June 10, 2020

Case #: 607663

VIA ELECTRONIC MAIL

Virgil Valdes, President & Owner
PrecisionMed Pharmacy
12615 Race Track Rd
Tampa, Florida 33626-1331

Mr. Valdes:

From March 11, 2019 to March 20, 2019, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, PrecisionMed Pharmacy, located at 12615 Race Track Rd, Tampa, Florida 33626. 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. 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 March 20, 2019. FDA acknowledges receipt of your facility's response, dated September 12, 2019. FDA also acknowledges your written commitment, dated March 20, 2019, to cease production and distribution of drug products for office stock. 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.

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 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. The non-patient specific prescriptions include, for example, Pyrogallol 25% Ointment, Lidocaine/Benzocaine/Tetracaine 6%/20%/4% Gel, and Lidocaine/Prilocaine/Tetracaine/Phenylephrine 12.5%/3%/12.5%/3% Gel.

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 investigator observed that hazardous drugs were produced without adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

Furthermore, the manufacture of the ineligible drug products is subject to FDA's CGMP regulations, Title 21, Code of Federal Regulations (CFR), parts 210 and 211. The FDA investigator observed significant CGMP violations at your facility, causing the ineligible drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations included, for example:

1. Your firm failed to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165(a)).

2. Your firm failed to conduct, for each batch of drug product, appropriate laboratory testing, as necessary, required to be free of objectionable microorganisms (21 CFR 211.165(b)).

3. Your firm failed to assure that the drug product bore an expiration date that was supported by appropriate stability testing (21 CFR 211.137(a)).

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.

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. 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 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, your response stated you are using (b)(4) as the cleaning agent in the commercial dishwasher used for cleaning some of the utensils (mortar and pestle) used for production of hazardous drug products. The cleaning agent manufacturer's information provided does not indicate that the cleaning agent contains a deactivation agent (e.g., oxidizing agent), and hence will not deactivate the drug residue. Therefore, we remain concerned that hazardous drug product residue not rendered inert or inactive by a deactivation agent, may be introduced into subsequent products. If your firm continues to use non-dedicated equipment, the cleaning agent used should contain a deactivation agent (e.g., oxidizing agent).

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.

[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).

Regarding issues related to the conditions of section 503A of the FDCA, your corrective actions appear adequate. We acknowledge your statement that "PrecisionMed pharmacy no longer fills for 'office use'. We only dispense patient specific prescriptions."

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.

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.

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 # **607663**.

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
Program Division Director
Office of Pharmaceutical Quality Operations, Division II

Cc:

Renee Alsobrook, Chief, Compliance and Enforcement
Division of Drugs, Devices and Cosmetics
Department of Business and Professional Regulation
2601 Blair Stone Road
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