U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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March 25, 2020

Pennsylvania State Board of Pharmacy
Melanie Zimmerman
Executive Secretary
PO Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Zimmerman:

The purpose of this letter is to refer to the Pennsylvania State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about practices observed during an FDA inspection at a pharmacy licensed by the Pennsylvania BOP, Keystone Rx LLC, located at 3070 Bristol Pike, Building 2, Suite 216-B, Bensalem, PA 19020-5364 (State of Pennsylvania Pharmacy License # PP482493, Exp. August 31, 2021).

FDA inspected the firm from July 8, 2019, to July 12, 2019. FDA investigators were accompanied by the Pennsylvania BOP state investigators on July 8, 2019. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/135894/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 investigators reviewed a small sample of records for products compounded by Keystone Rx LLC, 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 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. **Non-microbial contamination was observed in the production area**.

   Specifically, after producing 5% Flurbiprofen/ 2% Cyclobenzaprine/ 5% Lidocaine cream, and subsequent cleaning, a dried powder residue was observed in the front grate of the biological safety cabinet (BSC). There were approximately six grate holes observed with yellow residue near the

scale inside the hood, approximately three grate holes observed with white residue, and approximately another four grate holes observed with yellow residue.

Keystone Rx LLC committed to FDA in its response to the Form FDA 483 received on July 22, 2019 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 Pennsylvania 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 contact CDR James Mason, via email at james.mason@fda.hhs.gov or by phone at (570) 262-0519.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
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Date: 2020.03.25 11:27:42 -04'00'

Diana Amador-Toro
Program Division Director/District Director
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