June 17, 2021

Case # 609765

VIA ELECTRONIC MAIL

Aaron C. Clark, DPh
Vice President and Secretary
Blount Discount Pharmacy, Inc.
129 Gill Street
Alcoa, TN 37701-2656
aaron@blountdiscountpharmacy.com

Dr. Clark:

From February 10, 2020, to February 13, 2020, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Blount Discount Pharmacy, Inc., located at 129 Gill Street, Alcoa, TN 37701. 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. In addition, the investigator noted deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on February 13, 2020. FDA acknowledges receipt of your facility's response, dated March 3, 2020. 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 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, including Terpin Hydrate DM.

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 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. § 301(a)(2)(A)]. For example, the investigator observed that:

1. Hazardous and highly potent drugs were produced without providing adequate cleaning of work surfaces equipment, including utensils, to prevent cross-contamination. Built-up residue was observed on the scale, stained, and nicked spatulas, scratched and cloudy glassware used to produce non-sterile drug products. In addition, agents used for cleaning the laminar flow hood and other equipment between products do not include a deactivating agent (e.g. oxidizing agent) to prevent cross-contamination.

2. Using inactive ingredients that were not labeled or intended for use in the production of non-sterile drug products and whose quality you did not confirm.

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.

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, FDA acknowledges your letter, dated February 11, 2020, in which you inform FDA that "Blount Discount Pharmacy, Inc. will no longer compound Terpin hydrate/DM unless pursuant to a prescription from the patient's physician."

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.

In addition to the issues discussed above, you should note that CGMP requires the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products. *See* section 501 of the FDCA. If you choose to contract with a laboratory to perform some functions required by CGMP, it is essential that you select a qualified contractor and that you maintain sufficient oversight of the contractor's operations to ensure that it is fully CGMP compliant. Regardless of whether you rely on a contract facility, you are responsible for assuring that drugs you produce are neither adulterated nor misbranded. [*See* 21 CFR 210.1(b), 21 CFR 200.10(b)].]

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.

Your written notification should refer to case # **609765**.

Please electronically submit your reply, on company letterhead, to Jose R. Lopez, Compliance Officer, at ORAPHARM2_RESPONSES@fda.hhs.gov. In addition, please submit a signed copy of your response to JoseR.Lopez@fda.hhs.gov and John.Diehl@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact Jose R. Lopez via phone at (787) 729-8603 or email at JoseR.Lopez@fda.hhs.gov.

Sincerely,

Monica R. Maxwell -S

Digitally signed by Monica R. Maxwell -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300060034, cn=Monica R. Maxwell -S
Date: 2021.06.17 12:51:50 -05'00'

Monica R. Maxwell
Program Division Director
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Cc:

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