Via UPS

March 12, 2019

Allison Vordenbaumen Benz, Executive Director
Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-500
333 Guadalupe Street
Austin, Texas 78701

Dear Ms. Benz:

The purpose of this letter is to refer to the Texas 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 Texas State BOP, Peoples Pharmacy, Inc. (#2), located at 3801-B S. Lamar Blvd., Austin, TX 78704 (Community Pharmacy, # 5333).

FDA inspected the firm from November 28, 2017, to December 7, 2017. An FDA investigator was accompanied by a Texas State Board of Pharmacy investigator for one day. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm589302.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 Peoples Pharmacy, Inc. (#2) 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 investigator observed deviations from appropriate non-sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, non-pharmaceutical grade components were used in the formulation of non-sterile drug products. In addition, the investigator observed that equipment and utensils used in the production of non-sterile drug products were not clean and properly maintained.

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
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Peoples Pharmacy, Inc. (#2) committed to FDA in its response to the Form FDA 483, dated December 22, 2017, to correct the deviations 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 Texas 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 there is any question, please contact Shawn Larson - Compliance Officer, at (214) 253-5216, or by email at Shawn.Larson@fda.hhs.gov.

Sincerely,

Rebecca A. Asente -S

Digitally signed by Rebecca A. Asente -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300062562, cn=Rebecca A. Asente -S
Date: 2019.03.12 13:23:45 -05'00'

Rebecca Asente, M.S., R.D.
Acting Director, Compliance Branch
Office of Pharmaceutical Quality Operations Division II

Cc: William L. Swail, RPh, President/Owner
Peoples Pharmacy, Inc. (#2)
3801-B S. Lamar Blvd.
Austin, TX 78704