WARNING LETTER

Empower Clinic Services, LLC dba Empower Pharmacy

MARCS-CMS 700964 — APRIL 02, 2025

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Delivery Method:

Via Electronic Mail - Delivery and Read Receipt Requested

Product:

Drugs

Recipient:

Jules D'Souza

Director of Quality

Empower Clinic Services, LLC dba Empower Pharmacy

7601 N Sam Houston Pkwy W Ste 100

Houston, TX 77064-3595

United States

Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

WARNING LETTER WL # 700964

April 2, 2025

Dear Mr. D'Souza:

From September 24, 2024, to October 4, 2024, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Empower Clinic Services, LLC dba Empower Pharmacy, located at 7601 N Sam Houston Pkwy W Ste 100, Houston, TX 77064. During the inspection, the investigators noted serious deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on October 4, 2024. FDA acknowledges receipt of your facility's responses, dated October 28, 2024, and January 31, 2025. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (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)].

B. Violations of the FDCA

Adulterated Drug Products

The 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 that:

1. Your firm failed to perform adequate routine environmental monitoring. Specifically, your cleanroom certification consists of nonviable airborne particulate and viable airborne particulate sampling of locations surrounding your **(b)(4)** filling line, but does not include sampling within the critical area where aseptic processing occurs.

2. Your media fills were not performed under the most challenging or stressful conditions. Therefore, there is a lack of assurance that your firm can aseptically produce drug products within your facility.

3. Your firm failed to appropriately sterilize equipment located in the ISO 5 area. Specifically, your firm did not sterilize the stopper sorting bowl, supply hopper, and insertion station that come into contact with stoppers used in the production of injectable drug products.

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.

C. Corrective Actions

We have reviewed your firm's responses to the Form FDA 483. Regarding your response related to the insanitary conditions, some of your corrective actions appear adequate; however, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. Regarding your certification of your ISO-5 filling room (Room 1267), your response makes reference to sampling in accordance with ISO standard 14644-1:2015. However, we note that the nonviable particulate sampling conducted during your April 2024 and October 2024 certifications did not conform to this standard in that the sampling locations did not appear to be divided across the whole cleanroom and did not appear to be of equal area. In addition, ISO standard 14644-1:2015 states that sampling locations are to be representative in that features such as cleanroom layout as well as equipment disposition be considered and that additional sampling locations may be selected for locations considered critical.

Within Room 1267, your **(b)(4)** filing line area is the most critical because sterilized drug product, containers, and closures are exposed to environmental conditions that must be designed to maintain product sterility. The exposed product is vulnerable to contamination as it will not be subsequently sterilized in its immediate container. One significant aspect of environmental quality is the particle content of the air as particulates can enter a product as an extraneous contaminant and can also act as a vehicle for microorganisms.

We acknowledge your commitments that, “the certification procedure will be updated to include assessments of both viable and non-viable air samples within the filler. Additionally, A-SOP-SCP-0013 Environmental Monitoring—Aseptic Suite will be amended to include **(b)(4)** air-viable sampling at critical locations within the ISO-5 environment during dynamic operations.”

Regarding your established environmental monitoring alert and action levels, your response states that your ISO 5 surface sampling action level will remain at greater than or equal to **(b)(4)** CFU. Please note that any microbial contamination in the ISO 5 area is a serious concern and considered an insanitary condition. If any recovery occurs within the critical aseptic processing area, you should immediately assess the impact on drug products produced. This assessment should include a thorough evaluation of how contamination could have entered this critical area, and over what period of time the contamination could have existed, as well as drug products that remain on the market that could have been affected.

2. Regarding your media fills, we acknowledge your commitments to expand your media fill batch sizes and strengthen your personnel qualification as well as revise your existing procedures. However, it is unclear when you plan to conduct media fills within your ISO 5 filling machine in Room 1267 as you did not provide completed media fills according to the recent changes outlined in Protocol – B&S Process Verification Media Fill.

3. We reviewed your **(b)(4)** validation for sterilizing the stopper sorting bowl, supply hopper, and insertion station and acknowledge your process improvements. In your response you stated that, “Empower has also implemented a **(b)(4)** schedule for the stopper sorting bowl and associated components to improve sterility assurance while awaiting additional spare parts.” It is unclear how you determined the adequacy of “a **(b)(4)** schedule” to ensure the equipment remains sterile. We remain concerned with your continued injectable drug production while lacking assurance that equipment, which comes into contact with product contact components, is sterile.

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.

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.

D. 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.

Your response and any questions regarding the contents of this letter should be sent to compoundinginspections@fda.hhs.gov. In your response, refer to the Warning Letter Number above # 700964 and include a subject line that clearly identifies the submission as a Response to Warning Letter.

Sincerely,
/S/

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