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

September 16, 2019

VIA PARCEL CARRIER

Paul W. Thompson
Interim Executive Director
New York State Board of Pharmacy
89 Washington Avenue, 2nd Floor
Albany, New York 12234-1000

FEI: 3010987875

Dear Mr. Thompson:

The purpose of this letter is to refer to the New York 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 New York State BOP, Buffalo Pharmacies, Inc., located at 6035 Transit Road, East Amherst, New York 14051 (license # 021602).

FDA inspected the firm from July 23, 2018, to July 26, 2018. New York State BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. A copy of the Form FDA 483 that documents our investigator's observation from the inspection can be found at [https://www.fda.gov/media/129953/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 Buffalo Pharmacies, 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 a deviation from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. The deviation observed during our inspection involved the use of a non-pharmaceutical grade component in the formulation of a drug product.

Buffalo Pharmacies, Inc. committed to FDA in its written responses dated July 31, 2018, and May 10, 2019, to correct the deviation and provided documentation in support of its corrective actions. In addition, the deviation identified appears 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 New York 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 human or animal 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 any questions, please reach out to Compliance Officer, Juan Jimenez, at email: Juan.Jimenez@fda.hhs.gov or phone: 518-453-2314 ex.1014.

Please send additional electronic correspondence to orapharm1_responses@fda.hhs.gov.

Diana Amador-toro -S

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Diana Amador-Toro
Program Division Director/District Director
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