WARNING LETTER

Empower Clinic Services, LLC dba Empower Pharma

MARCS-CMS 700962 — APRIL 02, 2025

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Delivery Method:

VIA Electronic Mail

Product:

Drugs

Recipient:

Arta Shaun Noorian

Chief Executive Officer

Empower Clinic Services, LLC dba Empower Pharma

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United States

Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

WARNING LETTER

WL # 700962

April 2, 2025

Dear 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 December 6, 2024. From August 1, 2024, to August 28, 2024, FDA investigators inspected your facility, Empower Pharma located at 5980 West Sam Houston Parkway North, Suite 300, Houston, TX 77041. During the inspection, the investigators 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. In addition, the investigators noted serious deficiencies in your practices for producing drug products intended or expected to be sterile, which put patients at risk.

FDA issued a Form FDA 483 to your facility on August 28, 2024. FDA acknowledges receipt of your facility's responses, dated September 19, 2024, and January 31, 2025. Additionally, FDA acknowledges your firm's recall of Pyridoxine HCL Injection Solution, 100mg/mL, lot 609763 on September 5, 2024. 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.

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)]).

B. Failure to Meet the Conditions of Section 503B

During the inspection, FDA investigators noted that drug products produced by your facility failed to meet the conditions of section 503B. Your facility's drug products, such as Pyridoxine HCl (B6) Injection Solution, did not include the following information on the container: 1) information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 and 2) directions for use, including, as appropriate, dosage and administration.

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

Adulterated Drug Products

FDA investigators noted that drug products intended or expected to be sterile 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 investigators observed:

1. You did not perform adequate product evaluation and take appropriate corrective action after microbial contamination was recovered within the ISO 5 aseptic processing area.

2. Your firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area. Therefore, your products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination.

FDA investigators also noted CGMP violations at your facility, that caused your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations include, for example:

1. Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).

2. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

3. Your firm failed to establish an adequate system for maintaining equipment used to control the aseptic conditions (21 CFR 211.42(c)(10)(vi)).

4. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

5. Your firm failed to establish written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).

Outsourcing facilities must comply with CGMP requirements under section 501(a)(2)(B) of the FDCA. FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to promulgate more specific CGMP regulations for outsourcing facilities. FDA has issued a revised draft guidance, *Current Good Manufacturing Practice — Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act*. This draft guidance, when finalized, will describe FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, 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.

Unapproved New Drug Products

You do not have any FDA-approved applications on file for drug products that you compound.[3] 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.[4] 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 responses to the Form FDA 483. We acknowledge your firm's recall of Pyridoxine HCL Injection Solution, 100mg/mL, lot 609763 on September 5, 2024, due to lack of sterility assurance.

Some of your corrective actions appear deficient:

1. Your firm released a batch of a drug product intended to be sterile even though positive microbial growth was detected during environmental monitoring (EM) within the ISO 5 production area. You did not provide an adequate product impact assessment for Pyridoxine HCL lot 609763 compounded on April 18, 2024, when our investigators identified the observation during the inspection. As noted above, we acknowledge your recall of this lot on September 5, 2024. Your response stated you have revised your EM response program procedure to include the requirement that any recovery of a microorganism within an ISO 5 area during final aseptic filtration and filling shall result in the rejection of the associated batch. However, your revision was limited to only two processing steps for aseptic filling and filtration, although any operation in the ISO 5 area has the potential to be affected. Your responses did not provide an investigation update for the microbial failure in which 1 CFU of Bacillus altitudinis/pumilus/safensis was recovered on a surface contact plate inside the ISO 5 laminar airflow hood (LAFH) during aseptic filling. You identified the likely root cause as man (human) and a contributing factor as method due to sampling error, but your investigation did not include any documented preventive actions regarding proper aseptic technique and proper sampling.

2. Our investigators observed 6-inch horizontal gaps below the back wall of the ISO 5 LAFH and the bar holes on the side wall of the ISO 5 E2150 LAFH. Your smoke study from June 26, 2023, was not conducted under dynamic conditions to demonstrate unidirectional airflow to include the impact of the gaps and bar holes on your aseptic process in your ISO 5 LAFHs, and to show that airflow could exit through the gaps in the back wall, which could prevent airflow from the ISO 7 cleanroom from entering the ISO 5 LAFH. We acknowledge that you executed an addendum to the original protocol and provided a summary table within document number B-REP-QAL-0168. However, your response did not include an executed protocol per B-PROT-QAL-0069 with documentation completed nor a video with your visual airflow study for review. Your response also lacked an assessment on product impact on lots within expiry made since the smoke study was performed to mitigate any potential concerns until your addendum was completed.

