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

EMAIL DELIVERY
RETURN RECEIPT REQUESTED

July 15, 2022

Rodolfo Dellorusso
Supervising Pharmacist
Healthy Choice Compounding Pharmacy, LLC
250 Clearbrook Rd
Elmsford, NY 10523-1305

FEI: **3013118095**

Dear Mr. Dellorusso:

From September 17, 2020, to September 24, 2020, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Healthy Choice Compounding Pharmacy, located at 250 Clearbrook Rd, Elmsford, NY 10523. 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 September 24, 2020. FDA acknowledges receipt of your facility's response, dated October 6, 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)].

One 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

FDA at Title 21 CFR Part 216 of drugs that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (section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. Specifically, the investigator noted that your firm compounded chloroform, which appears on the withdrawn or removed list at 21 CFR § 216.24.[1]

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. For example, the investigators observed that:

1. You produced hazardous drugs without providing adequate segregation, cleaning of work surfaces, and cleaning of utensils to prevent cross-contamination.
2. Your firm failed to confirm that the quality of water was suitable for its intended use in the production of non-sterile drug products.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, 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.

In addition, our investigator noted that your firm released and distributed drug products in which the potency differed from the label claim. Specifically, your firm released and distributed the following compounded drug products: Di-Est SR 2.0 mg capsule, Naltrexone 4.5 mg capsule, Estriol DHEA 0.5/6.25 mg/gm vaginal, Estradiol (olive oil) 0.01% (0.1 mg/gm) vaginal, and Hydroxychloroquine zinc 200/10 mg caps. Under section 501(c) of the FDCA [21 U.S.C. § 351(c)], a drug is adulterated if it does not purport to be or is not represented as a drug the name of which is recognized in an official compendium and its strength differs from, or its quality or purity falls below, that which it purports or is

[1] The withdrawn or removed list includes all drug products containing chloroform.

represented to possess. The strength of these compounded drug products differed from the strength represented on their labels, causing them to be adulterated under section 501(c) 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.

Under section 502(a) of the FDCA [21 U.S.C. § 352(a)], a drug product is misbranded if its labeling is false or misleading in any particular. According to your own test results, the strength of compounded products Di-Est SR 2.0 mg capsule, Naltrexone 4.5 mg capsule, Estriol DHEA 0.5/6.25 mg/gm vaginal, Estradiol (olive oil) 0.01% (0.1 mg/gm) vaginal, and Hydroxychloroquine zinc 200/10 mg caps, differed from the strength represented on their labels. . The false representations of strength on the labeling of these drug products cause them to be misbranded under section 502(a) 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 responses to the Form FDA 483. Regarding your response related to the insanitary conditions, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. You have not provided supporting documentation regarding which cleaning agent and deactivating agents are being used. Specifically, your response stated that you will use sodium hypochlorite solution. However, this was not reflected in your SOP 02-54.01 Non-Sterile Compounding Area Cleaning, which only states the following: "Bleach concentrate or appropriate cleaning agent." Not enough information was provided in your SOP to specify which cleaning agent and deactivating agent are being used. Your SOP 02-54.01 lacks specific directions for how cleaning agents and deactivating agents are to be used to clean equipment and utensils. Please provide clarification regarding the use of your deactivating agent, such as which agents are you using and how you prepare them, as well as evidence of training.

2. Your firm stated that you would use sterile water for irrigation in your non-sterile compounded drug products. However, you did not provide evidence of such use (e.g., the package insert and a formula worksheet reflecting its use).

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 that the licensed pharmacist or licensed physician does not compound a drug product that

[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).

appears on a list published by 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)).

With respect to your failure to meet a condition of section 503A of the FDCA, FDA acknowledges your verbal commitment to cease producing chloroform-containing drug products. Please indicate in your written response to this letter whether you have, in fact, ceased compounding such products.

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. 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.

A. 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 any violations 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 address any violations. Please include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. This letter notifies you of our concerns and provides you an opportunity to address them. If you believe that your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within thirty (30) working days, state the reason for the delay and the time within which you will do so.

Send your electronic response to orapharm1_responses@fda.hhs.gov. Please identify your response with FEI # 3013118095.

If you have any questions, contact Compliance Officer, Juan Jimenez, at juan.jimenez@fda.hhs.gov or at 973-832-9409.

Sincerely,

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Nerizza Guerin
Acting Program Division Director/District Director
U.S. Food and Drug Administration
OPQO Division I /New Jersey District