DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Florida District Office 555 Winderley Place Suite 200 Maitland, FL 32571 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	September 08, 09, 10, 11, 14, 15, 16 and 23, 2026
	FEI NUMBER 3010166880

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: John E. Streger, President & CEO

FIRM NAME	STREET ADDRESS
LEESAR, INC.	2727 Winkler Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Fort Myers, Florida 33901	503B Outsourcing Facility

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1:

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, you failed to properly maintain the equipment inside the ISO 5 classified areas of your (b)(4) Compounding Systems. During the inspection of the (b)(4) systems located in (b)(4) Room Suite (b)(4) Room Number (b)(4) the following conditions were observed:

1. On 09/09/2026, what appeared to be rust and chipping paint was observed at the fixed base of the (b)(4) inside the ISO 5 classified area of (b)(4), and at the junction between the fixed base and rotating section of the (b)(4) In addition, on 09/10/2026, a reddish-colored seal at the base of the (b)(4) appeared to have been coated with paint after the base was repainted.

2. On 09/09/2026, what appeared to be extensive rust and chipping paint was observed at the fixed base of the (b)(4) inside the ISO 5 classified area of (b)(4), including significant deterioration and corrosion at the junction where the (b) (4). In addition, on 09/10/2026, a reddish-colored seal at the base of the (b)(4) appeared to have been coated with paint after the base was repainted.

On 09/09/2026, you were observed manufacturing Oxytocin 30U into 500mL 0.9% NaCl IV Bags, Lot # OXYT3020260909, in both (b)(4) and (b)(4). In addition, from 08/24/2026 to 08/26/2026, (b)(4) were used to perform sterile manufacturing operations for:

- Heparin Sodium 5000U into 500mL 0.9% NaCl IV Bags, Lot # HEPA500020260824, and
- Phenylephrine HCL 40mg into 250mL 0.9% NaCl IV Bags, Lot #s PHEN4020260824, PHEN4020260825 and PHEN4020260826.

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OBSERVATION 2:

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

Specifically, your firm's environmental monitoring (EM) program does not adequately address the identification, evaluation and corrective actions that should be taken for microorganisms recovered in your facility. For example,

A. As per SOP 6.22 rev 04 Environmental Monitoring Program, you have established microbial contamination alert and action limits for air and surface sampling performed in your classified areas and personnel monitoring that are not appropriate for ISO 5 classified areas. Surface sample alert ((b)(4) CFU) and action ((b)(4) CFU) levels permit recovery of microorganisms in critical ISO 5 areas, including the (b)(4) containment cells and vestibules, without warranting a formal investigation, corrective action, or preventive measure. Samples from ISO 5 environments should yield no microbiological contaminants, and any recovery in these critical areas should prompt a formal investigation and corrective action.

B. Your firm has not conducted a risk assessment of your facility to justify the sampling locations of your environmental monitoring nor have you identified microorganisms that may be considered objectionable.

C. Your firm has failed to adequately identify and investigate the recurring recovery of the endospore-forming microorganism Bacillus spp. during environmental and personnel monitoring activities in ISO 5, 7, and 8 classified areas. Between August 2025 and May 2026, your firm documented at least 17 monitoring excursions involving Bacillus spp. across six (6) separate investigations. The majority of these excursions, 13 of (b)(4) samples were repeatedly associated with (b)(4) monitoring of the same (b)(4) with CFU counts as high as >100 CFU. The other excursions were documented at surface and active air monitoring locations, including ISO 5 (b)(4) vestibule sites and the ISO 7 (b)(4) Room, with counts reaching 50 CFU. Despite your firm's repeated classification of these events as "low" risk, the continued and recurring recovery of Bacillus spp. over at least nine months is inconsistent with your conclusion that environmental and cleaning controls remain effective. Additionally, your firm's failure to identify Bacillus spp. isolates beyond the genus level prevents adequate assessment of pathogenic potential, determination of a common strain, and evaluation of the effectiveness of corrective actions.

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D. Your firm is not trending the microbiology data from your routine monitoring to evaluate the significance of environmental isolates recovered during routine monitoring to assess your process controls, including the effectiveness of your cleaning procedures. The failure to trend this data could have contributed to your firm's inability to recognize the escalating pattern of Bacillus spp. recoveries documented between August 2025 and May 2026 and to implement timely and effective corrective actions in response.

