Option Care 7/20/17

Office of Regulatory Affairs
Division of Pharmaceutical Quality
Operations 1
New Jersey District Office
10 Waterview Blvd.; 3rd Floor
Parsippany, NJ 07054
Telephone: (973) 331-4900
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
WL # 523000
July 20, 2017

Douglas L. Dumler, General Manager
Option Care Enterprises, Inc. dba Option Care
9140 Guilford Road, Suite K
Columbia, MD 21046-1811

Dear Mr. Dumler:

From June 20, 2016, to June 28, 2016, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Option Care Enterprises, Inc., dba Option Care, located at 9140 Guilford Road, Suite K, Columbia, MD 21046-1811. During the inspection, the investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA-483 to your firm on June 28, 2016. FDA acknowledges receipt of your facility's response on July 20, 2016. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products 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. For example, the investigator observed that your firm uses non-sterile wipes and used a non-sterile disinfectant as part of your disinfection program for the aseptic processing areas. The investigator also observed what appeared to be rust and white residue on the **(b)(4)** back grill of your ISO 5 hood. A technician was observed using her gloved hand and gowned arm to push trash into a trash container, with her hand and arm inside the trash container at least up to her elbow; the technician continued to work without sanitizing or changing the gloves or gown. In addition, a technician was observed bringing materials and components from the ISO 8 area and placing them inside the

ISO 5 hood without first disinfecting. Finally, the investigator observed that your media fills do not closely simulate aseptic production operations, including worst-case activities. Therefore, your products may be produced in an environment that poses a significant contamination risk.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act.

B. Corrective Actions

We have reviewed your firm's response to the Form FDA-483.

Regarding the insanitary condition observations in the Form FDA-483, several of your proposed corrective actions appear adequate; however, others are inadequate. For example, your response indicated that neither state regulations nor USP <797> requires the use of sterile wipes. In addition, your response indicates that USP <797> does not require disinfectants to be sterile. The use of non-sterile wipes and the use of non-sterile disinfectants increase the potential for contamination to be introduced into the aseptic processing area and are insanitary conditions.

In addition, some of your responses cannot be fully evaluated due to a lack of adequate supporting documentation. For example, you stated that the areas of the ISO 5 hood were cleaned, oxidation was removed, and a replacement for the current grill was ordered, but you did not provide adequate documentation demonstrating that these corrective actions were implemented. In your response to our observation regarding your media fill simulations, you stated that the aseptic validation kit was changed from the **(b)(4)** to **(b)(4)**. However, you did not provide documentation for our review.

For more information on compounding, please see FDA's website, at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A [21 U.S.C. §353a].

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance materials, and systems. In particular, this review should assess your aseptic processing operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you 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, including 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 (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the violations. Please include an explanation of each step being taken to prevent the recurrence of the 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. If you cannot complete corrective action within fifteen (15) working days, state the reason for the delay and the time within which you will complete the correction.
Your written notification should refer to the Warning Letter Number above (523000).
Please address your reply to:

Ernest F. Bizjak
Compliance Officer, OPQ Div. 1
FDA
11919 Rockville Pike
Rockville, MD 20852

If you have questions regarding the contents of this letter, please contact Ernest Bizjak by phone at (301) 796-4081 or by email at Ernest.Bizjak@fda.hhs.gov.

Sincerely,
/S/
Diana Amador-Toro,
Division Director/OPQ Division 1
New Jersey District Office

cc:
Option Care Enterprises, Inc.
3000 Lakeside Drive, Suite 300N
Bannockburn, IL 60015-5405