DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/4/2020-3/11/2020* FEI NUMBER 3009571102

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christine A. Givant, Co-Owner and Pharmacist in Charge

FIRM NAME	STREET ADDRESS
La Vita Compounding Pharmacy, LLC	3978 Sorrento Valley Blvd Ste 300
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92121-1436	Producer of Sterile and Non-Sterile Drugs

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 WE OBSERVED:

OBSERVATION 1

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, the firm purchases Methylcobalamin active ingredient from (b) (4) for use in the production of Methylcobalamin solution for injection. The firm has purchased and used (b) (4) lots of this active ingredient that lacks a description of grade. These ungraded active ingredient batches were used in the production of (b) (4) finished product batches:

(b) (4)

OBSERVATION 2

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, on 3/9/20 we observed Sterile Technician (b) (6) gowning. The sleeves of the cleanroom suit (non-sterile) came in contact with the floor of the ISO 8 ante room. The technician proceeded to enter the ISO 5 zone and produce Methylcobalamin batch 183570@8 BUD 9/5/20. Uncovered and non-sanitized sleeves were observed within the ISO 5 space.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Zachary A Bogorad, Investigator Nathaniel B Phillips Sylvain, Investigator	X Zachary A Bogorad Investigator Signed By: Zachary A. Bogorad -S Date Signed: 03-11-2020 15:09:57	3/11/2020

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OBSERVATION 3

The ISO 5 classified aseptic processing areas had particle-generating and visibly dirty equipment or surface.

Specifically, the following equipment conditions were observed within the ISO 7 buffer room containing the ISO5 zone:

1. Rust-like discoloration below the seat of the chair at the ISO 5 LAFH. As well, white specks were observed on the seat of the chair on 3/4/20 while the room was in a cleaned status.

2. Rust-like discoloration of the garbage can was observed across all surfaces. The can is positioned within approximately 6 inches of the ISO 5 LAFH.

3. Extensive cracks are present on the (b) (4) of the (b) (4) the ISO 7 buffer room and the ISO 8 ante room respectively. More than four cracks pass through the entire depth of the (b) (4) The (b) (4) is constructed of composite board with a plastic sheet coating glued together. All materials entering the ISO7 buffer room (b) (4) . The (b) (4) the (b) (4) composite boards to (b) (4) .

OBSERVATION 4

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area adjacent to the ISO 5 classified aseptic processing area during aseptic production.

Equipment within or in close proximity to the ISO 5 area could compromise the area in the ISO 5 area. Specifically, you keep a (b) (4) in the ISO 7 buffer room. During the cleanroom recertification activity on 1/25/19 third party cleanroom certification business (b) (4) identified an airborne viable environmental monitoring OOS (15 CFU) at location (b) (4) corresponding to the (b) (4) . The PIC identified a preventative action of not permitting the operation of the (b) (4) during cleanroom recertification activities and a

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corrective action of cleaning and re-sampling the environment of the classified spaces. You have failed to investigate and eliminate the identified potential source of air contamination in the ISO 7 buffer room, background to the ISO 5 LAFH.

***DATES OF INSPECTION**
3/04/2020(Wed), 3/05/2020(Thu), 3/06/2020(Fri), 3/09/2020(Mon), 3/10/2020(Tue), 3/11/2020(Wed)

X

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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 judgment, 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."