Option Care 9/28/17

U.S. FOOD & DRUG ADMINISTRATION

Division of Pharmaceutical
Quality Operations III
300 River Place, Suite 5900
Detroit, Ml 48207
Telephone: (313) 393-8100
Fax: (313) 393-6139

September 28, 2017

WARNING LETTER

Case# 538040

UPS NEXT DAY
SIGNATURE REQUIRED

Paul F. Mastrapa, CEO
Option Care Enterprises, Inc.
3000 Lakeside Drive, Suite 300N
Bannockburn, IL 60015-5405

Dear Mr. Mastrapa:

From September 1, 2016, to September 21, 2016, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Option Care Enterprises, Inc., dba Option Care, located at 1226 N Michael Drive, Suite A, Wood Dale, IL 60191-1056. 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 September 21, 2016. FDA acknowledges receipt of your facility's response, dated October 12, 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 investigators 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, investigators observed that operators demonstrated poor aseptic practices, such as moving rapidly within the ISO 5 area; quick movement of personnel disrupts the airflow and increases the risk of bringing lesser quality air into the ISO 5 area. In addition, your firm did not completely disinfect components and materials at each transition from areas of lower quality air to areas of higher quality (e.g., ISO 7 cleanroom to ISO 5 hood). Furthermore, **(b)(4)** wipes, for use in the ISO 5 hood, are removed from the original packaging and stored in a manner which increases the potential for contamination to be introduced onto the wipes.

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. Further, it is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] 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 and results in the drug being adulterated.

B. Corrective Actions

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

Regarding the insanitary conditions observed during the inspection, we are unable to fully evaluate the following corrective action due to a lack of adequate supporting documentation:

In your response to our observation of inadequate disinfection of components and materials at each transition from areas of lower quality air to areas of higher quality, you stated that all appropriate staff had been retrained on SOP P-132, Aseptic Technique Procedures. However, you have not provided supporting documentation such as training logs to fully evaluate your corrective actions.

Moreover, the following corrective actions appear inadequate to address the insanitary conditions noted:

1. In response to our observation regarding employees **(b)(4)** products within the ISO 5 hood, you indicated that your firm would perform smoke studies which simulate this practice to demonstrate that it does not introduce lesser quality air into the ISO 5 hood. However, we remain concerned about this poor aseptic practice, because quick movement of personnel disrupts the airflow and increases the risk of bringing lesser quality air into the ISO 5 area.

2. Regarding our observation about the storage of your wipes used in the aseptic processing area, your response stated that storing wipes within an open-top plastic bin in the ISO 7 clean room area is consistent with both USP General Chapter <797> and best pharmacy practice. However, this practice increases the potential for contamination to be introduced onto the wipes.

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].

Should you compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations.

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.

Please address your reply to:

Russell Riley, Compliance Officer
U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
Chicago Office
550 W. Jackson Blvd., Suite 1500
Chicago, IL 60661

Refer to the Unique Identification Number (Case# 538040) when replying. If you have questions regarding the contents of this letter, please contact Russell Riley by phone at (312) 596-4219 or by email at Russell.Riley@fda.hhs.gov.

Sincerely,
/S/

Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations III

cc:
Cynthia S. Kunzendorf, General Manager
Option Care Enterprises, Inc.
1226 N Michael Drive, Suite A
Wood Dale, IL 60191-1056