May 18, 2020

VIA Electronic Mail

Allison Vordenbaumen Benz
Executive Director
Texas State Board of Pharmacy
333 Guadalupe, Suite #3-500
Austin, Texas 78701

Ms. Vordenbaumen 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 sterile practices observed during an FDA inspection at a pharmacy licensed by the Texas BOP, Dougherty's Pharmacy, located at 5959 Royal Lane Suite 515, Dallas, TX 75230-3890 (pharmacy license #3246).

FDA inspected the firm from June 19, 2019, to July 1, 2019. The FDA investigator was accompanied by a Texas state investigator for three (3) days. 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/130816/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 Dougherty's Pharmacy 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 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 produced drugs without adequate controls to prevent contamination of the production environment.
2. Poor aseptic technique was observed in the critical ISO5 zone where sterile drugs are processed.
3. Media fill procedures do not simulate worst case scenarios or most challenging conditions.

Dougherty's Pharmacy committed to FDA in its response to the Form FDA 483, received July 12, 2019, to correct the deviations in the Form FDA 483 and provided documentation in support of those

corrective actions.

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 you have additional questions, please contact Dr. Shawn Larson - Compliance Officer, at phone number 214-253-5216, or by email at Shawn.Larson@FDA.HHS.GOV.

Sincerely,

John W. Diehl -S3

Digitally signed by John W. Diehl -S3
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S3, 0.9.2342.19200300.100.1.1=2000099727
Date: 2020.05.18 11:34:22 -05'00'

CDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

Cc: VIA Electronic Mail

Mr. Stewart I. Edington
President/CEO
Dougherty's Pharmacy
5924 Royal Lane Suite 250
Dallas, Texas 75230