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FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

August 25, 2020

VIA ELECTRONIC MAIL

Kenneth R. GiaQuinto, President & Co-owner
Rye Beach Pharmacy Inc.
464 Forest Avenue
Rye, New York 10580

Dear Mr. GiaQuinto:

From January 6, 2020, to January 10, 2020, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Rye Beach Pharmacy Inc. located at 464 Forest Avenue, Rye, NY 10580. During the inspection, the investigator noted that the 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 acknowledges receipt of your firm's correspondence dated January 9, 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.

Another condition for the exemptions under section 503A of the FDCA is that the licensed pharmacist or licensed physician preparing it does not compound a drug product that appears on a list published by

[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.

FDA at Title 21 CFR Part 216 of drugs that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (section 503A(b)(1)(C)).

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 compounded potassium chloride 10 mEQ capsules, an oral dosage form of a size that appears on the withdrawn or removed list at 21 CFR §216.24.[2] The potassium chloride 10 mEQ is equivalent to 745 mg.

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

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.[3] 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 correspondence dated January 9, 2020. You state that, "our procedure going forward is to be committed to adhering to the current Do Not Compound list. Rye Beach Pharmacy will make sure all compounding activities with potassium chloride are as followed:

[2] The withdrawn or removed list includes potassium chloride for all solid dosage form drug products containing potassium chloride that supply 100 milligrams or more of potassium per dosage unit (except for controlled-release dosage forms and those products formulated for preparation of solution prior to ingestion).
[3] 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).

> *Potassium chloride*: All solid oral dosage form drug products containing potassium chloride that supply 100 milligrams or more of potassium per dosage unit (except for controlled-release dosage forms and those products formulated for preparation of solution prior to ingestion)."

We would also like to remind you that during the inspection, the FDA investigator noted that your firm had Tranilast bulk drug substance in inventory. Please be aware that for a compounded drug product to qualify for the exemptions under section 503A of the FDCA, bulk drug substances used to compound it must: (I) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (II) if such a monograph does not exist, be components of drugs approved by the Secretary; or (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appear on a list developed by the Secretary through regulation ("503A bulks list") (section 503A(b)(1)(A)(i) of the FDCA). Tranilast was nominated for inclusion on the 503A bulks list and after evaluating it FDA determined that Tranilast would not be placed on the 503A bulks list, found at 21 C.F.R. 216.23(a). *See* 21 C.F.R. 216.23(b). Drug products compounded using Tranilast are not eligible for the exemptions provided by section 503A(a) because Tranilast is not the subject of an applicable USP or NF monograph, is not a component of an FDA-approved human drug, and was evaluated and not placed on the 503A bulks list. Based on our conversation with Mr. Raimondi we understand that you intend to discard the remaining Tranilast bulk drug substance.

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.[4]

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)].

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.

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

Within thirty (30) working days of receipt of this letter, please confirm to this office in writing 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 any corrective action within thirty (30) working days, state the reason for the delay and the time within which you will complete the correction.

If you have any questions, please send your inquiry to orapharm1_responses@fda.hhs.gov and contact Compliance Officer Juan Jimenez at juan.jimenez@fda.hhs.gov or call to 518-453-2314 ex.1014.

Please identify your correspondence with FEI #1000119861.

Sincerely,

Craig W. Swanson -S

Digitally signed by Craig W. Swanson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300092363, cn=Craig W. Swanson -S
Date: 2020.08.25 10:21:51 -04'00'

for Diana Amador-Toro
Program Division Director/District Director
U.S. Food and Drug Administration
OPQO Division I / New Jersey District