DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	4/2/2018-4/18/2018* FEI NUMBER 3013468187

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kyle F. Skiermont, Chief Operating Officer for Fairview Pharmacy Services

FIRM NAME	STREET ADDRESS
Fairview Compounding Phamacy	711 Kasota Ave SE
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Minneapolis, MN 55414-2842	Producer of Sterile and Non-Sterile 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 WE OBSERVED:

OBSERVATION 1

Non-sterilized and Non-depyrogenated equipment was used in sterile drug production.

Specifically,

On April 3rd, 2018, we observed an employee use non-sterile aluminum foil to cover a non-sterile product and transport it from the unclassified area into the ISO 5 aseptic processing area. The employee removed the aluminum foil inside the ISO 5 area and continued aseptic processing of Triple Agent UTZ (Papav, Phentol, Alprost) injectable product with lot #180403-28. The firm conducted non-sterile production of the papaverine stock solution and phentolamine mesylate stock solution in the non-sterile area which is unclassified. The depyrogenated glassware was also stored in the unclassified area.

OBSERVATION 2

The use of sporicidal agents in the cleanrooms and ISO 5 classified aseptic processing area was inadequate.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Anthony J Ladner, Investigator Tenzin Jangchup, Investigator	X Tenzin Jangchup Investigator Signed By: Tenzin Jangchup -S5 Date Signed: 04-18-2018 10:57:38	4/18/2018

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On April 3rd, 2018, we observed your daily cleaning of ISO 5 aseptic processing areas were done without the use of any sporicidal agents. Also, on April 6th, 2018, we observed your weekly deep cleaning of the ISO 5 and 7 areas were done without the use of any sporicidal agent. Currently, you do not use a sporicidal agent on a regular basis.

OBSERVATION 3

Personnel did not disinfect and change gloves frequently enough to prevent contamination.

Specifically,

On April 2, 2018, we observed:

a) an employee producing various allergy serums in an ISO 5 classified aseptic processing hood remove their hands from the hood and touch the supply cart located in the ISO 7 classified area. The employee then re-engaged in aseptic processing in the hood without changing or sanitizing gloves.

b) a separate employee producing Acetylcysteine (PF) 10% Ophthalmic drops, lot #180402-05 remove their hands outside of the ISO 5 classified aseptic processing area numerous times to discard items from the hood to a bin in the ISO 7 area and re-engage in aseptic processing without changing or sanitizing gloves.

OBSERVATION 4

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	Anthony J Ladner, Investigator Tenzin Jangchup, Investigator	X Tenzin Jangchup Investigator Signed By: Tenzin Jangchup -S5 Date Signed: 04-18-2018 10:57:36	4/18/2018

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

Specifically,

On April 3rd, 2018, we observed an employee clean the ISO 5 hood with sterile 70% IPA and non-sterile wipes before starting aseptic processing of Triple Agent UTZ (Papav, Phentol, Alprost) with lot #180403-28.

OBSERVATION 5

Biological indicators were not used to verify the adequacy of the sterilization cycle.

Specifically,

a) Progesterone 100 mg/ml in ethyl oleate injection sterilization cycle of 150 Degrees Celsius for 150 minutes does not include the use of a biological indicator to verify adequacy of the sterilization cycle.

b) Glassware used for aseptic processing is sterilized and depyrogenated with a cycle of 250 Degrees Celsius for 150 minutes and does not include the use of a biological indicator to verify adequacy of the sterilization cycle.

OBSERVATION 6

ISO 5 classified areas were not certified under dynamic conditions.

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Specifically,

The certification documents for your ISO 5 aseptic processing areas do not describe the dynamic conditions under which they were tested.

***DATES OF INSPECTION**
4/02/2018(Mon), 4/03/2018(Tue), 4/04/2018(Wed), 4/05/2018(Thu), 4/06/2018(Fri), 4/18/2018(Wed)

X Anthony J Ladner
Investigator
Signed By: Anthony J. Ladner -S
Date Signed: 04-18-2018 10:58:26

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	Anthony J Ladner, Investigator Tenzin Jangchup, Investigator	X Tenzin Jangchup Investigator Signed By: Tenzin Jangchup -S5 Date Signed: 04-18-2018 10:57:38	4/18/2018