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 Industry Information: www.fda.gov/oc/industry	07/16/2014 - 08/05/2014* FEI NUMBER 3010955218

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Stuart E. Rosenberg, President and CEO

FIRM NAME	STREET ADDRESS
Johnson Memorial Cancer Center	142 Hazard Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Enfield, CT 06082	Producer of 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 WE OBSERVED:

OBSERVATION 1

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

A. The facility is not designed to prevent the ingress of microbial contamination to classified areas. Specifically, we observed water stains marks in the plenum right on top of the Ante Room (ISO 7). The firm has not evaluated the potential impact in the air quality since plenum air penetrates the classified room through unsealed openings in the drop ceiling tiles. This room is used for gowning and component preparation operations prior to reconstitution of sterile products.

B. The (b) (4) HEPA filters located in the chemotherapeutic room, utilized in the preparation of sterile drug products, were observed to contain what appeared to be yellowish discoloration within the HEPA filters.

C. Differential pressure is not adequately balanced and controlled between clean rooms. Specifically:

   a. The firm did not institute appropriate corrective actions after the failure of the ante room air pressure to the mixing room on February 12, 2014 (Room Pressurization: Acceptance Criteria: Min 0.02"w.g. positive to Ante Room. Reported findings Mixing Room (IV Prep) is 0.01"w.g. positive to the Ante Room). The firm did not investigate the potential product impact of this event. The firm has not evaluated the potential for ingress of microbial contaminants to the controlled areas.

   Furthermore, the firm did not institute appropriate corrective actions after the failure

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of the ante room air pressure to the adjacent uncontrolled space on February 12, 2014 (Room Pressurization: Acceptance Criteria: [redacted (b) (4)]

b. There are no visible or audible alarms when differential pressure problems occur.

c. The firm has not performed air flow pattern studies in their ISO 5 hoods under dynamic conditions that are used for the reconstitution of drug products.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. The environmental monitoring and conditions of the aseptic core are deficient for the following reasons:

a. Personnel monitoring is limited to the assessment of the pharmacy technician's fingers and this sampling is done only on an [redacted (b) (4)] basis.

b. Environmental monitoring (e.g. viable and non-viable) of the ISO 5 laminar flow hood and [redacted (b) (4)] hood is not performed. Sterile drug products are aseptically manipulated in these hoods as part of daily operations. However, environmental monitoring for the inside of the ISO 5 hoods is not performed.

c. The infusion center recovered 55 environmental monitoring time points of mold, 1cfu and above, from classified ISO 7 areas (surfaces and air) during the reconstitution of sterile injectable drug products in 2013 and 2014. There is no documented evidence that suggests that a health hazard evaluation was initiated nor conducted in order to assess the potential quality impact of isolates present during the reconstitution of sterile drug products.

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OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A. The following was observed in the [redacted] (b) (4) (ISO 5) located in the chemotherapeutic room, utilized in the preparation of sterile drug production:

a. We observed what appeared to be various colors of dried material beneath the metal surfaces where the pharmacist reconstitutes sterile drug product, within the ISO 5 hood at approximately face-level to the operator.

b. We observed what appeared to be whitish, opaque structures upon the [redacted] (b) (4), below the HEPA filter, within the hood at approximately face-level to the operator.

c. Wood Ledge is located in both the mixing room and chemotherapeutic rooms (ISO 7 areas) as part of the window sill which is a porous material and creates a surface difficult to clean.

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

Specifically,

A. The sterile technique qualification (media fills) do not represent your routine operating conditions and does not evaluate worst-case activities that can provide a challenge to manual aseptic operations. For example: maximum number of personnel and their activities, and an evaluation of critical routine and non-routine interventions (e.g. the continuous entering and exiting of the ISO 5 hoods used in the manufacture of sterile drug products.)

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OBSERVATION 5

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

A. Gowning used to manufacture sterile drug products is inadequate in that the personnel gowns are not sterile

*** DATES OF INSPECTION:**
07/16/2014(Wed), 07/17/2014(Thu), 07/22/2014(Tue), 07/23/2014(Wed), 07/24/2014(Thu), 08/05/2014(Tue)

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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."