DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556 ORAPHARM1_RESPONSES@fda.hhs.gov	9/20/2021-10/21/2021* FEI NUMBER 3010955218

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stuart E. Rosenberg, President

FIRM NAME	STREET ADDRESS
Johnson Memorial Cancer Center	142 Hazard Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Enfield, CT 06082-4520	Producer of 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

You produced hazardous drugs without providing adequate cleaning of work surfaces to prevent cross-contamination.

Specifically, poor cleaning practices were observed during the production of hazardous sterile drug products in the firm's ISO 5 Biological Safety Cabinet (BSC) located in the IOS 7 (b) (4) room.

1) On 09/21/2021, a Pharmacy Technician was observed producing Cisplatin Order # (b) (4), Pembrolizumab Order # (b) (4), and Etoposide Order # (b) (4) in the ISO 5 BSC. The technician failed to clean the internal (ISO 5 side) of the BSC view screen between producing the sterile drug products in the BSC.

2) On 09/22/2021, a Pharmacy Technician was observed cleaning the ISO 5 BSC and then producing Bortezomib Order # (b) (4) in the ISO 5 BSC.

- The technician failed to clean the internal (ISO 5 side) of the BSC view screen immediately prior to performing sterile production activities.
- The technician used a stainless steel "mop handle" with sterile wipes instead of the appropriate mop head to clean the interior of the ISO 5 BSC with (b) (4) and Sterile (b) (4). By using sterile wipes instead of the appropriate mop head, the technician was unable to reach and clean the entire interior surface of the BSC, including the (b) (4) bar and the corners by the top, back and sides of the interior of the BSC. The result was incomplete cleaning of the interior of the ISO 5 BSC immediately prior to performing sterile production activities.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jonathan G Matrisciano, Investigator	X Jonathan G Matrisciano Investigator Signed By: Jonathan G. Matrisciano -S Date Signed: 10-21-2021 12:29:26	10/21/2021

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- The technician was observed inserting an un-sanitized bottle of (b) (4) and an un-sanitized bottle of Sterile (b) (4) from the ISO 7 (b) (4) Room into the ISO 5 BSC to saturate sterile wipes used to clean the interior of the ISO 5 BSC immediately prior to performing sterile production activities.

OBSERVATION 2

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, on 09/22/2021, a Pharmacy Technician was observed cleaning the ISO 5 BSC and then producing Bortezomib Order # (b) (4) in the ISO 5 BSC. During the production of Bortezomib, the technician failed to clean the septum of each of the two vials of sterile drug product with Sterile (b) (4) immediately prior to performing sterile production activities.

OBSERVATION 3

You had inadequate HEPA filter coverage and airflow over the area to which sterile product was exposed.

Specifically, you conducted air pattern analyses (smoke studies) on 08/21/2020, 02/22/2021 and 08/19/2021 for the ISO 5 Biological Safety Cabinet (BSC) used to produce chemotherapeutic drug products and the ISO 5 Laminar Flow Hood (LFH) used to produce non-hazardous drug products. The smoke studies performed were deficient:

- The 08/2020 studies for the BSC and LFH, and the 08/2021 study for the LFH did not include the transfer of all starting components and materials into the ISO 5 classified areas.
- The 8/2020 studies for the BSC and LFH, the 02/2021 studies for the BSC and LFH, and the 08/2021 studies for the BSC and LFH failed to include all manipulations and transfers performed by the operator during production.
- In addition, the smokes studies performed in the BSC failed to simulate the most complex product produced, which was identified as Leucovorin.

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This is a repeat of Observation # 6 from the 2018 inspection.

OBSERVATION 4

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

Specifically, you use non-sterile disinfecting agent (b) (4) to disinfect the interior surfaces of your ISO 5 Biological Safety Cabinet (BSC) and the interior surfaces of your ISO 5 Laminar Flow Hood (LFH).

*DATES OF INSPECTION

9/20/2021(Mon), 9/21/2021(Tue), 9/22/2021(Wed), 9/23/2021(Thu), 9/27/2021(Mon), 9/28/2021(Tue), 9/29/2021(Wed), 9/30/2021(Thu), 10/06/2021(Wed), 10/21/2021(Thu)

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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."