U.S. FOOD & DRUG ADMINISTRATION

January 26, 2024

VIA ELECTRONIC MAIL
Caroline Juran, Executive Director
Virginia Board of Pharmacy
Perimeter Center, 9960 Maryland Drive, Suite 300
Henrico, VA 23233-1463
Email: pharmbd@dhp.virginia.gov
Caroline.Juran@DHP.Virginia.gov

Ref: CMS Case # 522093, FEI # 3025984445

State Referral Letter

Dear Ms. Caroline Juran:

The purpose of this letter is to refer to you, the Virginia State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile pratices observed during an FDA inspection at a pharmacy you licensed, Sentara Enterprises dba Sentara Infusion Services (Blue Ridge), located at 920 East High Street, Charlottesville, Virginia 22902-4850.

FDA inspected the firm from July 6, 2023, to July 14, 2023. FDA investigators were accompanied by your state investigator for part of the inspection.

A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at: https://www.fda.gov/media/175345/download, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 and/or the EIR that includes certain nonpublic information. You may also choose to request such documentation directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for drug products compounded by Sentara Infusion Services (Blue Ridge) and FDA does not intend to take further actions at this time related to conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Additionally, the FDA investigators observed deviations from appropriate practice

U.S. Food & Drug Administration
Office of Regulatory Affairs
Office of Pharmaceutical Quality Operations, Division I
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
Telephone (973) 331-4900
www.fda.gov

standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. Personnel placed components within the ISO 5 work area that had the potential to block the movement of first air to critical in-process operations. A technician was observed blocking first air with their left hand while making aseptic connections.

2. Personnel engaged in aseptic processing while exposing skin within the ISO 5 aseptic processing area. A technician was observed leaning into the ISO 5 hood with exposed skin around eyes and forehead while producing drug products intended to be sterile.

3. The firm did not disinfect materials during transfer from the ISO 7 cleanroom into the ISO 5 hood. A technician was observed introducing a sterile IPA bottle into the ISO 5 hood without first sanitizing the outer surface.

4. Media fills were not performed under the most challenging or stressful conditions. Therefore, there is a lack of assurance that the firm can aseptically produce drug products within their facility. In addition, media fills were not representative of container-closer types, equipment, and the quantity and volume of finished drug products per batch.

5. The firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area. Therefore, products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination. In addition, smoke studies were not representative of typical aseptic processing practices and did not demonstrate manipulations of the automated compounding device and repeater pump used in actual production processes.

Sentara Infusion Services (Blue Ridge) committed to FDA in its response to the Form FDA 483 received on August 4, 2023, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the records, FDA does not intend to take further action at this time with regard to the findings of this inspection. FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to you for follow up to ensure appropriate corrective action has been taken. We believe you, the State, are in the best position to conduct follow-up and routine regulatory activities at this firm to ensure the ongoing quality of drug products they produce. Please notify us if you become aware of any adverse events or product quality concerns associated with drug products made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Sena Dissmeyer, Compliance Officer, by email at sena.dissmeyer@fda.hhs.gov. Please use the reference numbers CMS Case # 522093 and FEI # 3025984445 cited in the heading of the document.

Sincerely,

Lisa M. Harlan -S

Digitally signed by Lisa M. Harlan -S
Date: 2024.01.26 08:18:12 -05'00'

Lisa Harlan
Program Division Director
Office of Pharmaceutical Quality Operations
Division I

Cc: Via Electronic Mail
Dr. Jamin Engel, Regional Director Pharmacy Operations
Sentara Enterprises dba Sentara Infusion Services (Blue Ridge)
920 E High Street
Charlottesville, VA 22902-4850
Email: jcengel@sentara.com