DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	6/21/2016-6/29/2016* FEI NUMBER 2570172

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jane Mericle , Chief Nurse Executive and Vice President Patient Care Operations

FIRM NAME	STREET ADDRESS
Alfred I. duPont Hospital for Children	1600 Rockland Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wilmington, DE 19803-3607	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 I OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

1. The ISO 8 Ante Room where technicians gown in preparation for aseptic processing is not sufficiently designed in that

    a. Personnel movement in the room allowed for Gowned Technicians to freely interact with un-gowned personnel prior to entering the Clean room.

    b. The room is equipped with porous, unsealed and non-cleanable ceiling tiles. Additionally, a door separating the Ante room from the ISO 7 Clean room is partially constructed of wood material not readily cleanable.

2. There is no evidence that smoke studies conducted (b) (4) are dynamic. There is no description of what conditions are created by the vendor at the time that would represent or mimic actual processing conditions. It was also reported that technicians are not present to conduct simulated processing at the time smoke studies are performed by the vendor.

OBSERVATION 2

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Thomas E Friel, Investigator 6/29/2016 X Thomas E Friel Thomas E Friel Investigator Signed by: Thomas E. Friel -S	6/29/2016

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Specifically,

1. Technicians were observed introducing non-sterile components into the ISO 5 Hood without disinfecting.

2. Technicians were observed frequently exiting the ISO 7 Clean room to the Ante room to obtain (b) (4) containing product staged for aseptic processing.
Additionally, technicians were observed using non-sterile lint free wipes as a barrier between the gloved hand and door handle to regain access to the ISO 7 Clean room to continue aseptic processing. Sterile gloves were not changed during the process.

OBSERVATION 3
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

1. No investigation was conducted into the 6 colony forming units (CFU) identified as part of the technician glove tip monitoring dated February 8, 2016. Additionally, it was reported that (b) (4) is sampled.

2. The frequency of environmental monitoring of surfaces for microbial contamination in the ISO 5 area is inadequate. Your firm has only performed sampling (b) (4) in 2016. There is no documentation that environmental monitoring of surfaces for microbial contamination was conducted in 2015.

3. Environmental monitoring for non-viable particulates and viable air counts is not performed during routine sterile operations. Such monitoring has only been documented for the most recent (b) (4) Additionally, there is no documentation that environmental monitoring for non-viable particulates and viable air counts was conducted in 2015.

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OBSERVATION 4

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

Specifically,

1. The firm does not use a sporicidal agent to disinfect the clean room including the ISO 5 area (b) (4) cleaning of the ISO 5 critical areas consists of Sterile (b) (4) [redacted].
2. The walls and ceiling of the clean room are not cleaned at a predefined frequency.
3. Non-sterile lint free wipes are used to clean the ISO 5 area.

OBSERVATION 5

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

Gowns/coveralls, facemasks and bouffant hair nets worn by operators working inside ISO 5 zones are not sterile. The technician's face and neck are not fully covered allowing exposed facial skin and hair. Technicians were observed leaning upper torso into ISO 5 critical zone while cleaning with (b) (4) sterile (b) (4)

*DATES OF INSPECTION

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6/21/2016(Tue),6/24/2016(Fri),6/29/2016(Wed)

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