U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
Telephone: (973) 331-4900
Fax: (973) 331-4969
www.fda.gov

April 23, 2020

VIA ELECTRONIC MAIL
Deena Speights-Napata
Executive Director
Maryland State Board of Pharmacy
P.O. Box 1991
Baltimore, MD 21203

Dear Ms. Speights-Napata:

The purpose of this letter is to refer to the Maryland 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 Maryland BOP, Option Care Enterprises, Inc., dba Option Care, located at 9140 Guilford Road, Suite K, Columbia, MD 21046-1811 (Pharmacy License Type: Pharmacy Waiver #PW0345).

FDA inspected the firm from June 20, 2016, to June 28, 2016. The Maryland BOP was informed of the inspection but 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/99306/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., dba Option Care 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. In the response to the Form FDA 483, received on July 20, 2016, the firm advised FDA that "Option Care is a Maryland State-licensed pharmacy that compounds and dispenses human medications that comply with Section 503A of the Federal Food, Drug, and Cosmetic Act ('*Section 503A*')."

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. Deficiencies regarding the cleaning and disinfection of the room and equipment used to

produce aseptic conditions.

2. Infrequent monitoring of differential pressure.
3. Clothing of personnel engaged in drug processing was not appropriate for the duties performed.
4. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.
5. Deficiencies regarding the flow of air in the clean rooms.

Option Care Enterprises, Inc., dba Option Care committed to FDA in its response to the Form FDA 483 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 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 Maryland State 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 send your electronic inquiries to orapharm1_responses@fda.hhs.gov and use reference FEI# 3012335395.

You may also contact Compliance Officer Juan Jimenez at juan.jimenez@fda.hhs.gov or call 1-518-453-2314 X-1014.

Diana Amador-toro -S

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Diana Amador-Toro
Program Division Director/District Director
U.S. Food and Drug Administration
OPQO Division I / New Jersey District