

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER U.S. Food and Drug Administration 555 Winderley Place, Suite 200 Maitland, FL 32751 Phone: (407)475-4700 Fax:(407)475-4768 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 2/3,4,5,6,7,10,12/2020
	FEI NUMBER 3015859129

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** Joseph M. Eudy, President

FIRM NAME Family Pharmacy of Statesville	STREET ADDRESS 208 Old Mocksville Rd
CITY, STATE AND ZIP CODE Statesville, NC 28625-1953	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-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**

Sporicidal agents were not used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area.

Specifically, you did not have a sporicidal cleaning agent and your cleaning log does not indicated that a sporicidal cleaning agent has been used in your ISO 5 classified aseptic processing area.

In addition to this, trending data indicates that on 7/30/2019 viable air sampling in your Chem hood (ISO 5) recovered 1 CFU of coagulase-negative Staphylococcus spp. and Clean Bench (ISO 5) recovered 1 CFU of Micrococcus/Kocuria spp. These hoods are used to produce sterile drug products for injection and intrathecal administration.

**OBSERVATION 2**

You have no assurance that the endotoxin level of your intrathecal drug products is safe, since you do not have any endotoxin data and your firm doesn't perform endotoxin testing for the finished product. These preparations are made using non-sterile starting material. Furthermore, there is no endotoxin testing data for your API.

Specifically you prepared morphine sulfate bupivacaine 20 mg/ 4mg for intrathecal injection lot 01272020@6 and did not perform endotoxin testing. This was made using morphine sulfate USP (b) (4) lot (b) (4) and bupivacaine HCl USP lot (b) (4) which are also not tested for endotoxin.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Joanne E. King -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Joanne E. King, Investigator	DATE ISSUED 02/12/2020
	<small>Digital signed by Joanne E King S          DN: cn=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Joanne E King, s=9 2342 10200300 100 11-1300174867          Date: 2020.02.12 10:29:03 -05'00'</small>		

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**OBSERVATION 3**

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

Specifically, you did not use sterile (b) (4) to clean your ISO 5 Chemo hood on 2/5/2020 during the processing of hydromorphone HCl 2 mg/ml infusion lot 02052020@2 in 0.9 % NaCl for injection. The spray bottle labeled to contain sterile (b) (4) lot (b) (4) was expired on 10/19. It did not contain the (b) (4) listed on the label. It contained another suppliers sterile (b) (4) with an unknown lot and expiration date. The reuse of spray bottles and sterile lint free wipes exposed to uncontrolled conditions such as the interior of the (b) (4) with no HEPA filtration may compromise the sterile nature of this disinfection agent and wipes.

**OBSERVATION 4**

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

Specifically,

- A. The unclassified (b) (4) opens from an unclassified room to your ISO 7 buffer room. On 2/3/2020 and 2/5/2020 this (b) (4) had visible dust on the (b) (4) which were difficult to clean and prone to dust collection. There was also observable dust in the uncontrolled room ceiling vent above this (b) (4).
- B. The ante-room where you gown before entering the ISO 7 buffer room has no HEPA air filtration.

**OBSERVATION 5**

You produced hazardous drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

Specifically, on 10/10/2019 you prepared the hazardous and potent sterile drug fluorouracil 10 mg / ml ophthalmic solution in 10 ml 0.9% preservative free NaCl in your sterile ISO 5 aseptic processing area.

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		Joanne E. King, Investigator	02/12/2020

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**OBSERVATION 6**  
 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.

**OBSERVATION 7**  
 Your firm failed to confirm that the quality of water was suitable for its intended use in the production of non-sterile drug products.

**OBSERVATION 8**  
 The calibration of instruments, apparatus, gages and recording devices is not done at suitable intervals in accordance with an established written program.

Specifically, your scale used for the weighing of metronidazole USP , lidocaine HCl USP, and chlorpromazine HCl USP have not been calibrated **(b) (4)** This scale was used to determine these bulk drug substances in the following non-sterile drug products:

1. Metronidazole 4%, Lidocaine 5% topical ointment lots:

- 10232019@1
- 12122019@6
- 12092019@2

2. Chlorpromazine HCl 50 mg suppository lots:

- 01132020@2
- 01172020@1

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**OBSERVATION 9**

Air is recirculated to production areas, without adequate measures to control recirculation of dust.

Specifically, your uncontrolled lab ceiling vent had visible dust and the filter alarm in your (b) (4) hood indicated that filters in this hood containing both scales needed to be changed. This area is where you prepare the following non-sterile drug products:

1. Metronidazole 4%, Lidocaine 5% topical ointment lots:

- 10232019@1
- 12122019@6
- 12092019@2

2. Chlorpromazine HCl 50 mg suppository lots:

- 01132020@2
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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."