**WARNING LETTER**

# Empower Clinic Services, LLC dba Empower Pharmacy

**MARCS-CMS 613792 — OCTOBER 15, 2021**

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**Delivery Method:**

VIA Electronic Mail

**Product:**

Drugs

**Recipient:**

Arta Shaun Noorian

Owner

Empower Clinic Services, LLC dba Empower Pharmacy

5980 West Sam Houston Parkway North

Suite 300

Houston, TX 77041-5251

United States

**Issuing Office:**

Office of Pharmaceutical Quality Operations, Division II

United States

October 15, 2021

**Case #: 613792**

**WARNING LETTER**

Mr. Noorian:

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 July 16, 2016, and most recently on October 26, 2020. From February 12, 2020, to March 6, 2020, an FDA investigator inspected your facility, Empower Clinic Services, LLC dba Empower Pharmacy located at 5980 West Sam Houston Parkway North, Suite 300, Houston, Texas 77041. 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 March 6, 2020. FDA acknowledges receipt of your facility's response, dated March 27, 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. § 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, the labeling of the drug must include certain information (section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)]).

Further, 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)]), as well as 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)]).

Moreover, subject to certain exceptions, a compounded drug product cannot qualify for the exemptions under section 503B if it will be sold or transferred by an entity other than the outsourcing facility that compounded such drug (section 503B(a)(8) of the FDCA [21 U.S.C. §353b(a)(8)]).

**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 investigator noted:

1. Some of your facility's drug products, including HCG (LYO) 12,000 IU Injectable, Testosterone Cypionate in GSO (5ml) 200mg/ml Injectable, FSH (LYO) 1,500 IU Injectable, and Menotropins (HMG)(LYO) 500 IU Injectable, did not include the following information on the container to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088. [Section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)]].

2. Your facility failed to submit a complete report to FDA in December 2019 and again in June 2020, identifying all the drug products that you compounded during the previous 6-month period, including Leuprolide Acetate 40mcg/0.2ml 10ml Injectable. [Section 503B(b)(2) of the FDCA [21 U.S.C. §353b(b)(2)]].

3. Your facility did not 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.[3] Specifically, your facility's procedures for reporting adverse events are inadequate. For example, your documented procedures for reporting adverse events do not include a requirement to promptly investigate and submit a follow-up report regarding a serious, unexpected adverse event within 15 calendar days of receipt of new information or as requested by FDA. [Section 503B(b)(5) of the FDCA [21 U.S.C. §353b(b)(5)]; 21 CFR 310.305(c)(2)].

4. Your facility compounded a drug product, **(b)(4)**, that was sold by an entity other than your firm, the outsourcing facility that compounded such drug [Section 503B(a)(8) of the FDCA [21 U.S.C § 353b(a)(8)]].

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

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. §§ 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.

**Failure to Report Drugs**

As noted above, your facility failed to submit a complete report to FDA in December 2019 and again in June 2020, identifying the drug products that you compounded during the previous 6-month period (section 503B(b)(2) of the FDCA). The failure to report drugs by an entity that is 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.

Regarding observations related to the conditions of section 503B of the FDCA, some of your corrective actions appear adequate. For example, you state that you have "completed a change control to place the necessary information onto the primary packaging, which now includes the required adverse event reporting contact information."

In addition, regarding observations related to the conditions of section 503B of the FDCA, some of your corrective actions appear deficient. For example, we acknowledge your statement that you "are fully prepared to report any adverse event to FDA." However, we have reviewed the Standard Operating Procedure (SOP) you submitted during the inspection, which "describes the steps Empower Pharmacy follows to fulfill the regulatory requirements for adverse event reporting." Although the SOP addresses adverse event reporting for adverse events "within 15 calendar days of initial report," this SOP does not appear to adequately address adverse event reporting. For example, your SOP does not include information regarding follow-up reports or investigation procedures, and there is no timeline for investigating or providing a follow-up report of an adverse event. When making any corrections, also ensure that your procedures for adverse event reporting comply with the requirements in 21 C.F.R. 211.198.