OBSERVATION 3:

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. Your firm's Quality Unit (QU) failed to exercise adequate oversight and did not implement appropriate corrective and preventive actions in response to microbial contamination recovered within the (b)(4) ISO 5 containment cell. On 10/25/2025, surface sample(b)(4) from (b)(4) yielded 1 CFU identified as Serratia marcescens, a gram-negative opportunistic pathogen with known clinical significance. This recovery was documented under deviation UDR 2025-10 and classified as an out-of-trend (OOT) statistical outlier, within established EM alert and action limits. The QU classified this event as major yet assessed the risk as minimal. The QU approved the investigation's conclusion that the probable root cause was "contaminated material introduced during compounding," despite the investigation explicitly noting that these materials were "discarded prior to deviation detection and unavailable for testing." The QU approved the conclusion that the event was a "sporadic environmental contamination" and that "no further corrective actions are required at this time." The QU failed to ensure systemic actions were implemented to prevent recurrence; the only action taken was voluntarily discarding (b) (4) units of Norepinephrine 8mg in 0.9% NaCl 250mL bag Lot#(b) (4) compounded in (b)(4) during the affected production period.

B. Your firm issued SOP 6.34 rev 00 Annual Product Review Procedure on 05/30/2025 but has not conducted annual product reviews for 16 of the (b) (4) drug products compounded at your facility for calendar year 2025. Additionally, this procedure is inadequate as it defines that "an APR shall be prepared for the product for which more than (b)(4) batches are compounded during the calendar year" instead of for each drug product compounded within the year.

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C. Your quality unit is not adequately reviewing the (b)(4) compounding unit service reports for any discrepancies nor providing oversight of maintenance work performed on these units. This failure undermines your firm's ability to assure that critical sterile manufacturing equipment is properly maintained and in a state of control. For example, the Preventative Maintenance (b)(4) Check List for (b)(4) dated 04/01/2025, document a system failure and reference service case #67084 as the corrective service performed. However, service case #67084 is associated with service performed on 02/16/2024 for (b)(4), a unit located at a different, unaffiliated manufacturing facility in Temple Terrace, Florida and not at your facility. This discrepancy raises significant concerns about whether the documented corrective maintenance was actually performed on your equipment. Despite having nine days to review this record, your quality unit signed off on the service reports on 04/10/2025 without identifying this critical discrepancy, demonstrating that the review was not conducted with adequate scrutiny. Refer to Inspectional Observation 7C.

D. As per SOP 6-13 rev 03 Receiving Procedure, your quality assurance team is responsible for reviewing and signing the certificate of analysis for all incoming finished drug product vials used in the compounding and repackaging of your finished drug products for conformance to specifications. However, your quality department failed to identify the discrepancy between the manufacturer's specifications and your repackaged finished drug product's specifications for repackaged Dexmedetomidine HCl 20 mcg/5 mL syringes. The Dexmedetomidine HCl manufacturer's COA specifies an assay acceptance criterion of (b)(4) of label claim; however, your firm applies a substantially wider acceptance criterion of (b)(4) for the repackaged product. This wider specification lacks scientific justification and has resulted in the release of drug product with potency results outside the manufacturer's defined range. This discrepancy was not identified by your quality unit and when it was brought to your quality unit they confirmed that they were unaware of the variability.

E. Your firm does not have a defined procedure, documentation or verification for changing the beyond-use-date that is (b)(4) altered on an approved template in the (b)(4) system. For example, the beyond-use-dates for Dexmedetomidine HCl 20 mcg/5 mL are dependent on the manufacturer source and must be (b)(4) altered in the (b) (4) system template. Your firm does not maintain a written procedure with defined instructions for personnel to follow when making such changes, and had no evidence of a (b)(4) verification step to confirm that the correct BUD had been entered. The absence of procedural controls, documentation, and independent verification for this (b)(4) process creates significant risk of error, including the assignment of incorrect or unsupported BUDs to compounded drug products distributed to patients.

