



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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VIA UNITED PARCEL SERVICE

August 16, 2018

Melanie Zimmerman
Executive Secretary
Pennsylvania State Board of Pharmacy
P.O. Box 2649
Harrisburg, PA 17105

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 poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Pennsylvania BOP, Jeffreys Drug Store, located at 1 N. Central Ave., Canonsburg, PA 15371 (Pharmacy license numbers # PP411156L and # PP481350).

FDA inspected the firm from July 25, 2017, to August 4, 2017. The FDA investigator was accompanied by an inspector from the Pennsylvania State Bureau of Enforcement and Investigations on the first day of the 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/ORAElectronicReadingRoom/UCM573174.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 investigator reviewed a small sample of records for products compounded by Jeffreys Drug Store 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.

Office of Pharmaceutical Quality Operations, Division of Pharmaceutical Quality Operations I

New England District Office: One Montvale Avenue, 4th Floor Stoneham, MA 02180-3500 T- (781) 587-7500 F- (781) 587-7556

New York District Office: 158-15 Liberty Ave Jamaica, NY 11433 T-(718) 340-7000 F-(718) 662-5661

Philadelphia District Office: US Customs House Room 900, 200 Chestnut St. Philadelphia, PA 19106 T- (215) 597-4390 F-(215) 597-4660

Baltimore District Office: 6000 Metro Drive, Suite 101 Baltimore, MD 21215 T-410-779-5455 F- 410-779-5407

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. The firm used non-sterile disinfectants in the cleaning of the ISO 5 hood.
2. The firm used non-sterile cleaning wipes within the ISO 5 hood.
3. The firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area.

Jeffreys Drug Store committed to FDA in its written responses dated August 24, 2017 and March 8, 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.

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 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 Yvette Johnson, Compliance Officer at (215) 717-3077, or by email at Yvette.Johnson@fda.hhs.gov.

Sincerely,

Diana
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Digitally signed by Diana Amador-
toro -S
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ou=HHS, ou=FDA, ou=People,
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Date: 2018.08.15 17:36:51 -04'00'

Diana Amador-Toro
OPQO Program Division I Director

Cc: Jeffreys Drug Store
1 N. Central Avenue
Canonsburg, PA 15317