DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 25301161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	3/7 - 3/9/2022, 3/11/2022
	FEI NUMBER 3015859129

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Joshua A. Eudy, CEO

FIRM NAME	STREET ADDRESS
Family Pharmacy of Statesville, Inc.	3478 E. Broad St.
CITY, STATE AND ZIP CODE Statesville, NC 28625	TYPE OF 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) (WE) OBSERVED:

OBSERVATION 1

Your facility was operated in a way that permits poor flow of materials.

Specifically,

A. During the compounding of Hydromorphone 1 mg/mL infusion lot #528, the pharmacy technician failed to wipe down the (b) (4) and the supplies with sterile (b) (4) prior to introduction into ISO 5 BSC.

B. Prior to and after compounding Hydromorphone 1 mg/mL infusion lot #528, the pharmacy technician failed to wipe down the sterile (b) (4) bottle prior to introduction into the ISO 5 BSC.

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, the sporicidal agent, (b) (4), that your firm uses to clean the surfaces inside of the ISO 5 BSC requires a (b) (4) contact time. Your technician stated that this product is used on an (b) (4) (b) (4) basis and left on the inside surface of the ISO 5 BSC to dry while he performs cleaning of the outside surfaces of the

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BSC then does a final wipe down inside with sterile (b) (4).

OBSERVATION 3

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

Specifically, the firm's (b) (4) media fill which mimics their high-risk infusion compound, Hydromorphone, was performed with (b) (4) IV bags of (b) (4) each for a total batch size of (b) (4). However, the firm's highest volume as seen on their (b) (4) batch log for this infusion compound is (b) (4).

(REPEAT OBSERVATION)

OBSERVATION 4

You did not have a HEPA filter over the area to which sterile product was exposed without any information to support that the components remained sterile throughout the storage period.

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Specifically, your firm states that the prescription laboratory room is classified as ISO 8 but there is no HEPA filter present. The (b) (4) glassware used in sterile processing are stored in this room.

OBSERVATION 5

The cycle parameters used for (b) (4) of materials used to prepare sterile injectable drug products were not verified using endotoxin indicators.

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Specifically, you do not use endotoxin indicators to ensure and verify that the temperature and time cycle used to sterilize and (b) (4) glassware is adequate.

(REPEAT OBSERVATION)

OBSERVATION 6

Your firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area.

Specifically,

A. According to our interview with the pharmacy technicians, no equipment or supplies were present in the ISO 5 BSC and they did not simulate the worst case scenario compounding activities during the smoke studies.

B. Your ISO 7 clean room was certified with both ISO 5 BSC turned on however, subsequent compounding and media fills were performed with (b) (4) hood running which could potentially impact the airflow.

OBSERVATION 7

Non-microbial contamination was observed in your production area.

Specifically, we observed what appeared to be rust inside the cabinet storing both hazardous bulk drug substances and hazardous chemicals. The bottom door hinges and the bottom shelf on this cabinet had visible rust shavings.

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OBSERVATION 8

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, the pressure between the ISO 8 anteroom and ISO 7 clean room is kept the same possibly leading to lower quality ISO 8 air entering ISO 7 clean room every time the door is opened.

OBSERVATION 9

The ISO-classified processing areas had difficult to clean equipment.

Specifically, your firm uses a non-cleanroom compliant metal folding chair in the ISO 7 cleanroom while working in the ISO 5 BSC.

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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."