April 24, 2019

CMS Case #: 574031

Allison Vordenbaumen Benz
Executive Director
Texas State Board of Pharmacy
William P. Hobby Building
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 State BOP, Stonegate Pharmacy LP, located at 2501 W. William Cannon Drive, Suite 203, Austin, Texas 78745 (License #24369; Expires October 31, 2019).

FDA inspected the firm from May 30, 2018, to June 11, 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/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM611636.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 Stonegate Pharmacy LP 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 the response to the Form FDA 483, received on June 26, 2018, the firm advised FDA that it "compounds and dispenses low, medium, and high-risk sterile patient-specific medications pursuant to receipt of a prescription from a licensed prescriber…".

During the inspection, the FDA investigator 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. Media fills did not closely simulate aseptic production operations incorporating, as appropriate, worst case activities and conditions that provide a challenge to aseptic operations. For example, simulations were not representative of batch sizes and container-closures used in production.

2. Tap water was observed splashing out of the sink and onto a technician's scrubs and the floor while they were washing their hands. Shoe covers, which may have been contaminated with tap water, were not changed prior to entering the ISO 7 buffer room where sterile drug processing occurs.

3. Vials of testosterone(b) (4) were(b) (4) sterilized(b) (4) There was no assurance that(b) (4) was(b) (4) microorganisms. Additionally,(b) (4) used(b) (4) sterilization(b) (4) did not appear to be(b) (4) according to the manufacturer's specifications.

4. (b) (4) used in(b) (4) were not subjected to the same conditions as(b) (4) pellets, specifically,(b) (4) into the(b) (4)

5. Stock solutions used as components of sterile finished drug products were not sterilized prior to being stored for an extended period of time, therefore, the potential proliferation of endotoxin during the storage period was not controlled.

6. Non-pharmaceutical grade water was used as a component in non-sterile drug products produced by the firm.

Stonegate Pharmacy LP committed to FDA in its responses, received June 26, 2018, July 2, 2018, October 30, 2018, November 20, 2018, and February 26, 2019, 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 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 Jose R. Lopez, Compliance Officer, at (787) 729-8603, or by email at JoseR.Lopez@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: 2019.04.24 16:21:28 -05'00'

CDR John W. Diehl, M.S.
Director, Compliance Branch
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Cc: Rene F. Garza, PharmD
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