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OBSERVATION 4:

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, your firm has established the Beyond-Use-Dates for repackaging finished drug product Dexmedetomidine HCl 20 mcg/5 mL into 10mL syringes based on assay specifications outside the defined manufacturer's specifications. Your firm has assigned BUDs of (b)(4) days at Controlled Room Temperature (CRT) and (b)(4) days under refrigerated conditions for this repackaged product but do not have data to support these timeframes. For example, the following technical study lots failed potency testing as per the manufacturer's specifications:

- Room temperature Lot (b)(4) compounded 02/08/2026, reported assay result of 89.7% on Day (b)
- Room temperature Lot compounded 02/09/2026, reported assay result of 92.6% on Day (b)
- Refrigerated Lot (b) (4), compounded 04/15/2026, reported assay result of 93.4.% on Day (b) (4)
- Refrigerated Lot (b) (4) compounded 04/16/2026, reported assay result of 88.4% on Day (b) (4)

Furthermore, the commercially distributed Lot #DEXM2020260204 compounded on 02/04/2026, reported an assay result of 93.4% on Day (b) (4) outside the manufacturer's defined specification of (b)(4) Additionally, the assay test method used by your contract laboratory for Dexmedetomidine HCl has not been validated, refer to Inspectional Observation 6A.

OBSERVATION 5:

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. Specifically,

A. Your firm established a pH specification of (b)(4) as of 08/19/2022 for finished compounded drug product Azithromycin 500mg in a 250mL Dextrose 5% IV Bag but expanded the specification to (b)(4) on 12/03/2025 without adequate scientific justification or any supporting data.

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B. Your firm is not using the finished drug manufacturer's defined assay specifications for repackaged Dexmedetomidine HCl 20 mcg/5 mL syringes and applies a wider acceptance criteria without adequate scientific justification. The finished drug manufacturer's Certificate of Analysis (COA) specifies an assay acceptance criterion of (b)(4) of label claim; however, your firm applies an acceptance criterion of (b)(4) -

As a result of this unjustified wider specification, Dexmedetomidine HCl 20 mcg/5 mL syringes have been released with potency results outside the manufacturer's specifications. For example, Lot #DEXM2020260204, compounded 02/04/2026, reported an assay result of 93.4% on 02/11/2026 ((b)(4) days before the assigned BUD), which is outside the manufacturer's defined range of (b)(4) but was accepted under your firm's broader internal criterion and the batch was released.

OBSERVATION 6:

The accuracy, sensitivity, specificity, reproducibility of test methods have not been established and documented.

Specifically,

A. The assay method used to test the repackaged drug product Dexmedetomidine HCL 20 mcg/5 mL has not been validated. Documentation, QUF-414-V1 Certificate of Analysis dated 08/07/2026, obtained from your contract testing laboratory indicates that the potency method used met system suitability requirements under a non-cGMP analysis protocol, and that product-specific method validation was not performed for the sample. The contract laboratory further noted that the reported specifications were provided for informational purposes only, and that your firm bears responsibility for verifying that the specification and analyte reported are appropriate for the product being tested. Your firm was unable to provide any evidence demonstrating that the method used to test this product has been appropriately validated.

B. Your firm outsources your finished drug product sterility testing to a third-party laboratory who performs an ATP-bioluminescent method. Since August 2025, an established method USP <73> has been implemented but you do not have evidence to demonstrate that the laboratory's ATP-bioluminescent method is equivalent to USP <73>

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ATP bioluminescence-based microbiological methods for the detection of contamination in short-life products. Additionally, you do not have evidence to demonstrate that this method is capable of identifying organisms that have been in recovered in your facility including Serratia marcescens.

OBSERVATION 7:

Written procedures are not established or followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

A. Your (b)(4) cleaning procedures are deficient since they fail to define the use of a sporicidal agent to clean and disinfect the ISO 5 vestibule areas of your (b)(4) Compounding Systems which operators use to clean components, containers and closures prior to loading them into each (b)(4) System. Your cleaning procedure only includes a cleaning log which states "(b) (4) the vestibules with (b) (4) ." Your procedure does not require operators to use a sporicidal cleaning agent as part of your cleaning process for the ISO 5 vestibules. During environmental monitoring activities on 05/15/2026, you recovered the endospore-forming microorganism Bacillus spp in the ISO 5 (b)(4) vestibule and the ISO 5 (b)(4) vestibule. Your procedures do not require the use of sporicidal agents to ensure the ISO 5 vestibules are free from endospore-forming microorganisms.

