VIA ELECTRONIC MAIL
READ/DELIVERY RECEIPT REQUESTED

November 21, 2025

John E. Streger, President and CEO
LeeSar, Inc.
2727 Winkler Avenue
Fort Myers, FL 33901-9358

Dear Mr. Streger:

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 April 30, 2014, and most recently on December 19, 2024. From April 29, 2025, to May 9, 2025, an FDA investigator inspected your facility, LeeSar, Inc. located at 2727 Winkler Avenue, Fort Myers, FL 33901. 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. In addition, the investigator noted 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 May 9, 2025. FDA acknowledges receipt of your facility's response, dated June 2, 2025. 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]

[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.

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)]).

Specific violations are described below.

B. Failure to Meet the Conditions of Section 503B

During the inspection, an FDA investigator noted that drug products produced by your facility failed to meet the conditions of section 503B. For example, the investigator noted that some of your facility's drug products, such as Diltiazem HCl 125mg added to Dextrose 5% 100mL (1mg/mL), Lidocaine HCl 2% Solution 60mg/3mL (20mg/mL), and Phenylephrine HCl 40mg added to NaCl 0.9% 250mL (160mcg/mL), did not include the following statements on the label: the established name of the drug as required by section 503B(a)(10)(A)(iii)(II) of the FDCA.

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

An FDA investigator 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 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).

2. Your firm failed to establish adequate written responsibilities and procedures applicable to the quality control unit and to follow such written procedures (21 CFR 211.22(d)).

3. Your firm failed to maintain written records so that the quality standards of each drug product can be evaluated at least annually to determine the need for changes in drug product specifications, manufacturing, or control procedures (21 CFR 211.180(e)).

4. Your firm's quality control unit did not review and approve written procedures for production and process control, including any changes to them, designed to ensure that the drug products you manufacture have the identity, strength, quality, and/or 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.

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.

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.[3] Further, it is 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.

[3] 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).

D. Corrective Actions

We have reviewed your facility's response to the Form FDA 483.

Some of your corrective actions appear deficient:

1. Regarding your failure to fully investigate the out-of-specification pH result for Azithromycin 500mg in 250mL Dextrose 5% IV Bag before release and distribution, your firm plans "to reopen UDR2025-02 for a comprehensive validation of Azithromycin pH to fully demonstrate the product complies with USP pH specifications and the measured pH of the product in its final diluted form in 5% dextrose demonstrated expected and scientifically justified behavior." However, your firm has not completed formal studies to demonstrate that the increased pH does not compromise the drug product's stability.

2. Regarding the pH range for Azithromycin 500mg in 250mL Dextrose 5% IV Bag, which was listed as (b) (4) during the inspection, it was noted that this pH range falls outside of compendial specifications. You have not provided adequate justification for expanding the pH specification to (b) (4), nor adequate data to demonstrate that the higher pH would not increase the risk of degradation or impurity formation in the product formulation.

We are unable to fully evaluate some of your corrective actions due to the lack of adequate supporting documentation:

1. Regarding your outdated written procedure 6-27 rev 01 "Quality Assurance Program" that did not reflect current operations, you removed the potency testing requirement from your SOP and updated your "Product Release Specifications" form to include the missing Dexmedetomidine specifications. However, you did not provide evidence that you conducted a comprehensive evaluation of other SOPs to ensure they reflect current practices, and you do not have an established procedure for regular SOP review and updates to prevent similar discrepancies.

2. Regarding your failure to maintain written records for annual product reviews of your aseptically produced drug products, you created a new SOP detailing what will be included in annual product reviews. However, you did not provide training records for the new procedures.

3. Regarding your failure to establish written procedures for production and process controls, including a lack of a change control program to define and describe how to properly document and evaluate changes within your processes, you stated that changes to procedures included "training of the impacted personnel with manual signatures of each employee after being trained on a new written procedure." However, training records or documentation demonstrating that personnel were trained on the newly implemented "Change Control Program" SOP 6.33 rev 00 were not submitted.

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).]

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.

Within thirty (30) 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 thirty (30) working days, state the reason for the delay and the time within which you will do so.

All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. If you have questions regarding the contents of this letter, please contact compoundinginspections@fda.hhs.gov.

Sincerely,

Frances G. Bormel -S

Digitally signed by Frances G. Bormel -S
Date: 2025.11.21 14:05:54 -05'00'

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