October 25, 2019

Case # 548694

VIA UPS EXPRESS

Richard E. Appling, Owner and President
Right Value Drug Store, Inc. dba Carie Boyd's Prescription Shop
8400 Esters Boulevard, Suite 190
Irving, Texas 75063

Mr. Appling:

You registered with the U.S. Food and Drug Administration (FDA) as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353b][1] on January 11, 2016, and again on November 7, 2018. From April 25, 2017, to May 12, 2017, an FDA investigator inspected your facility, Right Value Drug Store, Inc. dba Carie Boyd's Prescription Shop, located at 122 Grapevine Highway, Hurst, Texas 76054-2406. We acknowledge that your firm has moved its compounding operations to a new facility, located at 8400 Esters Boulevard, Suite 190, Irving, Texas 75063. You registered this facility as an outsourcing facility on July 3, 2019.

During the inspection of the Hurst, Texas facility, the investigator observed that you failed to meet the conditions under section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain requirements under the FDCA. FDA issued a Form FDA 483 to your facility on May 12, 2017. FDA acknowledges receipt of your facility's responses, dated June 2, 2017, August 8, 2017, September 29, 2017, and your subsequent notification, dated November 29, 2017. Based on this inspection, it appears you produced drugs that violated the FDCA.

A. Compounded Drugs under the FDCA

Under section 503B(b) of the FDCA, a compounder can register as an outsourcing facility with FDA. Drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility qualify for exemptions from the drug approval requirements in section 505 of the FDCA [21 U.S.C. § 355(a)], the requirement in section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] that labeling bear adequate

[1] *See* Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

directions for use, and the Drug Supply Chain Security Act requirements in section 582 of the FDCA [21 U.S.C. § 360eee-1] if the conditions in section 503B of the FDCA are met. [2]

An outsourcing facility, which is defined in section 503B(d)(4) of the FDCA [21 U.S.C. § 353b(d)(4)], is a facility at one geographic location or address that — (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section. Outsourcing facilities must comply with other applicable provisions of the FDCA, including section 501(a)(2)(B) [21 U.S.C. § 351(a)(2)(B)], regarding current good manufacturing practice (CGMP), and section 501(a)(2)(A) [21 U.S.C. § 351(a)(2)(A)], regarding insanitary conditions. Generally, CGMP requirements for the preparation of drug products are established in Title 21 of the Code of Federal Regulations (CFR) parts 210 and 211.

In addition, for a compounded drug product to qualify for the exemptions under section 503B, bulk drug substances used to compound it must appear on a list established by the Secretary identifying bulk drug substances for which there is a clinical need ("503B bulks list"), or that appear on the drug shortage list in effect under section 506E of the FDCA at the time of compounding, distribution, and dispensing (section 503B(a)(2)(A)(i) of the FDCA [21 U.S.C. § 353b(a)(2)(A)(i)]).

Further, for a compounded drug product to qualify for the exemptions under section 503B, the labeling of the drug must include certain information (section 503B(a)(10) of the FDCA [21 U.S.C. § 353b(a)(10)]).

Lastly, for a compounded drug product to qualify for the exemptions under section 503B, it must be compounded in an outsourcing facility that is in compliance with the registration and reporting requirements in section 503B(b) including the requirement to submit a report to FDA upon initially registering as an outsourcing facility, once in June of each year, and once in December of each year identifying the drug products compounded during the previous 6-month period (section 503B(b)(2) of the FDCA [21 U.S.C. §353b(b)(2)]).

B. Failure to Meet the Conditions of Section 503B

During the inspection of your firm, the FDA investigator observed that drug products produced by your facility failed to meet the conditions of section 503B. For example, the investigator observed:

1. Your facility compounded drug products using certain bulk drug substances that are not eligible for the exemptions provided by section 503B, including 4-aminopyridine, 7-keto dehydroepiandrosterone (DHEA), arginine, boric acid,

[2] 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 503B of the FDCA.

human chorionic gonadotropin (HCG), chrysin, desonide, diphenhydramine, ICU Bottom Paste (b) (4) kojic acid, lidocaine, tetracaine, magnesium sulfate, menthol, methylcellulose, nystatin, opium tincture, phenobarbital, potassium bromide, potassium hydroxide, pregnenolone micronized, propylene glycol, quinine, selenium, thymol, trichloroacetic acid, triglycerides, tryptophan, xanthan gum, zinc chloride, dimethyl sulfoxide (DMSO), belladona, DHEA, and leucovorin. Drug products compounded using these bulk drug substances are not eligible for the exemptions provided by section 503B, because they do not appear on the 503B bulks list, and are not used to compound a drug that appears on the drug shortage list.[3]

2. Some of your facility's drug products' containers did not include the following information on the container to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088. Additionally, some of your facility's drug products did not include the following information on the label: the statement, "This is a compounded drug." The products in question instead contained the statement "This is a compound drug," which could be misleading.

