020 02 12 09:46 49 06'00'

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OBSERVATION 3

The facility design of your segregated production area does not have a suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

A. Your firm's Hazardous Area (Room (b) (4)), containing the ISO-5 Classified (b) (4) (b) (4) where aseptic operations are performed, was observed to have:
   a. A wooden door that separates Room (b) (4) from a corridor that is readily accessible to the public. This corridor is located near an exterior entrance door. This room is under (b) (4) pressure.
   b. A refrigerator with a fan unit which intakes and exhausts air through two vents located above the refrigerator door. The refrigerator is located approximately 30 inches from the (b) (4)

B. Your firm's Non-Hazardous Area (Room (b) (4)), containing the ISO-5 Classified (b) (4) (b) (4) where aseptic operations are performed, was observed to have:
   a. A wooden door that separates Room (b) (4) from a common hallway accessible to the public.
   b. Flooring that is not smooth and even (e.g. crevices and gaps were observed).

According to your firm's most recent certification report, dated September 2019, these "segregated compounding areas" (SCAs) contain (b) (4) Laminar Flow (b) (4) ISO-5 Classified) in unclassified areas. These areas were converted to SCAs in May 2017 and are used to aseptically produce sterile drug products.