DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707 ORAPHARM1_RESPONSES@fda.hhs.gov	7/6/2023-7/14/2023*
	FEI NUMBER 3025984445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jamin C. Engel, Regional Director of Pharmacy

FIRM NAME	STREET ADDRESS
Sentara Enterprises dba Sentara Infusion Services (Blue Ridge)	920 E High St
CITY, STATE, ZIP CODE, COUNTRY Charlottesville, VA 22902-4850	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted.

Specifically, on July 11, 2023, while Technician (b) (6), (b) (7)(C) was working in ISO 5 classified (b) (4) laminar airflow hood (equipment ID (b) (4)), producing MYCAMINE 100MG IN 100ML HOMEPUMP Rx #(b) (6), (b) (7)(C) (b) (6), (b) (7)(C) was observed blocking first pass air with left hand (holding small vial) while making aseptic connections.

OBSERVATION 2

Personnel performed aseptic manipulations with exposed hair or skin.

Specifically, on July 11, 2023, while Technician (b) (6), (b) (7)(C) was working in ISO 5 classified (b) (4) laminar airflow hood (equipment ID (b) (4) , producing SOLUMEDROL 1GM IN NS 100ML Rx #(b) (6), (b) (7)(C) HOMEPUMP (b) (6), (b) (7)(C) was observed leaning into ISO 5 classified (b) (4) laminar airflow hood with exposed skin (around eyes and forehead) while making aseptic connections.

OBSERVATION 3

Lack of disinfection of supplies at each transition from areas of lower quality air to areas of higher quality air.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Tekalign Wondimu, Investigator Sena G Dissmeyer, Compliance Officer	X Tekalign Wondimu Investigator Signed By: Tekalign Wondimu -S Date Signed: 07-14-2023 10:36:53	7/14/2023

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Specifically, on July 11, 2023, while Technician (b) (6), (b) (7)(C) was observed working in ISO 5 classified (b) (4) laminar airflow hood (equipment ID (b) (4), producing SODIUM CHLORIDE 0.9% 2000ML Rx #(b) (6), (b) (7)(C) (b) (6), (b) (7)(C) was observed introducing sterile IPA bottle into ISO 5 classified (b) (4) laminar airflow hood without sanitizing the outer surface.

OBSERVATION 4

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically, your media fills do not include representative container-closure types (elastomeric pumps and large IV bags), equipment (b) (4) automated compounding device) and the quantity and volume of finished drug products per order.

OBSERVATION 5

Smoke studies were inadequately performed under dynamic conditions.

Specifically, unidirectional airflow was not verified under dynamic conditions representative of your typical production process. Smoke studies conducted in May 2023 in your ISO 5 laminar air flow hoods (equipment ID #(b) (4)) did not show manipulations or conditions performed ((b) (4) automated compounding device or repeater pump in use) that would be representative of the dynamic process used in actual production processes.

*DATES OF INSPECTION

7/06/2023(Thu), 7/07/2023(Fri), 7/10/2023(Mon), 7/11/2023(Tue), 7/12/2023(Wed), 7/14/2023(Fri)

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Tekalign Wondimu, Investigator
Sena G Dissmeyer, Compliance Officer

X Tekalign Wondimu
Investigator
Signed By: Tekalign Wondimu -S
Date Signed: 07-14-2023
10:36:53

DATE ISSUED
7/14/2023

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."