DATE:11/30/2022

Case #: 639201

State Referral Letter

VIA ELECTRONIC MAIL

Timothy Tucker, Executive Director
Texas State Board of Pharmacy
George H. W. Bush State Office Building
1801 Congress Avenue
Suite 13100
Austin, TX 78701

Dear Mr. Tucker:

The purpose of this letter is to refer to you, the Texas 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 you licensed, Davis City Pharmacy, Inc., located at 111 Trinity Street, Weatherford, Texas 76086-3358.

FDA inspected the firm from February 15, 2022, to February 18, 2022. FDA investigators were accompanied by your state investigators for part of the inspection.

A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/159422/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 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 and/or the EIR that includes certain nonpublic information. You may also choose to request such documentation directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for drug products compounded by Davis City Pharmacy Inc and FDA does not intend to take further actions at this time related to conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

U.S. Food and Drug Administration
Office of Pharmaceutical Quality Operations, Division II
1201 Main Street, Suite 7200
Dallas, Texas 75202
www.fda.gov

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. The firm failed to provide adequate cleaning and containment methods during the production of hazardous or highly potent drug products.

Davis City Pharmacy committed to FDA in its response to the FDA dated August 15, 2022, 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 records, FDA does not intend to take further action at this time with regard to the findings of this inspection. FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to you for follow up to ensure appropriate corrective action has been taken. We believe you, the State, are in the best position to conduct follow-up and routine regulatory activities at this firm to ensure the ongoing quality of drug products they produce. Please notify us if you become aware of any adverse events or product quality concerns associated with drug products 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 Dayna I. Martinez, Compliance Officer, at 787-729-8608, or by email at dayna.martinez@fda.hhs.gov. Please use the reference numbers cited in the heading of the document.

Sincerely,

Ronda R. Loyd-jones -S

Digitally signed by Ronda R. Loyd-jones -S
Date: 2022.12.01 09:49:25 -07'00'

Ronda Loyd-Jones
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

Cc: Brandi M. Chane-Lee
Davis City Pharmacy Inc.
P.O. Box 640
Weatherford, TX 76086