3. Your firm exceeded your action level of non-viable particles in the ISO 5 hood during the production of Ascorbic Acid Preserved 500 mg/mL Injection 30 mL lot **(b)(4)** filled on June 17, 2024. The **(b)(4)** system **(b)(4)** counter recorded a total plate count (TPC) that exceeded the action level for particles greater than or equal to **(b)(4)** microns, according to your internal specification. Your investigation stated the likely contributing factor to the failure was the machine or operator. Your investigation concluded no known product impact, and you released the full batch of Ascorbic Acid Preserved 500 mg/mL Injection 30 mL lot **(b)(4)**. Your investigation stated the operator was properly gowned and maintained proper aseptic practices, but it did not provide an adequate rationale for releasing the whole batch. Your investigation also did not adequately assess the impact of the failure to the ISO 5 environment, for example investigating other operations that had occurred in the ISO 5 area. Any excursion that exceeds an established action level could potentially affect product quality. This is a repeat violation that was discussed during the May 4, 2023, regulatory meeting regarding your failure to establish and follow appropriate written procedures to prevent microbiological contamination.

4. Your firm's investigation of EM out of specification (OOS) results during aseptic batch processing was inadequate. The investigators noted that a fungus, *Rhodotorula bacarum*, was identified on fingertip samples from an operator during the filling operations on May 4, 2023, of Lipo-B/Methionine/Choline Chloride/Cyanocobalamin 25/50/1 mg/mL, lot **(b)(4)**. Your firm investigated this issue under non-conformance (NC)-000518, but did not determine a definitive root cause. The most probable cause was identified as inadequate gowning or aseptic technique by the operator. Consequently, the operator was disqualified from aseptic production and the batch was rejected. However, the investigation was inadequate as it lacked an assessment on any batches the operator produced before the EM results were available. Also, your

investigation stated this employee was working as your **(b)(4)** equipment lead operator, “which increases the risk of a potential impact to the final product.” Your investigation did not include an assessment of potential other batches involving this operator that utilized the **(b)(4)** equipment before the EM results were available.

In addition, your firm opened approximately fourteen non-conformances (NCs) to investigate EM excursions between August 16 through September 14, 2023. According to your investigation report NC-000673, there were approximately thirty-two NCs for EM excursions reported between August 24 through September 14, 2023. Your investigation report stated the presence of a significant number of EM excursions spanning this period “raises concerns regarding the overall state of control within the 503B aseptic processing suites.”

During a review of the combined NC investigation for these EM excursions, your firm failed to extend the investigation to other batches produced. For example, your firm did not include injectable drug product Glutathione 200mg/mL, lot **(b)(4)**; however this lot was manufactured on August 16, 2023. In addition, *Pseudomonas luteola* was identified in a routine EM sample collected from the gowning room on August 16, 2023, the same day this lot was aseptically filled. Your response did not include an investigation regarding lot **(b)(4)**. You stated you have revised your Environmental Monitoring Excursion Response Program procedure to extend investigations to other products and lots that may be impacted by the EM excursion. However, it does not appear that your firm is taking a holistic approach to this topic by only making updates to the EM response program procedure. We acknowledge your investigation into these EM excursions stated that most of the referenced batches will be rejected, however we remain concerned with your investigations not always extending to other batches and processes that may be affected. This has been a reoccurring concern from the last inspection and this violation was discussed with you during the May 4, 2023, regulatory meeting.

5. Our investigators observed discolored stains and scratches inside both of your ISO 5 LAFHs on August 12, 2024. Your response stated, “the insufficient maintenance of these areas at the time of inspection represented a deviation from established procedures and enhancements to Empower’s program for preventive maintenance of the classified area.” We acknowledge the pictures you provided showing maintenance was performed on the ISO 5 LAFHs based on the cleaning chemical that was used. However, the scratches appear to be embedded in the stainless equipment and may not be removed by cleaning alone. There is a lack of assurance that your newly created checklist forms have adequate details to prevent reoccurrence because they do not include details defining what is considered clean. Your response also stated you performed retraining on preventive maintenance inspections per *B-SOP-FACE-0020* E2019-CR Preventive Maintenance. However, that procedure was not provided in your response and there was no assessment provided to mitigate any product impact concerns with other released drug products intended to be sterile that were made in the affected ISO 5 LAFH. This is a repeat observation from your August 5, 2022, inspection regarding discoloration on equipment in the ISO 5 area.

