December 21, 2017

Gay Dodson
Executive Director
Texas State Board of Pharmacy
333 Guadalupe, Ste 3-500
Austin, TX 78701

Dear Ms. Dodson:

The purpose of this letter is to refer to the Texas State Board of Pharmacy (TSBP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about deficient sterile practices observed during an FDA inspection at a pharmacy licensed by the TSBP, Oakdell Pharmacy, LLC, located at 7220 Louis Pasteur Drive, Suite 176, San Antonio, TX 78229-4535 (Community Sterile Compounding Pharmacy, License #125).

FDA inspected the firm from March 20, 2017, to March 29, 2017. TSBP was informed of the inspection but did not accompany FDA investigators during the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM551615.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 Oakdell Pharmacy, LLC 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.

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. A non-sterile disinfectant was used for the cleaning and disinfection in the ISO-5 hood which was applied using non-sterile wipes.

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
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2. The firm's media fills were not performed under the most challenging or stressful conditions. Therefore, their products may be produced in an environment that poses a significant contamination risk.

Oakdell committed to FDA in its responses to the Form FDA 483, dated April 19, 2017, May 16, 2017, and July 28, 2017, 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 Board of Pharmacy 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 Thao Ta, Compliance Officer, at 214-253-5217, or by email at Thao.Ta@fda.hhs.gov.

Sincerely,

John W. Diehl -S

Digitally signed by John W. Diehl -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S, 0.9.2342.19200300.100.1.1=2000099727
Date: 2017.12.21 16:00:29 -06'00'

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

Cc:

John J. Carson, R.Ph., Chief of Staff
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