

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Baltimore District Office 6000 Metro Drive, Suite 101 Baltimore, MD 21215 410-779-5455 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 7/31/2018, 8/1/2018, 8/2/2018, 8/3/2018, 8/6/2018
	FEI NUMBER 3011627411

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: James R. Schwamburger, Director, Pharmacy Operations

FIRM NAME Sentara Enterprises Inc., dba Sentara Home Infusion Pharmacy Services	STREET ADDRESS 535 Independence Parkway, Suite 300
CITY, STATE AND ZIP CODE Chesapeake, VA 23320	TYPE OF ESTABLISHMENT INSPECTED Producer of sterile drug products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Equipment used in the processing of drug products are not maintained in a clean and sanitary condition.

Specifically,

(A) Brownish stains were observed on the HEPA filter and/or the HEPA filter grills of the following ISO 5 hoods:


- ISO 5 (b) (4) laminar flow hood (b) (4)
- ISO 5 (b) (4) laminar flow hood (b) (4)
- ISO 5 (b) (4) laminar flow hood (b) (4)
- ISO 5 (b) (4) laminar flow hood (b) (4)

(B) Brownish stains were observed on the legs of the worktable of the ISO 5 (b) (4) laminar flow hood (b) (4)

OBSERVATION 2

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

Specifically, the (b) (4) used to transfer materials and components for sterile drug production into the ISO 7 cleanroom, originates in an unclassified room.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Mindy Chou, Investigator	DATE ISSUED 08/06/2018
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ORAPham1_Responses@fda.hhs.gov

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OBSERVATION 3

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

Specifically,

(A) The (b) (4) plates used in environmental monitoring of the aseptic processing areas and personnel gloved fingertip sampling were incubated at (b) (4) below the optimal temperature range conducive to multiplication of microorganisms.


(B) The media-filled samples from the media-fill testing performed in April, May, and June 2018 were stored at room temperature in an uncontrolled environment. The room temperature log shows the daily room temperatures were below (b) (4) for the entire month of April 2018 and only three days in May and June 2018 had a temperature within the required incubation temperature of (b) (4)

*** THIS IS A REPEAT OBSERVATION ***

OBSERVATION 4

Cleaning pads or wipes used in the ISO 5 aseptic processing areas are not sterile.

Specifically, the (b) (4) Wipes used in the cleaning and disinfection of the surfaces inside the ISO 5 laminar flow hoods and the biological safety cabinet are not sterile.

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OBSERVATION 5

Sporicidal agents were not used in your facility's ISO 5 classified aseptic processing area.

Specifically, sporicidal agents are not used to clean the ISO 5 laminar flow hoods and the biological safety cabinet. Additionally, expired (b) (4) Sterile, Sporicidal Disinfectant and Cleaner (Exp. 11/2017) is currently being used to clean the ISO 7 and ISO 8 areas.

*****THIS IS A REPEAT OBSERVATION*****

OBSERVATION 6


Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically, on 8/1/2018, I observed the pharmacy technician mopping the floor one minute after application of the (b) (4) Disinfectant. The manufacturer's direction of use for (b) (4) Disinfectant indicate that a (b) (4) contact time is required to achieve efficacy.

OBSERVATION 7

Personnel engaged in aseptic processing were observed with exposed face.

On 8/1/2018, I observed the pharmacy technician's face, head, and shoulder entered the plane of ISO 5 laminar flow hoods during cleaning. The face mask that the pharmacy technician wore did not fully cover the technician's face. The technician's face and forehead were exposed above the face mask in the ISO 5 area during cleaning.

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OBSERVATION 8

You produced beta-lactam drugs without providing adequate containment, segregation, and cleaning of work surfaces to prevent cross-contamination.

Specifically, beta-lactam drug products are produced in the same laminar flow hoods as other products separated only by a wipe down of hood surfaces with (b) (4). You do not have a specific process to deactivate and remove any beta-lactam product spillage that may occur within the laminar flow hoods or facility during handling, processing, or filling operations.

***DATES OF INSPECTION**

7/31/2018 (Tue), 8/1/2018 (Wed), 8/2/2018 (Thu), 8/3/2018 (Fri), 8/6/2018 (Mon)

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