June 11, 2020

Case #: 603873

VIA ELECTRONIC MAIL

Clayton E. Johnson, President
North Laurel Discount Pharmacy, Inc.
dba Quinn Pharmacy
3160 Audubon Drive, P.O. Box 23
Laurel, Mississippi 39440

Dear Mr. Johnson:

From August 14, 2018, to August 16, 2018, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, North Laurel Discount Pharmacy, Inc. dba Quinn Pharmacy, located at 3160 Audubon Drive, Laurel, Mississippi 39440. 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 August 16, 2018. FDA acknowledges receipt of your firm's response, dated August 29, 2018, as well as your subsequent correspondence. 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 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.

[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.

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
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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 one of the conditions of section 503A. Specifically, 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 and are not eligible for the exemptions in that section from 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. § 351(a)(2)(B)]. For example, the investigator observed that your firm used non-pharmaceutical grade components in the formulation of non-sterile drug products and produced hazardous drugs using non-dedicated equipment.

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.

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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).

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 and subsequent correspondence.

Regarding the insanitary condition observations in the Form FDA 483, we are unable to fully evaluate your corrective actions due to lack of adequate supporting documentation. Specifically,

1. You state that you purchased (b)(4) from (b)(4) but do not state the dates that (b)(4) was used or include any sort of supporting documentation or certificates of analysis. The response also includes vendor information from (b)(4) describing the (b)(4) which states it is designed to meet/exceed USP standards (b)(4) However, it is unclear from your firm's correspondence whether you are currently using the purchased (b)(4) or using the (b)(4) to (b)(4) (b)(4) for the production of non-sterile drug products. Further, it is unclear whether any (b)(4) your firm uses after (b)(4) through this (b)(4) meets USP standards.

2. You include the firm's policy PH-44, Cleaning Hazardous Drug Compounding Area (Non-Sterile). The policy states that your firm will maintain a method and schedule to deactivate, decontaminate, and clean the surfaces in the compounding room to include, but not limited to, those used in the preparation of hazardous drugs. However, the policy states the "appropriate agent" should be used, but does not specify the agent to be used. You do not address any additional controls (related to the containment or segregation of hazardous drugs) to reduce the risk of cross-contamination of hazardous and non-hazardous drugs.

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 of the FDCA, including the condition on receipt of a prescription for an identified individual patient prior to compounding and distributing drug products.

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 502(f)(1) and fully implement corrections that meet the minimum requirements of the CGMP regulations. [3]

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 introduce into interstate commerce 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 # **603873**.

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 .

[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 Jose R. Lopez via phone at (787) 729-8603 or email at JoseR.Lopez@fda.hhs.gov .

Sincerely,

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

Cc:

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