U.S. Food and Drug Administration
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FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

May 29, 2020

VIA ELECTRONIC MAIL

Deena Speights-Napata
Executive Director
Maryland State Board of Pharmacy
PO 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 practices observed during an FDA inspection at a pharmacy licensed by the Maryland BOP, Professional Arts Pharmacy, located at 2015 Lord Baltimore Dr., Baltimore, MD 21244. (Pharmacy License #P01022). This firm has since changed ownership and is now known as Maryland Specialty and Compounding Pharmacy, LLC.

FDA inspected the firm from December 7, 2017, to December 12, 2017. FDA investigators were accompanied by a Maryland state investigator for the entire inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM597717.pdf, 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 investigators reviewed a small sample of records for products compounded by Professional Arts Pharmacy 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.

During the inspection, the FDA investigators observed deviations from appropriate 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. Production of hazardous drug products without providing adequate containment, segregation, and cleaning or work surfaces and utensils to prevent cross contamination.

2. Non-pharmaceutical grade components were used in the formulation of non-sterile drug products.

Professional Arts Pharmacy committed to FDA in its written responses dated January 3, 2018, February 20, 2018, and June 11, 2018, 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. FDA acknowledges that the previous owner also ceased sterile production.

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 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. In addition, the firm is under new ownership and may resume sterile production. Please notify FDA if you become aware that this firm is resuming production of sterile drug products.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have questions regarding the contents of this letter, please contact Juan Jiménez, Compliance Officer, by telephone at 518-453-2314 X-1014, or by email Juan.Jimenez@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000 11579, cn=Diana Amador-toro -S
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Diana Amador-Toro
Program Division Director
U.S. Food and Drug Administration
OPQO - Division I