DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202 ORAPHARM2_RESPONSES@fda.hhs.gov	7/18/2022-8/12/2022* FEI NUMBER 3015826782

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lacy D. Wood, Pharmacy Manager	
FIRM NAME Carolina Infusion	STREET ADDRESS 95 Bees Creek Rd
CITY, STATE, ZIP CODE, COUNTRY Ridgeland, SC 29936	TYPE ESTABLISHMENT INSPECTED 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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Your firm produced drug products with materials that had not been verified to assure that they did not contribute endotoxin contamination that may be objectionable given the product's intended use.

Specifically, you have no assurance that the endotoxin levels of your intrathecal drug products are safe.

a. Your firm does not release your intrathecal finished drug product based on endotoxin limit. For example, on 07/25/2022, your firm used a (b) (4) system to test for endotoxin in Sample Lot "7589/72322@(b) (4)" for Sample ID "BUPHYDROFENTGABA," yielding a Sample Value of (b) (4) EU/mL and Sample Lot "7590/7600/72322@(b) (4) for Sample ID "BUPBACFENTMORPH," yielding a Sample Value of (b) (4) EU/mL. These products were distributed to patients.

b. Your firm does not control for endotoxins in intrathecal products.

   i. Due to the absence of your (b) (4) test equipment for maintenance, your firm distributed approximately (b) (4) intrathecal drug product prescriptions between 05/10/2022 and 06/02/2022 which were not tested for endotoxin prior to being dispensed to patients. For example, Patient (b) (6) was dispensed Morphine 40 mg/mL on 05/18/2022 per Rx (b) (6)

   ii. Non-sterile bulk drug substances (BDSs) and other components used to produce intrathecal

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products have no endotoxin testing data. For example, Baclofen USP (b) (4), Lot 172103/G, does not have endotoxin testing data. Baclofen USP (b) (4), Lot 172103/G, was used to produce Baclofen 1100 mcg/mL, Lot 07162022@(b) (4), BUD 07/20/2022.

c. Your firm inappropriately pools (combines) different finished compounded intrathecal drug products into one sample unit during endotoxin testing. As such, the reported endotoxin result is not a true representation of original drug product lots. For example, testing performed on 07/25/2022 for Sample ID "7590/7600/072322@(b) (4) and Sample ID "7589/72322@(b) (4)" included multiple intrathecal products.

OBSERVATION 2

Your media fills were not performed under the most challenging or stressful conditions.

Specifically, there is a lack of assurance that your firm can aseptically produce drug products within your facility. Your firm utilizes a media fill kit from (b) (4) which involves (b) (4) ; however, your firm produces more complex preparations during sterile drug production. For example, 500 mL of Lidocaine, 2% Injectable was produced on 06/08/2022.

OBSERVATION 3

ISO-5 classified areas were not certified under dynamic conditions.

Specifically, unidirectional airflow in the ISO-5 hood (b) (4) within the sterile compounding cleanroom was not verified under operational conditions during the certification testing performed on June 25, 2022.

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This hood is used by personnel in the production of sterile drug products, including products intended for intrathecal injection. Intrathecal pain products may contain fentanyl, sufentanil, baclofen, bupivacaine, morphine, and hydromorphone. During production the hood is loaded with items which potentially impact the unidirectional airflow such as a balance, transfer basket, vials, syringes, and (b) (4) tubes.

OBSERVATION 4

Inadequate pressure differentials between higher quality air rooms and lower quality air rooms were observed.

Specifically, your sterile compounding cleanroom, certified as ISO 6, failed to meet the pressure differential specification of (b) (4) W.G. or greater during verification testing performed on 02/23/2022. It is adjacent to a hallway which has neutral pressure and has no evidence of ISO certification.

(b) (4) Report # J53373-(b) (4) identifies your sterile compounding room (Compound #(b)) as requiring a (b) (4) or greater" pressure differential and reports the average reading using calibrated equipment as 0.0140.

On the same day, viable air sampling was performed in your controlled cleanrooms by (b) (4) and they were processed by (b) (4) under Sample IDs 28702 and 28703. The samples taken in your Ante Room, which is pressure neutral to the hallway adjacent to the sterile compounding cleanroom, "recovered both highly pathogenic organisms and CFU counts that exceeded the action limit for the sampling area." Recovered organisms include, but are not limited to, *Trichophyton sp.*, *Staphylococcus epidermidis*, and *Staphylococcus caprae*.

Your sterile compounding room is used to produce sterile drug products, including products intended for intrathecal injection.

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OBSERVATION 5

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically, your firm produces non-sterile drug products using (b) (4) that is not intended for use in pharmaceutical preparations and is labeled in part, "For improved food preparation." For example, (b) (4), Lot (b) (4), was used to produce Dyclonine (Peppermint), 1% Oral Solution, Lot 07212022@(b) (4) BUD 10/19/2022, on 07/21/2022.

***DATES OF INSPECTION**

7/18/2022(Mon), 7/19/2022(Tue), 7/20/2022(Wed), 7/21/2022(Thu), 7/22/2022(Fri), 7/25/2022(Mon), 7/26/2022(Tue), 7/27/2022(Wed), 7/28/2022(Thu), 7/29/2022(Fri), 8/01/2022(Mon), 8/02/2022(Tue), 8/03/2022(Wed), 8/05/2022(Fri), 8/08/2022(Mon), 8/11/2022(Thu), 8/12/2022(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 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."