U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OPQO DIVISION OF PHARMACEUTICAL QUALITY OPS 3

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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July 1, 2020

UPS NEXT DAY
SIGNATURE REQUIRED

Dr. Yashwant Amin
Director of Drug Compliance
Division of Professional Regulation
100 W Randolph St
Suite 9-300
Chicago, IL 60601

Dear Dr. Amin:

The purpose of this letter is to refer to the Illinois State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Illinois BOP, Option Care Enterprises, Inc., located at 1226 N Michael Drive Suite A, Wood Dale, Illinois 60191-1056 (License Number 054014573).

FDA inspected the firm from January 17, 2018, to February 8, 2018. Illinois BOP did not accompany the FDA investigator during the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at [https://www.fda.gov/media/111380/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 you are a Commissioned Official or 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 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Option Care Enterprises, Inc. and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

Additionally, during the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

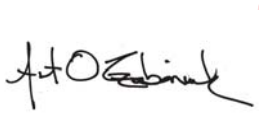
1. Observation of poor aseptic practices during sterile drug production.
2. Use of non-sterile disinfectant wipes to disinfect areas used for sterile drug production.
3. Allowance of the influx of poor quality air into a higher classified area.
4. Performance of media fills not under the most challenging or stressful conditions.

On September 17, 2018, Option Care Enterprises attended a regulatory meeting with the FDA's Office of Compliance at FDA Headquarters, located at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. The purpose of the meeting was to discuss the compliance status of Option Care Enterprises, Inc. (Option Care), including the firm' efforts to bring Option Care's operations, facilities, and procedures into compliance with requirements of the Federal Food, Drug, and Cosmetic Act. The firm's response to the meeting included the submission of revised smoke studies and revised procedures for disinfectant wipes, which appeared to be acceptable upon review.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Illinois BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs 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 Russell Riley, Compliance Officer, at 630-323-2763 x. 101, or by email at ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,



Digitally signed by Art O. Czabaniuk -S
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Date: 2020.07.01 13:03:54 -04'00'

Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations III
Office of Regulatory Affairs
U.S. Food and Drug Administration

CC: John C. Rademacher, President and CEO
Option Care Enterprises, Inc.
3000 Lakeside Drive, Suite 300N
Bannockburn, IL 60015-5405