September 21, 2020

CMS #: 287223

VIA ELECTRONIC MAIL

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Ms. Vordenbaumen:

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, Stonegate Pharmacy, LP, located at 2501 W. William Cannon Drive, Suite 203, Austin, Texas (Community Sterile Compounding License #24369).

FDA inspected the firm from July 30, 2019, to August 9, 2019. The FDA investigator was accompanied by Texas state inspectors for one day. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/131663/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 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.

Additionally, 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 included:

1. Technicians did not gown apparel in a manner that adequately prevented skin exposure to the ISO 5 LAF hoods and contamination of the gowning apparel.

2. Materials or supplies were not disinfected prior to entering the aseptic processing areas.

3. Components not intended for injections are used in the formulation of sterile injectable drug products.

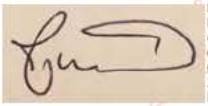
4. The firm produced hazardous drugs without providing adequate containment and segregation to prevent cross-contamination.

Stonegate Pharmacy, LP committed to FDA in its response to the Form FDA 483, received August 16, 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. On June 22, 2020, FDA issued a Request for Additional Information (RAI) email to the firm to address the firm's compounding of tranilast, a bulk drug substance that has been identified in a final rule and will not be placed on a list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act. The firm responded to the RAI by email on June 22, 2020, and committed to cease all compounding of drug products containing tranilast.

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 Jose R. Lopez, Compliance Officer, at (787) 729-8603, or by email at JoseR.Lopez@fda.hhs.gov .

Sincerely,



John W. Diehl, M.S.
Director, Compliance Branch
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Cc:
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