B. Your (b)(4) cleaning procedures are deficient since they fail to define the process operators are required to follow when cleaning and disinfecting the ISO 5 vestibule areas of your (b)(4) Compounding Systems which operators use to clean components, containers and closures prior to loading them into each (b)(4) System. Your contract service company (b)(4) provided a cleaning method for operators to follow to properly clean each ISO 5 vestibule. Your cleaning procedure does not include the manufacturer's recommended cleaning process and only includes a cleaning log which states (b) (4) the vestibules with (b) (4) ." Your procedures do not define the method operators need to follow to ensure each ISO 5 vestibule is properly cleaned per the manufacture's recommendations.

C. You failed to follow your maintenance procedures prior to performing manufacturing operations inside the ISO

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5 classified areas of your (b)(4) Compounding Systems. Your procedures require a contract (b)(4) to perform (b)(4) and (b)(4) preventive maintenance activities for all (b)(4) systems, and to sign and date a preventative maintenance checklist when all activities are completed. If any of the checklist steps fail, the (b) (4) Field Service Engineer indicates the failure on the checklist and documents the service case number for the service performed to correct the issue on the checklist. Your preventative maintenance checklists do not accurately represent the work performed on your (b)(4) Compounding Systems. For example,

• The Preventative Maintenance (b)(4) Check List for (b)(4) dated 04/01/2025, shows "Section 4 – Checking and Calibration of the PDS" failed the preventative maintenance check. The (b) (4) Field Service Engineer referenced service case number 67084 on the checklist. The report for service case number 67084 is for service performed on 02/16/2024 for (b)(4), a (b)(4) located in a different, unaffiliated manufacturer's facility located in Temple Terrace, Florida.

OBSERVATION 8:

The persons double-checking the cleaning and maintenance are not dating, signing or initialing the equipment cleaning and use log.

Specifically, you failed to verify that the cleaning operations for your (b)(4) s and (b)(4) cleanrooms were performed at the time cleaning operations were conducted. Your Good Documentation Practices procedure requires critical steps or operations to be verified by a second person, and for the second person to sign/initial and date when the operation is performed indicating the second person observed/witnessed the entire step or operation. Your (b)(4) cleaning records, and (b)(4) Room cleaning records require operators who perform cleaning operations to complete, sign/initial and date each form. The forms also require QA to verify each cleaning operation was performed by also signing/initialing and dating each form. Multiple instances were observed on your cleaning records where the QA verifier initialed and dated the cleaning records days after the cleaning operations were performed. The QA verifier failed to initial and date the forms at the time cleaning operations were conducted. For example,

• On 08/25/2026, operators cleaned (b)(4) and (b)(4) as well as (b)(4) Room (b)(4) and

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(b)(4) Room (b)(4) where the (b)(4) are located. The cleaning records for the (b)(4) and (b)(4) Rooms were not verified by QA until 08/31/2026.

• On 08/26/2026, operators cleaned (b)(4) and (b)(4) as well as (b)(4) Room (b)(4) and (b)(4) Room (b)(4) where the (b)(4) are located. The cleaning records for the (b)(4) and (b)(4) Rooms were not verified by QA until 08/31/2026.

OBSERVATION 9:

Samples of representative units were not visually examined for correct labeling at the completion of finishing operations.

Specifically, you failed to visually inspect representative samples of your finished drug products to ensure they contain the correct labeling. Your Visual Inspection Program requires 100% visual inspection of your syringe and IV bag drug products for defects such as leaks, particles, metal, fiber and hair. Inspectors document the results of their inspection on Visual Inspection Worksheets which are included with each product's batch manufacturing record. Your procedure does not require inspectors to perform a visual inspection of finished drug products for the correct labeling. Your Visual Inspection Worksheets also do not show finished product labeling is visually examined, including the worksheets for Heparin Sodium 5000U into 500mL 0.9% NaCl IV Bags, Lot # HEPA500020260824, and Phenylephrine HCL 40mg into 250mL 0.9% NaCl IV Bags, Lot #s PHEN4020260824, PHEN4020260825 and PHEN4020260826.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."