DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	7/3/2017-7/12/2017* FEI NUMBER 3010166880

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Robert A. Simpson , President/CEO

FIRM NAME	STREET ADDRESS
LEESAR, INC	2727 Winkler Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Myers, FL 33901-9358	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, the firm uses non-sterile cleaning agents for all (b) (4) (ISO 5), (b) (4) (b) (4) Room (ISO 7), and (b) (4) Room (ISO 8) on a routine basis.

OBSERVATION 2

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

Specifically, on 07/03/2017, we observed your pharmacy technicians gathering drug components and supplies, located outside the ISO 5 area, without changing or sanitizing their gloved hands (b) (4) times while loading and unloading your firm's (b) (4) (regulated as a Class II medical device by FDA), (b) (4) systems that maintain ISO-5 environments.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	June P Page, Investigator Jennifer Lalama, Investigator Justine Tomasso, Investigator Ian F Deveau, FDA Center Employee or Employee of Other Federal Agencies	X June P Page Investigator Signed By: 2000405709 Date Signed: 7/12/2017	7/12/2017

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Specifically,

1. Your firm failed to open investigations for 3,855 rejections in 2016 and 2,278 rejections in 2017 by your firm's (b) (4) injectable drug compounding systems.
    a. Your firm relies on the (b) (4) compounding system's internal weigh balance to perform an accurate (b) (4) to achieve the intended concentration.
        i. In 2016: 2,286 rejections occurred for weight errors or invalid dosing volume, resulting in 59.30% of all rejections.
        ii. In 2017: 1,511 rejections occurred for weight errors or invalid dosing volume, resulting in 66.33% of all rejections.
2. Your firm failed to adequately investigate 3 related complaints for mislabeled product that was released by your quality unit.
    a. On 12/21/2015, your firm received a complaint regarding twenty-four (24) Vancomycin bags labeled with two different strengths of Vancomycin on the same bag.
    b. On 03/22/2016, your firm received a complaint regarding one (1) Vancomycin bag labeled with two different strengths of Vancomycin on the same bag.
    c. On 6/15/2017, your firm received a complaint regarding nine (9) bags of Heparin 10,000u were found to be mislabeled with Diltiazem 125mg/125ml.
3. Your firm failed to open an investigation regarding rejected products found in your quarantined area.
4. Your firm failed to adequately investigate the microbial growth found during the environmental monitoring of your personnel and aseptic operations area.
5. Your firm failed to adequately investigate sterility failures conducted by your contract laboratory. For example, the following investigations conducted by your firm concluded the

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failures were induced during the (b) (4) process at the laboratory, without evidence and no root cause was identified:

a. On 08/14/2014, your firm received a sterility test failure on aseptically produced campaign batches of Amiodarone 900MG at day (b) (4) identified as *Bacillus pumilus/safenis* by your contract laboratory, which impacted batches AMIO-05-AUG-14 and AMIO-06-AUG-14.
b. On 08/01/2015, your firm received a turbid sample on aseptically produced campaign batches of Amiodarone 900MG, identified as *Bacillus simplex* and impacted batches AMIO-13-APR-15 and AMIO-14-APR-15.

OBSERVATION 4

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

THIS IS A REPEAT OBSERVATION

Specifically,

1. Airflow studies performed under dynamic conditions did not follow the vendor's written protocol.
2. The airflow studies performed since the last FDA inspection were deficient in determining if the processing equipment does not alter or impede the unidirectional cascade of air from the HEPA filters to the ISO 5 classified area where sterile drug products are manipulated.
3. Room certifications conducted for 2015 and 2016 did not account for the increase from (b) (4) personnel performing aseptic operations in the ISO 7 area.

OBSERVATION 5

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The establishment of laboratory control mechanisms including any changes thereto, are not reviewed and approved by the quality control unit.

Specifically, your firm's visual inspection process is deficient.

1. On 07/03/17, we observed your quality assurance personnel (b) (4)Hydromorphone 50mg added to 0.9% NaCl Bag 250 mL, Lot HYDRO-23-JUN-17, during the visual inspection process.
2. Thirty-four (34) mislabeled products, from 3 separate lots, failed to be detected by your firm's visual inspection process.
3. The visual inspection of finished products for particulate matter is not conducted against a contrasting background or adequate lighting to optimize the viewing conditions.
4. Labels affixed to your final product limit the visual inspection process.

***DATES OF INSPECTION**

7/03/2017(Mon),7/05/2017(Wed),7/06/2017(Thu),7/07/2017(Fri),7/10/2017(Mon),7/11/2017(Tue),7/12/2017(Wed)

X Jennifer Lalama
Investigator
Signed By: Jennifer Lalama -S
Date Signed: 7/12/2017

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

June P Page, Investigator
Jennifer Lalama, Investigator
Justine Tomasso, Investigator
Ian F Deveau, FDA Center Employee or Employee of Other Federal Agencies

X June P Page
Investigator
Signed By: 2000405709
Date Signed: 7/12/2017

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7/12/2017

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Date: September 14, 2017

Mr. Robert A. Simpson
LEESAR, INC
2727 Winkler Ave
Fort Myers, FL 33901-9358

Subject: System Notification

Dear Mr. Robert A. Simpson,

We are notifying you that due to a technical error related to a software update, the FDA Form 483 you received recently inadvertently included a sentence meant only for medical device firms. That statement says, "Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

This statement refers to quality system requirements applicable only to medical device establishments, but was inadvertently included on certain Form 483's issued to non-device establishments for a brief period of time. Please note that the statement has no bearing on the inspection observations themselves, which remain applicable as of the date that you were issued the Form FDA 483.

Should you have any questions, please send to AskORAIT@fda.hhs.gov.

Sincerely,

Lisa Creason
Director, Office of Information Systems Management
Office of Regulatory Affairs
Food and Drug Administration