



March 24, 2021

Case #: 600324

VIA ELECTRONIC MAIL

Allison Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy
333 Guadalupe Street, Suite #3-500
Austin, TX 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 practices observed during an FDA inspection at a pharmacy licensed by the Texas BOP, Hallettsville Pharmacy, LLC, located at 304 N. Texana Street, Hallettsville, TX 77964-2322 (pharmacy license #25318).

FDA inspected the firm from November 5, 2018, to November 8, 2018. Texas State BOP was informed of the inspection but did not accompany the FDA investigator during 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/120622/download>, with any nonpublic information redacted. Additionally, FDA issued an Untitled Letter to the firm on September 29, 2020 (posted here when available <https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions>), which was electronically mailed to you on that date. 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 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:

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

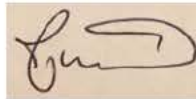
1. Inadequate cleaning of work surfaces and utensils to prevent cross-contamination.
2. Use of non-pharmaceutical grade components for the formulation of drug products.
3. Failure to test samples of each drug product component for conformity with written specifications for purity, strength and quality.

Hallettsville committed to FDA in its response to the Form FDA 483, as well as its response to the Untitled Letter, received November 21, 2018, and November 10, 2020, respectively, to correct the deviations in the Form FDA 483 and Untitled Letter, 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. 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 Dayna Martinez, Compliance Officer, at (787) 729-8608, or by email at Dayna.Martinez@fda.hhs.gov.

Sincerely,



Digitally signed by John W. Diehl -S4
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=John W. Diehl-
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Date: 2021.03.24 21:51:39 -05'00'

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

Cc: Paula H. Grahmann, Pharm.D.
Owner
Hallettsville Pharmacy, LLC
304 N. Texana Street
Hallettsville, TX 77964-2322