October 28, 2020

Via Electronic Mail

John C. Kirtley, PharmD
Executive Director
Arkansas State Board of Pharmacy
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Dr. Kirtley:

The purpose of this letter is to refer to the Arkansas 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 Arkansas BOP, Custom Compounding Center, located at 11700 Kanis Rd, Suite 1, Little Rock, Arkansas 72211 (retail pharmacy license#: AR20273, expires 12/31/2021).

FDA inspected the firm from May 29, 2019, to June 4, 2019. The FDA investigator was accompanied by Arkansas state investigators for two days. 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/128777/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 Custom Compounding Center 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 14, 2019 and February 19, 2020, the firm advised FDA that it prepares "non-sterile preparations for patient-specific, patient based orders."

Additionally, 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:

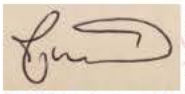
1. Hazardous drugs were produced without providing adequate cleaning of work surfaces and utensils to prevent cross-contamination.

Custom Compounding Center committed to FDA in its responses to the Form FDA 483, received June 14, 2019, and February 19, 2020, 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 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 Arkansas 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 Thao Ta, Compliance Officer, at 214-253-5217, or by email at thao.ta@fda.hhs.gov.

Sincerely,



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

cc:
VIA E-MAIL
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