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

VIA SIGNATURE CONFIRMED DELIVERY

July 17, 2019

Marcelino P. Casal
President and CEO
Well Care Discount Pharmacy, LLC
dba Well Care Compounding Pharmacy
3300 W. Charleston Blvd., Suite A
Las Vegas, NV 89102

Dear Dr. Casal:

From June 25, 2018, to June 27, 2018, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Well Care Discount Pharmacy, LLC dba Well Care Compounding Pharmacy, located at 3300 W. Charleston Blvd., Suite A, Las Vegas, NV 89102. 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 June 27, 2018. FDA acknowledges receipt of your facility's responses, dated July 9, 2018, and March 11, 2019. 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.

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In addition, for a compounded drug product to qualify for the exemptions under section 503A, 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).

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:

1. Your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

2. Your firm compounded drug products using domperidone. Drug products compounded using domperidone are not eligible for the exemptions provided by section 503A(a), because domperidone is not the subject of an applicable USP or NF monograph, is not a component of an FDA-approved human drug, and does not appear on the 503A bulks list.[2]

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.

[2] On June 9, 2016, FDA issued a final guidance titled, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. This guidance describes FDA's interim regulatory policy for State-licensed pharmacies, Federal facilities, and licensed physicians that compound human drug products using bulk drug substances that do not otherwise meet the conditions of section 503A(b)(1)(A)(i) while the 503A bulks list is being developed. Specifically, the guidance sets out the conditions under which FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician for compounding a drug product using a bulk drug substance that is not the subject of an applicable USP or NF monograph or a component of an FDA-approved drug, until the substance is identified in a final rule as included or not included on the 503A bulks list. These conditions include that the substance may be eligible for inclusion on the 503A bulks list, was nominated with adequate support for FDA to evaluate it, and has not been identified by FDA as a substance that appears to present significant safety risks pending further evaluation. Domperidone was nominated for inclusion on the 503A bulks list. It has been identified as a substance that appears to present significant safety risks. For additional information, see the guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf.

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, your firm failed to confirm the quality of water was suitable for its intended use in the production of non-sterile drug products.

In addition, our investigator noted that your firm released and distributed a drug product in which the strength exceeded the label claim. Specifically, your firm released and distributed testosterone 2 mg/gram cream which was determined to have 126% the amount of testosterone listed on the label. Under section 501(c) of the FDCA [21 U.S.C. § 351(c)], a drug is adulterated if it is unrecognized in an official compendium and its strength differs from, or its quality or purity falls below, that which it purports or is represented to possess. The strength of your testosterone cream differed from and exceeded the labeled amount of testosterone the product was purported to possess, causing it 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.[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 response to the Form FDA 483. Regarding your responses to the observations in the Form FDA 483, your corrective actions appear to be adequate.

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 receipt of a prescription for an identified individual patient prior to compounding and distributing drug products or the condition that bulk drug substances used to compound drug products either comply with an applicable USP or NF monograph, if no such monograph exits, is a component of an FDA-approved

[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).

human drug, or if no such monograph exists and the substance is not a component of an FDA approved drug product, appears on the 503A bulks list.

In addition, regarding the failure to meet the conditions of section 503A of the FDCA, we acknowledge your letter provided during the inspection, dated June 26, 2018, that states that "Well Care Discount Pharmacy will not dispense any products containing Domperidone as of June 26, 2018."

However, you have not addressed the compounding and distribution of drug products for office stock. As explained above, receipt of valid prescriptions for individually-identified patients is a condition of section 503A, which your firm failed to meet for a portion of the drug products you produced.

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 process, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations.

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 if you have taken any specific steps to correct the violations cited in this letter. 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 violated the FDCA, include your reasoning and any supporting information for our consideration. In addition, we note that you continue to compound only non-sterile drug products. Should you decide to resume production of sterile products, please give this office 30 days prior notice.

Please address your reply 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 or telephone at 510-337-6873 and reference unique identifier **584458**.

Sincerely,

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

SP:lmd

cc:
Jason Penrod, President
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
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