U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

April 12, 2018

VIA UPS Next Day Air
Mr. Alan Brown
President
Liberty Drug and Surgical
195 Main Street
Chatham, NJ 07928-2405

Dear Mr. Brown:

From May 3, 2017, to May 25, 2017, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Liberty Drug and Surgical, located at 195 Main Street, Chatham, NJ 07928-2405. 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.

Based on this inspection, it appears your firm is producing drugs that violated the FDCA.

A. Compounded Drug Products Under the FDCA

Section 503A [21 U.S.C. § 353a] 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 practices (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.

B. Failure to Meet the Conditions of Section 503A

During the inspection, FDA investigators noted that drug products produced by your firm failed to meet the conditions of section 503A of the FDCA [21 U.S.C. § 353A]. Specifically, the investigators noted that your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

Therefore, you compounded drug products that do not meet the conditions of section 503A of the FDCA and are not eligible for the exemptions from the FDA approval requirement of section 505 of the FDCA, the requirement under section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] that labeling bear adequate

[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 Act.

directions for use, and the requirement of compliance with CGMP under section 501(a)(2)(B) of the FDCA [21 U.S.C. § 351(a)(2)(B)]. In the remainder of this letter, we refer to your drug products that do not qualify for exemptions under section 503A of the FDCA as the "ineligible drug products."

Specific violations are described below.

C. Violations of the FDCA

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 [21 U.S.C. § 352(f)(1)]. 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

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. During the inspection close-out discussion with FDA investigators, this issue was discussed. Your response did not offer assurances that you would cease distribution of drug products that are not compounded pursuant to patient specific prescriptions in accordance with this explicit condition prescribed in federal law.

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.

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 if you have taken any steps to correct the violations. 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.

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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).

Your written response should be sent to CDR Liatte Closs, Compliance Officer, U.S. Food and Drug Administration, 10 Waterview Blvd. 3rd Floor, Parsippany, NJ 07054. If you have questions regarding the contents of this letter, please contact CDR Closs by phone at (973) 331-4933.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000 11579, cn=Diana Amador-toro -S
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Diana Amador-Toro
Division Director/OPQ Division 1
New Jersey District Office