Furthermore, you did not address certain observations related to the conditions of section 503B of the FDCA. For example, during the inspection, you noted to the FDA investigator that you wholesale drugs that you compound to **(b)(4)**. We remind you of section 503B(a)(8) of the FDCA [21 U.S.C. §353b(a)(8)]), entitled "Prohibition on Wholesaling," which states, in part, that the "drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug."

During the inspection, the FDA investigator noted that some of your facility's drug products intended for dispensing to patients pursuant to a prescription included the statement "For office use only." We remind you that for a compounded drug product to qualify for the exemptions under section 503B, the labeling of the drug must comply with the provisions of section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)].

During the inspection, the investigator observed that your facility compounded Pyridoxine HCL 100mg/ml injection using the bulk drug substance Pyridoxine. Pyridoxine is a component of an approved drug product. Please note that for a compounded drug product to qualify for the exemptions under section 503B, it must not be essentially a copy of one or more approved drugs (section 503B(a)(5) of the FDCA [21 U.S.C. § 353b(a)(5)]). The term "essentially a copy of an approved drug" means (A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing (section 503B(d)(2)(A) of the FDCA [21 U.S.C. § 353b(d)(2)(A)]); or (B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug (section 503B(d)(2)(B) of the FDCA [21 U.S.C. § 353b(d)(2)(B)]). For more information on the "essentially a copy" condition, including FDA's recommendations on documenting prescriber determinations of a clinical difference with respect to compounded drugs that would otherwise be copies under section 503B(d)(2)(B), please see FDA's guidance, "Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act."[6]

Furthermore, the FDA investigator noted that your facility produced biological products. Please be advised that federal law does not provide a legal pathway for marketing biological products that have been prepared outside the scope of an approved biologics license application (BLA). Specifically, section 351(a)(1) of the Public Health Service Act (PHS Act) prohibits the introduction into interstate commerce of any biological product unless "a biologics license . . . is in effect for the biological product" (i.e., an approved BLA). Additionally, biological products subject to licensure under section 351 of the PHS Act are not eligible for the exemptions for compounded drugs under sections 503A and 503B of the FDCA. We also note that, as required by the Biologics Price Competition and Innovation Act of 2009, on March 23, 2020, an approved application for a biological product under section 505 of the FDCA was deemed to be a license for the biological product (i.e., an approved BLA) under the PHS Act. This transition affects compounding under sections 503A and 503B of the FDCA because, beginning on March 23, 2020, these biological products that previously could have been submitted in a

marketing application under the FD&C Act are subject to licensure under section 351 of the PHS Act and thus are not eligible for the exemptions for compounded drugs under sections 503A and 503B of the FDCA. See Notice to Compounders: Changes that affect compounding as of March 23, 2020[7] and section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 for additional information. Although these biological products are not eligible for the exemptions in sections 503A and 503B, FDA issued guidance explaining conditions under which we do not intend to take action when certain biological products are mixed, diluted, or repackaged in a manner not described in their approved labeling. See Guidance for industry, Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (January 2018).[8]

**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. Failure to adequately address any violations may result in legal action without further notice, including, without limitation, seizure and injunction.

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

Your written notification should refer to case # **613792**.

Please electronically submit your reply, on company letterhead, to Jamillah Selby, Compliance Officer, at ORAPHARM2_RESPONSES@fda.hhs.gov. In addition, please submit a signed copy of your response to jamillah.selby@fda.hhs.gov and/or john.diehl@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact Jamillah Selby via phone at 214-253-5218 or email at jamillah.selby@fda.hhs.gov.

Sincerely,
/S/

Tamala Bogan
Acting Program Division Director
Office of Pharmaceutical Quality Operations,
Division II

Cc: Karen Tannert
Texas Department of State Health Services
karen.tannert@dshs.texas.gov

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

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

***6*** Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compounded-drug-products-are-essentially-copies-approved-drug-products-under-section-503b-federal.

***7*** Available at: https://www.fda.gov/drugs/human-drug-compounding/notice-compounders-changes-affect-compounding-march-23-2020.

***8*** Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/mixing-dilutingor-repackaging-biological-products-outside-scope-approved-biologics-license.