

IN THIS SECTION



WARNING LETTER

Rocky Mountain Pharmacy Inc.

MARCS-CMS 574231 – 09/05/2019

Delivery Method:

SIGNATURE CONFIRMED DELIVERY

Product:

Drugs

Recipient:

Holly F. Graff Rotar

Owner

Rocky Mountain Pharmacy Inc.

25 N. Willson Ave.

Suite C

Bozeman, MT 59715-3580

United States

Issuing Office:

Center for Drug Evaluation and Research

19701 Fairchild Road

Irvine, CA 92612-2506

United States

(949) 608-2900

Dear Ms. Graff Rotar:

From March 6, 2018, to March 13, 2018, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Rocky Mountain Pharmacy, Inc., located at 25 N. Willson Ave., Suite C, Bozeman, MT 59715-3580. 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 also noted serious deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on March 13, 2018, and an amended Form FDA 483 on April 17, 2018. FDA acknowledges receipt of your facility's response, dated June 18, 2018. 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.

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, such as **(b)(4)** topical gel and **(b)(4)** Cream.

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. For example, the investigator observed that:

1. Potent drug products were prepared without adequate containment, segregation, or cleaning of work surfaces and utensils to prevent cross-contamination. Specifically, your firm utilized non-dedicated equipment and utensils to produce drug product with no assurance that your cleaning process can deactivate and remove residual drug product.
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. In addition, non-pharmaceutical grade components, including **(b)(4)** alcohol, were used in production of non-sterile drug products.

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 establish and follow written procedures for cleaning and maintenance of equipment (21 CFR 211.67(b)).
2. Your firm failed to test samples of each component for conformity with all appropriate written specifications for purity, strength, and quality (21 CFR 211.84(d)(2)).
3. Your firm failed to conduct microbiological testing before use of each lot of a component with potential for objectionable microbiological contamination in light of its intended use (21 CFR 211.84(d)(6)).
4. 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)).
5. 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)).

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. Domperidone

The investigator also noted that your firm stocks domperidone. We acknowledge your letter, dated March 8, 2018, stating that “Rocky Mountain Pharmacy has ceased to compound with domperidone and will promptly remove the remaining powder from the inventory to be disposed of.”

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).

Drug products containing domperidone are not eligible for the exemptions under section 503A of the FDCA because domperidone is not the subject of an applicable USP or NF monograph, is not a component of an FDA-approved human drug, and it does not appear on the 503A bulks list.

E. Corrective Actions

We have reviewed your firm's response to the Form FDA 483, dated June 18, 2018. Regarding your responses related to the insanitary conditions cited above, some of your corrective actions appear to be adequate. However, the following corrective action appears to be deficient. In your response, you state that, "All compounds requiring water are to be mixed using Water USP." However, you have not provided your review or corrective actions for all other non-pharmaceutical grade components, including non-pharmaceutical grade (b)(4) alcohol, used in production.

FDA acknowledges your firm's commitment, as documented in a letter, dated March 8, 2018, to cease producing drug products without prescriptions, to cease producing drug products containing domperidone, to dispose of remaining inventory and to remove the substances from your firm's active chemical inventory.

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, e.g., 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 505 and 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 produce are neither adulterated nor misbranded. [See 21 CFR 210.1(b), 21 CFR 200.10(b)].

F. 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 fifteen (15) 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 15 working days, state the reason for the delay and the time within which you will complete the correction.

Your written notification should refer to the Warning Letter Number above (574231). Please address your written response to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food & Drug Administration
19701 Fairchild Road
Irvine, California 92612-2506

If you have questions regarding the contents of this letter, please contact Lance De Souza, Compliance Officer via email at lance.desouza@fda.hhs.gov (<mailto:lance.desouza@fda.hhs.gov>) or telephone at 510-337-6873 and reference unique identifier **574231**.

Sincerely,

/S/

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

[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.

[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).

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

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