3. Your facility failed to submit a report to FDA upon initial registration as an outsourcing facility in January 2016, identifying the drug products that you compounded during the previous 6-month period (Section 503B(b)(2) of the FDCA [21 U.S.C. § 353b(b)(2)]).

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[3] In January 2017, FDA issued a revised final guidance titled, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (the "*Interim Policy*"). This guidance describes FDA's interim regulatory policy concerning compounding by outsourcing facilities using bulk drug substances while the 503B bulks list is being developed in accordance with section 503B of the FD&C Act. Specifically, the guidance sets out conditions under which FDA does not intend to take action against an outsourcing facility for compounding a drug product using a bulk drug substance that is not included on the 503B bulks list and does not appear on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing. These conditions include that the substance may be eligible for inclusion on the 503B 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. 7-keto DHEA, arginine, chrysin, desonide, diphenhydramine, ICU Bottom Paste (b) (4) kojic acid, lidocaine, tetracaine, magnesium sulfate, menthol, methylcellulose, nystatin, opium tincture, phenobarbital, potassium bromide, potassium hydroxide, pregnenolone micronized, propylene glycol, quinine, selenium, thymol, trichloroacetic acid , triglycerides, tryptophan, xanthan gum, and zinc chloride were nominated for inclusion on the 503B bulks list but were not nominated with adequate support for FDA to evaluate the substance and were therefore not eligible for enforcement discretion under FDA's *Interim Policy* at the time of FDA's inspection. Boric acid, human chorionic gonadotropin, DHEA, DMSO, belladonna, and leucovorin were not nominated for inclusion on the 503B bulks list and therefore, under FDA's *Interim Policy* were not eligible for enforcement discretion at the time of the inspection. As of the date of the inspection, none of these bulk drug substances used to compound a human drug product appeared on the 503B bulks list, or appeared on the drug shortage list in effect under section 506E of the FDCA at the time of compounding, distribution, and dispensing. For additional information, see the guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf

Because your compounded drug products did not meet all of the conditions in section 503B, they were not eligible for the exemptions under section 503B from the FDA approval requirements in section 505, the requirement under section 502(f)(1) that labeling bear adequate directions for use, and the Drug Supply Chain Security Act requirements described in section 582 of the FDCA.[4]

Specific violations are described below.

C. Violations of the FDCA

Unapproved New Drug Products

You did not have any FDA-approved applications on file for the drug products that you compounded.[5] Under sections 301(d) and 505(a) of the FDCA [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FDCA is in effect for the drug. Marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA.

Misbranded Drug Products

You compounded drug products that were 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 layperson can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses causing them to be misbranded under section 502(f)(1) of the FDCA.[6] The introduction or delivery for introduction into interstate commerce of these products therefore violates section 301(a) of the FDCA. Further, it is also 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.

Failure to Report Drugs

As noted above, your facility failed to submit a report to FDA upon initial registration as an outsourcing facility in January 2016. The failure to report drugs by an entity that is

[4] See, e.g., section 503B(a)(11) of the FDCA [21 U.S.C. § 353b(a)(11)].
[5] The specific products made by your firm are drugs within the meaning of section 201(g) of the Act, [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases and/or because they are intended to affect the structure or any function of the body. Further, they are "new drugs" within the meaning of section 201(p) of the FDCA [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses.
[6] Your compounded 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).

registered with FDA in accordance with section 503B(b) is a prohibited act under section 301(ccc)(3) of the FDCA [21 U.S.C. § 331(ccc)(3)].

D. Corrective Actions

We have reviewed your facility's response to the Form FDA 483. We acknowledge that, since the inspection, your firm has adequately submitted product reports to FDA.

Regarding observations related to the conditions of section 503B of the FDCA, your corrective action to address your deficient container labels appear to be adequate. Specifically, in your Form FDA 483 response, dated August 17, 2017, you state that a label "will be applied immediately to all applicable drug product containers that includes the FDA toll-free phone number and website information for adverse event reporting." However, you have not indicated whether your firm will comply with the condition concerning the use of bulk drug substances. We refer you to FDA's revised final guidance titled, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act*. This guidance describes FDA's interim regulatory policy concerning compounding by outsourcing facilities using bulk drug substances while the 503B bulks list is being developed in accordance with section 503B of the FD&C Act.

In addition, as explained above, for compounded drug products to qualify for the exemptions under section 503B, the labeling of the drug must contain certain information, including the statement, "This is a compounded drug."

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, you should notify this office in writing of the specific steps 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 the corrective actions cannot be completed within thirty (30) working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written notification should refer to the Case Number above (Case #548694). Please electronically submit your signed reply on your firm's letterhead to CDR John W. Diehl, M.S., Director, Compliance Branch, at john.diehl@fda.hhs.gov and orapharm2_responses@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact Mr. Thao Ta, Compliance Officer, via phone at 214-253-5217 or e-mail at thao.ta@fda.hhs.gov.

Sincerely,

Monica R Maxwell

Digitally signed by Monica R. Maxwell -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300060034, cn=Monica R. Maxwell -S
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Monica R. Maxwell
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