

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 6/4/2018-6/8/2018
	FEI NUMBER 3009571102

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Chris A. Givant, RPh., Pharmacist-in-Charge and Co-Founder

FIRM NAME La Vita Compounding Pharmacy, LLC	STREET ADDRESS 3978 Sorrento Valley Blvd Ste 300
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CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92121-1436	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile and Sterile Drug Products
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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 OBSERVED:  
OBSERVATION 1**

Your firm produced drugs while construction was underway in an adjacent area without adequate controls to prevent contamination of the production environment and product.

Specifically,

Your firm produced non-sterile and sterile drugs while construction was underway in an adjacent area to (b) (4). Controls and cleaning frequency may not be adequate to prevent contamination of the production environment and product. Dust was observed in the ISO7 lab.

Entry to your non-sterile lab comes directly from a carpeted hallway and entry to the ISO controlled areas comes directly from the non-sterile lab directly adjacent to the new construction. There is construction containment in the hallway. An unused door in the non-sterile lab that leads directly to the new construction area was unsealed. There was no indication of carpet cleaning and no protective devices to prevent contamination from the carpet into the non-sterile lab

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Roger F Zabinski, Investigator	DATE ISSUED 6/8/2018
	<p align="center"> <small>Roger F Zabinski Investigator Signed By: Roger F. Zabinski -S Date Signed: 06-08-2018 11:47:09</small>  X _____ </p>	

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Your firm has multiple dogs as pets on site in the offices of the co-founder/business manager and the co-founder/pharmacist-in-charge. Both offices have plastic guard rails to contain the dogs and both offices are at ends of the carpeted hallway that leads to the labs.

**OBSERVATION 2**

Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically,

The ISO classified aseptic processing areas had difficult to clean, particle generating and visibly dirty equipment or surface. On 6/4/18 and 6/6/18 I observed that your ISO-8 ante-room and ISO-7 Cleanroom have ceiling tiles that are not sealed, have gaps between the tiles, and not impermeable to prevent dust or microbial contamination of the ISO7 room and ISO5 hood. The plastic cover of the light fixture directly above the ISO-5 hood had two broken and missing corners. This could contribute to dust and insanitary condition in the ISO controlled areas.

**OBSERVATION 3**

The segregated production areas surrounding the ISO 5 classified aseptic processing area contained dust-collecting overhangs without adequate and frequent cleaning.

Specifically,

On 6/4/18 and 6/6/18 I observed that the top of the ISO5 hood, the frame and door of the (b) (4), and the door and rear of the (b) (4) (b) (4) in the ISO7 room had visible dust and dirt.

**OBSERVATION 4**

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Personnel did not disinfect and change gloves frequently enough to prevent contamination.

Specifically,

Your firm uses non-sterile gloves and non-sterile wipes for work in the ISO-8 ante-room, ISO-7 clean-room, and ISO-5 hood. On 6/4/18 and 6/6/18 I observed your sterile compounding technician explain and demonstrate to me her aseptic processing cleaning and production techniques. The technician used non-sterile gloves and non-sterile wipes for cleaning in the ISO7 and ISO8 rooms. The technician then changed and donned sterile gloves to clean inside the ISO-5 hood using non-sterile wipes, water from a container that had been opened and dated 3/07/18, then sterile (b) (4) (b) (4) using non-sterile wipes. The technician left some of the used dirty non-sterile wipes in the ISO-5 hood. She continued to perform activities outside and inside of the ISO-5 hood. She used the same gloves that had been worn during cleaning for the aseptic production work without changing gloves and without frequent disinfecting.

**OBSERVATION 5**

Equipment was not disinfected prior to entering the aseptic processing areas.

Specifically,

a) On 6/4/18 and 6/6/18 I observed the sterile compounding technician explain and demonstrate to me her technique for cleaning, preparing the ISO-7 clean-room and ISO-5 hood, and to perform sterile compounding. She explained more than once that the (b) (4) is not cleaned on the inside except (b) (4) . Some of the equipment and glassware used in sterile processing were transferred from the ISO-8 ante-room, through the (b) (4) , and then to the ISO-5 hood but the glassware was not sanitized on the outside prior to being placed in the ISO5 hood. A 50ml graduate cylinder was taken from a cart in

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the ISO7 room and placed in the ISO5 hood lying down without being sanitized/wiped on the outside. Non-sterile wipes were used to clean the ISO5 hood and left in the hood during aseptic processing.

b) Your firm uses non-medical grade plastic containers to store (b) (4) drug (b) (4) at room temperature with up to a (b) (4) expiration. (b) (4), lot (b) (4) prepared on (b) (4), had an expiration of (b) (4). (b) (4) lot (b) (4) prepared on (b) (4), had an expiration of (b) (4). Your firm does not have container stability data to ensure that the products are stable in these containers.

c) Your firm uses non-medical grade amber plastic bottles for storing (b) (4) for use in non-sterile drug production. (b) (4); lot (b) (4) from (b) (4), had an expiration date of 4/14/19. (b) (4) lot (b) (4) from (b) (4) had an expiration of 9/30/18. (b) (4) listed as lot (b) (4) from (b) (4), had an expiration date of 12/31/2020. (b) (4), lot (b) (4) from (b) (4), had an expiration date of 11/30/19. The date that these liquids were dispensed into the plastic bottles was not listed.

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