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	5/5/2026-5/12/2026* FEI NUMBER 1174302

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. James Ronald Johnson Jr. , Executive Director

FIRM NAME	STREET ADDRESS
Richmond VA Medical Center	1201 Broad Rock Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Richmond, VA 23249-0001	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 05/05/2026, a compounding technician was observed preparing the following prescription in Buffer Room 1H-110A:

☐ RX# (b) (6), (b) (7)(C) – TPN, 2000 mL IV Bag

During the preparation of RX# (b) (6), (b) (7)(C) the following deficiency was observed:

While injecting components into the 2000mL IV bag, the technician's hand placement was observed blocking the bag port and needle. The technician's hands were positioned in a manner that obstructed the unidirectional first air between the HEPA filter face and the critical work surface, thereby compromising the sterility assurance of the critical area.

OBSERVATION 2

Personnel performed aseptic manipulations with exposed hair or skin.

Specifically,

a. The compounding technician was observed leaning into the ISO 5 Laminar Airflow Workbench

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	Tekalign Wondimu, Investigator Michael O Idowu, Investigator X Michael O Idowu Investigator Signed By: Michael O. Idowu -S Date Signed: 05-12-2026 13:07:04	5/12/2026

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(LAFW) with exposed skin around the eyes and forehead while performing aseptic manipulations of RX# (b) (6), (b) (7)(C) – TPN, 2000 mL IV Bag, increasing the risk of contamination to the critical work surface.

b. The compounding technician's upper torso was observed physically introduced into the ISO 5 LAFW environment during aseptic manipulations. As gowns are not sterile, the introduction of the technician's torso into the ISO 5 environment represents an independent contamination risk, regardless of the gown's condition. This action resulted in the technician's body blocking and disrupting the unidirectional HEPA-filtered airflow (first air) over the critical work surface, compromising the sterility assurance of the critical area.

OBSERVATION 3

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

Specifically,

On 05/05/2026, compounding technician was observed preparing the following prescription in Sterile Buffer Room 1H-110A:

- RX# (b) (6), (b) (7)(C) – TPN, 2000mL IV bag

During TPN compounding, the technician was observed operating a (b) (4) scanner connected to the (b) (4) TPN Compounder Computer while entering multiple times into and out of the ISO 5 LAFW without disinfecting the scanner or gloves each time. Additionally, the technician was observed touching the TPN formulation via the (b) (4) Control Panel (Version(b) (4)) touchscreen on the (b) (4) TPN Compounder Computer touchscreen, which is located outside of the ISO 5 LAFW, then going back into the ISO 5 hood to perform aseptic manipulations without disinfecting their gloves.

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OBSERVATION 4

Personnel were observed moving quickly in a critical area or in an area immediately adjacent to a critical area likely causing disruption of unidirectional airflow.

Specifically,

On 05/05/2026, compounding technician was observed preparing the following prescriptions in Buffer Room 1H-110A:

- RX#(b) (6), (b) (7)(C) – Remicade (Infliximab) 500mg/0.9%NS, 250mL IV bag

The compounding technician was observed moving quickly within the ISO 5 LAFW workspace during aseptic manipulations, disrupting unidirectional airflow and increasing the risk of introducing lesser-quality air into the ISO 5 critical area.

OBSERVATION 5

Use of a disinfectant in a manner insufficient to achieve adequate levels of disinfection.

Specifically,

On 5/6/2026 during (b)(4) cleaning operations, cleaning performed within the ISO 5 classified laminar airflow hood (LAFH), cleaning procedures were found to be inadequate in the following respects:

a. A compounding technician was observed wiping the interior surfaces of the ISO 5 LAFH without using overlapping wipe passes during the cleaning procedure. The absence of overlapping strokes resulted in visible gaps in surface contact, with some interior surface areas visibly not contacted or wetted by the disinfectant wipe.

b. The compounding technician was observed using a back-and-forth scrubbing motion while wiping the interior surfaces of the ISO 5 classified LAFH, rather than the required unidirectional wiping

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technique potentially spreading contaminants to previously cleaned areas and negating the effectiveness of the disinfection process.

OBSERVATION 6

Use of a sporicidal agent in the facility's ISO 5 areas was improper.

Specifically,

The compounding technician was observed performing the (b)(4) cleaning of the ISO 5 classified laminar airflow hoods and ISO 7 classified buffer room. The technician applied wetted sterile wipes treated with sterile (b) (4) (manufactured by (b) (4)) to the (b)(4) workbench and the (b)(4) and (b)(4) interior surfaces of the laminar airflow hoods. Following application, all treated surfaces were observed to air-dry within a couple of seconds. This is inconsistent with the sterile (b) (4) manufacturer's ((b) (4)) specified dwell time of (b)(4) for sporicidal effect.

OBSERVATION 7

Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO 5 area.

Specifically,

A (b)(4) light fixture housing in the ISO 5 laminar flow hood (LFH) is not properly seated, creating a gap between the housing and the surrounding surface. This gap constitutes a hard-to-clean area that may harbor particulate matter and microbial contamination, posing a risk to product quality.

OBSERVATION 8

Smoke studies were not performed under dynamic conditions.

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The smoke study videos for the pharmacy's (b)(4) laminar airflow workbenches (LAFWs) and (b)(4) biological safety cabinets (BSCs) did not demonstrate manipulations or conditions representative of the dynamic processes used in the compounding of sterile preparations; therefore, the studies were not conducted in a manner that adequately replicates the range, complexity, or pace of actual compounding operations performed at these workstations. As a result, the studies failed to verify unidirectional airflow within the ISO 5 classified area is sufficient to protect critical sites during representative aseptic manipulations. Additionally, the volume and/or density of smoke used during these studies was inadequate to sufficiently visualize airflow patterns and identify potential turbulence or contamination risks within the ISO 5 area.

***DATES OF INSPECTION**

5/05/2026(Tue), 5/06/2026(Wed), 5/07/2026(Thu), 5/08/2026(Fri), 5/12/2026(Tue)

X Tekalign Wondimu
Investigator
Signed By: TEKALIGN WONDIMU -S
Date Signed: 05-12-2026 13:07:59

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	Tekalign Wondimu, Investigator Michael O Idowu, Investigator	X Michael O Idowu Investigator Signed By: Michael O. Idowu -S Date Signed: 05-12-2026 13:07:04	5/12/2026

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."