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WARNING LETTER

AnazaoHealth Corporation

MARCS-CMS 613214 - AUGUST 18, 2021

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Recipient: Douglas F. Cammann Vice President of Operations **AnazaoHealth Corporation** 7465 W. Sunset Road, Suite 1200 Las Vegas, NV 89113-1944

Division of Pharmaceutical Quality Operations IV **United States**

Issuing Office:

WARNING LETTER

August 18, 2021

United States

Dear Mr. Cammann:

You registered your facility 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 September 23, 2014, and most recently on December 9, 2020. From September 9, 2019, to September 19, 2019, an FDA investigator inspected your facility, AnazaoHealth Corporation, located at 7465 W. Sunset Road, Suite 1200, Las Vegas, NV 89113. During the inspection, the investigator noted that drug products you produced failed to meet the conditions of section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain provisions of the FDCA.

FDA issued a Form FDA 483 to your facility on September 19, 2019. FDA acknowledges receipt of your facility's response, dated October 9, 2019, and subsequent correspondence the last of which was received on October 8, 2020. Based on this inspection, it appears you produced drugs that violate the FDCA.

A. Compounded Drug Products 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 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. §

compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and

353b(d)(4)], is a facility at one geographic location or address that - (i) is engaged in the

(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, 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 adverse event reports to FDA "in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations)" (section 503B(a)(1), (b)(5) of the FDCA [21 U.S.C. §353b(a)(1), (b)(5)]).

B. Failure to Meet the Conditions of Section 503B

During the inspection, the FDA investigator noted that drug products produced by your facility failed to meet the conditions of section 503B. For example, the evidence collected during the inspection indicates that your facility's drug products were not compounded in an outsourcing facility that is in compliance with the requirements of section 503B(b) (see section 503B(a)(1) of the FDCA). In particular, your facility does not comply with section 503B(b)(5) of the FDCA, which as noted above, requires an outsourcing facility to submit adverse event reports to FDA in accordance with the content and format requirements established through regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).³ Specifically, your facility's procedures for reporting adverse events are inadequate. For example, your documented procedures do not adequately define what constitutes an adverse event, do not include timelines for reporting adverse events to FDA and do not provide that adverse events should be reported utilizing FDA's Safety Reporting Portal (SRP) or Electronic Submission Gateway (ESG).

503B, they are not eligible for the exemptions in that section from the FDA approval requirements of 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.

Because your compounded drug products have not met all of the conditions of section

Specific violations are described below.

C. Violations of the FDCA

Unapproved New Drug Products You do not have any FDA-approved applications on file for drug products that you

compound.4 Under sections 505(a) and 301(d) of the FDCA [21 U.S.C. §§ 355(a) and 331(d)] 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 compound drug products that 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 causing them to be misbranded under section 502(f)(1) of the FDCA.⁵ 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. **D. Corrective Actions**

We have reviewed your facility's response to the Form FDA 483 dated October 9, 2019,

and subsequent correspondence the last of which was received on October 8, 2020. We are unable to fully evaluate your corrective actions. 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).] With respect to section 503B(b)(5) of the FDCA, you verbally stated that you will report

evaluate the corrective actions due to lack of adequate supporting documentation. As explained above, a facility must comply with adverse event reporting requirements

adverse events as required under 21 CFR 310.305. However, we are unable to fully

(section 503B(b)(5) of the FDCA [21 U.S.C. §353b(b)(5)]) in order to qualify for the exemptions under section 503B. Furthermore, your procedures for adverse event reporting must also comply with the requirements as specified in 21 CFR 211.198. Should you continue to compound and distribute drug products that do not meet the conditions of section 503B, the compounding and distribution of your drugs would be

subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the Drug Supply Chain Security Act requirements. **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 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. You should take prompt action to correct any violations cited in this letter. Failure to adequately address any violations may result in legal action without further notice,

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 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 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 fifteen (15) working days, state the

Your response should refer to unique identifier CMS 613214 and be sent electronically to ORAPHARM4_Responses@fda.hhs.gov or mailed 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 Jamie Dion,

reason for the delay and the time within which you will do so.

including, without limitation, seizure and injunction.

Compliance Officer via email at Jamie.Dion@fda.hhs.gov or telephone at 303-236-3133. Sincerely, /S/

found

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

1 See Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013). 2 We remind you that there are conditions, other than those discussed in this letter, that

3 For more information, see FDA's guidance, "Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act," which can be

must be satisfied to qualify for the exemptions in section 503B of the FDCA.

at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434188.pdf.

4 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. 5 Your compounded drug products are not exempted from the requirements of section

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502(f)(1) of the FDCA by regulations issued by the FDA (see, e.g., 21 CFR 201.115).

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