February 11, 2019

VIA UPS Overnight Mail

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy
333 Guadalupe, Suite #3-500
Austin,Texas 78701

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 sterile practices observed during an FDA inspection at a pharmacy licensed by the Texas BOP, Drug Crafters, located at 5680 Frisco Square Blvd., Suite 1100, Frisco, TX 75034 (Community Pharmacy License number 25301; expires October 31, 2020).

FDA inspected the firm from July 2, 2018, to July 11, 2018. An FDA investigator was accompanied by a Texas BOP investigator on July 3, 2018. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at: https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM614422.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 Drug Crafters 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.

In addition, the FDA investigator observed a deviation from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, a pharmacy technician was observed resting her elbows on the front of a laminar airflow hood while producing a sterile drug product.

Drug Crafters committed to FDA in its written responses, dated July 19, 2018, and

October 24, 2018, to correct the deviation and provided documentation in support of those corrective actions. In addition, the deviation identified appears 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 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 Shawn Larson, Compliance Officer, at (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: 2019.02.11 15:05:02 -06'00'

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

Cc: Mr. Kirk G. Peterson
President and Chief Executive Officer
Drug Crafters
5680 Frisco Square Blvd
Frisco, Texas 75034