August 21, 2020

CASE # 609981

VIA ELECTRONIC MAIL

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

Dr. McAlister:

From September 23, 2019 to October 3, 2019, U.S. Food and Drug Administration (FDA) investigators inspected your facility, McAlister Drug Corporation dba Conrad-Marr Drug, located at 948 S. Yukon Pkwy, Yukon, Oklahoma 73099. During the inspection, the investigators noted that drug products you produced failed to meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a] for exemption from certain provisions of the FDCA. In addition, the investigators noted deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on October 3, 2019. FDA acknowledges receipt of your facility's response, dated October 11, 2019. FDA further acknowledges the statement in your response letter indicating that your facility is "no longer going to do any office stock." Based on this inspection, it appears that you produced drug products that violate the FDCA.

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].[1] Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A.

[1] We remind you that there are conditions other than those discussed in this letter that must be satisfied to qualify for the exemptions in section 503A of the FDCA.

B. Failure to Meet the Conditions of Section 503A

During the inspection, the FDA investigators noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the investigators noted that your firm did not receive valid prescriptions for individually identified patients for a portion of the drug products you produced, including BENZO 20%/LIDO 8%/TETRA 8% CR and LIDO 20%/TETR 4%/PHENYL 2%.

Therefore, you compounded drug products that did not meet the conditions of section 503A and are not eligible for the exemptions in that section, including the FDA approval requirement of section 505 of the FDCA, the requirement under section 502(f)(1) of the FDCA that labeling bear adequate directions for use, and the requirement of compliance with CGMP under section 501(a)(2)(B) of the FDCA. In the remainder of this letter, we refer to your drug products that do not qualify for exemptions under section 503A as the "ineligible drug products."

Specific violations are described below.

C. Violations of the FDCA

Adulterated Drug Products

The FDA investigators noted that drug products were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA [21 U.S.C. §§ 351(a)(2)(A)]. For example, the investigators observed that your firm handled hazardous drug products without providing adequate cleaning of work surfaces and utensils to prevent contamination. In addition, your firm failed to confirm that the quality of water and other components were suitable for the intended use in production of non-sterile drug products.

Furthermore, the manufacture of the ineligible drug products is subject to FDA's CGMP regulations, Title 21, Code of Federal Regulations (CFR), parts 210 and 211. The FDA investigators observed CGMP violations at your facility, causing the ineligible drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations included, for example:

1. Your firm failed to assure that the drug product bore an expiration date that was supported by appropriate stability testing (21 CFR 211.137(a)).

2. Your firm failed to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (211.165(a)).

It is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

Misbranded Drug Products

The ineligible drug products you compounded are intended for conditions not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses.[2] Accordingly, these ineligible drug products are misbranded under section 502(f)(1) of the FDCA. It is a prohibited act under section 301(k) of the FDCA to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

D. Corrective Actions

We have reviewed your firm's response to the Form FDA 483. Regarding your response related to the insanitary conditions, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. You state that you will discontinue the use of non-pharmaceutical grade components. However, you have not provided supporting documentation or any information regarding how you will implement this corrective action.

2. You state that (b) (4) and (b) (4) will be used for cleaning but failed to provide specifics of hazardous material cross contamination control. A review of hazardous materials used on site and rationale for selection of deactivated agents to prevent cross contamination was not provided.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A, including the condition on receipt of a prescription for an identified individual patient prior to compounding and distributing drug products.

In addition, regarding issues related to the conditions of section 503A of the FDCA, your corrective actions appear adequate, in that you state your facility "is no longer going to do any office stock."

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[2] Your ineligible drug products are not exempted from the requirements of section 502(f)(1) of the FDCA by regulations issued by the FDA (see, e.g., 21 CFR 201.115).

Should you continue to compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations. Before doing so, you must comply with the requirements of section 505 and 502(f)(1) and fully implement corrections that meet the minimum requirements of the CGMP regulations.[3]

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. A third-party consultant with relevant drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

E. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within thirty (30) working days, state the reason for the delay and the time within which you will complete the correction.

Please electronically submit your signed reply on your firm's letterhead to CDR John W. Diehl, MS. - Director, Compliance Branch, at orapharm2_responses@fda.hhs.gov and Shawn.Larson@fda.hhs.gov.

[3] In this letter we do not address whether your proposed corrective actions would resolve the CGMP violations noted above.

If you have questions regarding the contents of this letter, you may contact Dr. Shawn Larson - Compliance Officer, via phone at 214-253-5216.

Sincerely,

Monica R. Maxwell
Program Division Director
Office of Pharmaceutical Quality Operations
Division II