September 29, 2020

Case # 600324

VIA ELECTRONIC MAIL

Paula H. Grahmann
Owner and Pharmacist-in-Charge
Hallettsville Pharmacy, LLC
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Ms. Grahmann:

From November 5, 2018, to November 8, 2018, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Hallettsville Pharmacy, LLC, located at 304 North Texana Street, Hallettsville, Texas 77964. During the inspection, the investigator 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.

FDA issued an FDA Form 483 to your firm on November 8, 2018. FDA acknowledges receipt of your facility's response, dated November 21, 2018. Based on this inspection, it appears that you produced drugs 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 investigator noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the investigator noted that your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced and distributed, including CCH STOMACH MIX and LIDO 10/PRILO 10/TETRA 4/PE 2% DENTAL GEL.

Therefore, you compounded drug products that do 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 investigator noted that drug products intended or expected to be sterile 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, your firm compounded drugs without adequate cleaning of work surfaces and utensils to prevent cross-contamination. In addition, your firm used water that was not labeled or intended for use in the production of non-sterile drug products and whose quality you did not confirm.

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 investigator observed a significant CGMP violation at your facility, causing the ineligible drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violation included, for example, that your firm failed to test samples of each component for conformity with all appropriate written specifications for purity, strength, and quality.

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 [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 misbranded.

D. Corrective Actions

We have reviewed your firm's response to the Form FDA 483.

Regarding observations related to insanitary conditions, your corrective actions appear deficient. For example, you did not provide your review or provide supporting documentation (e.g., revised procedures, training material, and training logs) that work surfaces and utensils were adequately cleaned to prevent cross-contamination after the production of highly potent drugs. In addition, you did not provide evidence (e.g., revised procedures, invoices, training material, and training logs) to demonstrate that the water you utilize in non-sterile drug production meets, at minimum, the specifications of Purified Water, USP.

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 of receipt of a prescription for an identified individual patient prior to compounding and distributing drug products.

Regarding observations related to the conditions of section 503A of the FDCA, as explained above, receipt of valid prescriptions for individually-identified patients is a condition of section 503A, which your firm failed to meet for a portion of the drug products you produced. We acknowledge your statement that your firm "is no longer compounding 'for office use only' non-sterile drugs."

Should you 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.

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

[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).

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 if you have taken any steps to correct the remaining concerns. Please include an explanation of each step being taken to prevent the recurrence of the 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 the corrective actions 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 reply on company letterhead to CDR John W. Diehl, MS, Director, Compliance Branch, at orapharm2_responses@fda.hhs.gov and John.Diehl@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact John Diehl, Director, Compliance Branch, via phone at (214) 253-5288 or email at john.diehl@fda.hhs.gov.

Sincerely,

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

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