DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	2/14/2023-3/9/2023* FEI NUMBER 3015468054

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Snapper D. Romano, Interim Co-Director Pharmacy

FIRM NAME	STREET ADDRESS
Maimonides Medical Center - Pharmacy	4802 10th Ave
CITY, STATE, ZIP CODE, COUNTRY Brooklyn, NY 11219-2916	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 WE OBSERVED:

OBSERVATION 1

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

Specifically, the Emergency Department (ED) Satellite Pharmacy unclassified "segregated compounding area" lacks adequate controls to ensure that an acceptable environment is maintained in and around the ISO 5 (b) (4) laminar flow hood to produce sterile drugs for in-patient use. The ED ISO 5 (b) (4) laminar flow hood is used to produce sterile drugs for in-patient immediate use including Amikacin Injectable (Equiv to: Amikin) 1000 mg/100 ml NS, Order # (b) (6), (b) (7)(C), MRN: (b) (6), (b) (7)(C) observed prepared on 02/17/2023 at 1215, Expiry: 02/18/2023 at 0020. The following objectionable conditions were observed in the ED Satellite Pharmacy:

a. An air-conditioner cassette with local manual temperature and fan speed control is fitted in the ceiling of the room above and adjacent to the ISO 5 (b) (4) laminar flow hood. You have not demonstrated that air delivered by the air-conditioner does not enter the ISO 5 (b) (4) laminar flow hood.

b. The air-conditioner cassette is located directly above the counter where components for sterile drugs are staged and (b) (4) disinfected for entry to the ISO 5 horizontal laminar flow hood. You do not have adequate controls to prevent contamination of the surfaces of drug components staged and (b) (4) disinfected directly beneath the air-conditioner cassette to avoid introduction of contaminants into the ISO 5 (b) (4) laminar flow hood where aseptic operations are to be

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Edmund F Mrak, Investigator Victoria Spivak, Investigator Karishma G Gopaul, Investigator X Edmund F Mrak Investigator Signed By: Edmund F. Mrak Jr -S Date Signed: 03-09-2023 10:1 :35	3/9/2023

performed.

c. The air-conditioner cassette is located directly above the counter where personnel don sterile gloves for aseptic operations in the ISO 5 (b) (4) laminar flow hood.

d. During the inspection on 02/14/2023 a buildup of dust and debris was observed in the air flow path on the fins of the air-conditioner cassette.

e. You reuse the disposable non-sterile frocks, donned for aseptic operations in the ISO 5 (b) (4) laminar flow hood, during an (b) (4) shift and store such frocks for reuse under unclassified conditions.

f. During the inspection on 02/14/2023 a mop used for cleaning and sanitizing the floor in the ED satellite pharmacy was observed improperly stored and leaning on the wall near the ISO 5 (b) (4) laminar flow hood.

OBSERVATION 2

Sinks or drains were present in the cleanroom where the ISO 5 classified aseptic processing area was located.

Specifically, in the Medical Intensive Care Unit (MICU) satellite pharmacy unclassified "segregated compounding area" a sink with water supply is located approximately 1.2 meters (just outside the line of demarcation) from the ISO 5 (b) (4) laminar flow hood. The MICU ISO 5 (b) (4) laminar flow hood is used to produce sterile drugs with a 12-hour BUD for in-patient use. During the inspection on 02/15/2023 we observed the pharmacist using the sink within the MICU to wash his hands as part of the

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personnel gowning process before performing aseptic operations in the ISO 5(b) (4) laminar flow hood to produce Phenylephrine Injection (Equiv to: Neo-Synephrine NS 100 mg/250 ml), Order # (b) (6), (b) (7)(C), MRN: (b) (6), (b) (7)(C) prepared on 02/15/2023 at 1515, Expiry: 02/16/2023 at 0315.

***DATES OF INSPECTION**

2/14/2023(Tue), 2/15/2023(Wed), 2/16/2023(Thu), 2/17/2023(Fri), 3/08/2023(Wed), 3/09/2023(Thu)

X Victoria Spivak
Investigator
Signed By: Victoria Spivak -S
Date Signed: 03-09-2023 10:15:55

X Karishma G Gopaul
Investigator
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Date Signed: 03-09-2023 10:17:14

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EMPLOYEE(S) SIGNATURE

Edmund F Mrak, Investigator
Victoria Spivak, Investigator
Karishma G Gopaul, Investigator

X Edmund F Mrak
Investigator
Signed By: Edmund F. Mrak Jr -S
Date Signed: 03-09-2023
10:1 :35

DATE ISSUED
3/9/2023

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."