FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

October 2, 2020

Via Electronic Mail

Dr. Marty Lee Hendrick - Executive Director
Oklahoma State Board of Pharmacy
2920 N. Lincoln Blvd
Suite A
Oklahoma City, OK 73105-3488

Dear Dr. Hendrick:

The purpose of this letter is to refer to the Oklahoma 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 Oklahoma BOP, McAlister Drug Corporation dba Conrad-Marr Drug, located at 948 S Yukon Pkwy, Yukon, OK 3099-4589 (Licensed Pharmacy #26-4538).

FDA inspected the firm from September 23, 2019, to October 3, 2019; FDA investigators were accompanied by an Oklahoma state investigator for one day. 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/135411/download, with any nonpublic information redacted. Additionally, FDA issued an Untitled Letter to the firm on August 21, 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. 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:

1. Use of non-pharmaceutical grade components in the formulation of drug products.
2. Production of hazardous drugs without providing adequate segregation to prevent cross-contamination.

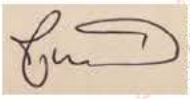
Conrad-Marr Drug committed to FDA in its responses to the Form FDA 483 and Untitled

Letter to correct the deviations. Responses reviewed by the agency also included partial documentation in support of those corrective actions.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Oklahoma 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 questions regarding the contents of this letter, you may contact Dr. Shawn Larson - Compliance Officer, via phone at 214-253-5216 or e-mail at Shawn.Larson@fda.hhs.gov.

Sincerely,



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

CC:

Craig W. McAlister, DPh
Co-Owner/Pharmacist-in-Charge
McAlister Drug Corporation dba Conrad-Marr Drug
948 S. Yukon Pkwy
Yukon, OK 73099-4589