6. Cleaning validation (CV) for multiple product contact equipment used in compounding implantable Testosterone and Estradiol pellets has not been completed although it appears that your firm continues to produce these products. You state you have already initiated the process of performing CV on the affected equipment prior to the inspection, but that **(b)(4)**. Your response did not provide any type of risk assessment for this gap nor state if your firm has any plans to stop making the product until CV has been performed. You also did not provide any assurance that this gap in CV does not exist for other product contact equipment involving your other numerous products.

We are unable to fully evaluate some of your corrective actions due to lack of adequate supporting documentation. For example, your aseptic operators working in both ISO 5 LAFHs equipment ID E2150 and 2151 were observed, via video, on July 31, 2024, sanitizing their gloves prior to performing personnel monitoring (PM). Your aseptic operators failed to immediately perform (PM) after concluding aseptic filling of sterile drug product Lipo-B/Methionine/Choline Chloride/Cyanocobalamin 25/50/1 mg/mL Injection Solution lot **(b)(4)**, as required by your procedure. This practice was

also observed concluding aseptic filling of sterile drug products Testosterone Cypionate 200mg/mL lot **(b)(4)** and Glutathione Preservative Free 200 mg/mL Lot **(b)(4)**, via video, on July 31, 2024. The PM of the aseptic operator who performed aseptic filling in ISO 5 hood equipment ID E2150 was performed by a supervisor.

Additionally, this aseptic operator failed to employ proper fingertip plating technique after conducting aseptic filling and was observed **(b)(4)** media plate, rather than **(b)(4)** to capture the gloved hands utilized during aseptic production. Your procedure B-SOP-QC-0009, Performing Personnel Monitoring, Revision 001, Effective date: 2- Jan-2024, Section 6.4.1.5 states, "**(b)(4)**." This practice was also observed concluding aseptic filling of your sterile drug product Testosterone 200mg/mL lot **(b)(4)** on August 6, 2024. Your response does not address the root cause as to why employees are not following procedures nor the impact of this practice on lots distributed since it is unknown how long this practice has been performed. You stated you will send documentation of periodic monitoring assessments of employees' aseptic technique in your subsequent 2024-Q4 response by providing copies of executed B-FRM-QC-0013 Environmental Monitoring Sampling Assessment forms as evidence of compliance. However, we have not received your supporting documentation to review. Your 2024-Q4 response dated January 31, 2025, stated you completed twenty-six assessment forms, but you will not provide them until **(b)(4)**. This observation affects multiple lots of drug products intended to be sterile. This is a repeat violation that was discussed with you during the May 4, 2023, regulatory meeting regarding failure by your firm to establish an adequate system for monitoring environmental conditions in aseptic processing areas.

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).]

Regarding issues related to the conditions of section 503B of the FDCA, we are unable to fully evaluate your corrective actions due to lack of adequate supporting documentation. Specifically, you state that your firm will "transition to standard minimum orderable quantities ("MOQs") which will allow for standard packaging configuration…This would allow for issuance and reconciliation of standard secondary packaging labels prior to the close out of the associated batch record and subsequent release of the product." However, you state that "**(b)(4)**."

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.

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

Repeat Violations at Facility

At a regulatory meeting held on May 4, 2023, FDA discussed similar CGMP violations. You proposed specific remediation for these violations in your response. Repeated failures demonstrate that executive management oversight and control over the manufacture of drugs is inadequate.

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 address 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 violations, as well as copies of related documentation. This letter notifies you of our concerns and provides you an opportunity to address them. If you believe 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.

All correspondence should refer to the Warning Letter Number above (# 700962). and include a subject line that clearly identifies the submission as a Response to Warning Letter. If you have questions regarding the contents of this letter, please contact compoundinginspections@fda.hhs.gov.

Sincerely,
/S/

F. Gail Bormel, JD, RPh
Director
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research

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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 The specific products made by your firm are drugs within the meaning of section 201(g) of the FDCA [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.

4 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).