Option Care Enterprises, Inc. 9/7/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Seattle District
Pacific Region
22215 26th Ave SE, Suite 210
Bothell, WA 98021

Telephone: 425-302-0340
FAX: 425-302-0402

September 7, 2016

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

In reply, refer to Warning Letter SEA 16-17

Maritza D. DeGagne, RPh
Area Vice President, NW
Option Care Enterprises, Inc.
728 134th Street SW, Suite 128
Everett, Washington 98204

WARNING LETTER

Dear Ms. DeGagne:

From February 9, 2016, to February 25, 2016, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, Option Care Enterprises, Inc. (formerly Walgreens Infusion Services), located at 8120 Evergreen Way, Everett, Washington 98203-6419.

During the inspection, the investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, our investigators noted that your firm uses non-sterile **(b)(4)** to clean the ISO 5 area. Furthermore, a technician was observed touching the inner liner of a waste receptacle and a metal cart and then performing aseptic operations in the ISO 5 hood without first disinfecting her gloves. Moreover, the door separating the ISO 7 area from the ISO 8 anteroom is made of wooden materials. Wooden material is difficult to clean and may harbor microbial contamination. Our investigators also observed staining on the metal grates covering the HEPA filter of the ISO 5 hood. Additionally, our investigators found that your firm failed to demonstrate through appropriate studies that your hoods are able to provide adequate protection of the ISO 5 areas in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk.

A Form FDA 483 was issued to your firm on February 25, 2016. FDA acknowledges receipt of your March 17, 2016, response to the Form FDA 483. Based on this inspection, it appears that you are producing drugs that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

FDA investigators observed that drug products that are intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA [21 U.S.C. §351(a)(2)(A)]. For example, our investigators noted that your firm uses non-sterile **(b)(4)** to clean the ISO 5 area. Furthermore, a technician was observed touching the inner liner of a waste receptacle and a metal cart and then performing aseptic operations in the ISO5 hood without first disinfecting her gloves. Moreover, the door separating the ISO 7 area from the ISO 8 anteroom is made of wooden materials. Wooden material is difficult to clean and may harbor microbial contamination. Our investigators also observed staining on the metal grates covering the HEPA filter of the ISO 5 hood. Additionally, our investigators found that your firm failed to demonstrate through appropriate studies that your hoods are able to provide adequate protection of the ISO 5 areas in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk.

It is a prohibited act under section 301(k) of the FDCA to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce of the components used to make the drug and results in the drug being adulterated.

B. Corrective Actions

We acknowledge your response to the Form FDA 483, dated March 17, 2016, which indicates that you will be relocating into a new facility on May 2016. Although several of your proposed corrective actions appear adequate, others are inadequate. For example, your response indicated that neither state regulations nor USP <797> requires the use of sterile **(b)(4)**. The use of non-sterile **(b)(4)** to disinfect the aseptic processing area may introduce microbial contamination. With regards to the staining on the metal grates covering the HEPA filter, your response indicated that the staining is not staining, but rather, discoloration caused by your cleaning agents, and as such, no corrective action is necessary. We remain concerned that your firm has not mitigated the risk associated with using such metal grates. In addition, some of your responses cannot be fully evaluated by FDA because of insufficient supporting documentation. For example, your firm committed to perform smoke studies under dynamic conditions; however, you have not provided documentation for our review.

FDA strongly recommends that your management immediately undertake a comprehensive assessment of your operations, including facility design, procedures, personnel, processes, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug manufacturing expertise could be useful in conducting this comprehensive evaluation.

C. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the

violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure, and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. Your written notification should be addressed to:

Maria Kelly-Doggett, Compliance Officer
FDA Seattle District Office
U.S. Food and Drug Administration
22215 26th Ave SE, Suite 210
Bothell, Washington 98021

If you have questions regarding any issues in this letter, please contact Ms. Kelly-Doggett via email at maria.kelly-doggett@fda.hhs.gov or by phone at (425) 302-0427.

Sincerely,
/S/
Miriam Burbach
District Director
Seattle District