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

VIA UPS SIGNATURE CONFIRMED DELIVERY

September 22, 2020

Natasha N. Vo, Pharmacist in Charge
Lifetime Value Pharmacy III, Inc.
301 East 17th Street
Santa Ana, CA 92706-2804

Dear Ms. Vo:

From January 10, 2019 to February 21, 2019, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Lifetime Value Pharmacy III, Inc., located at 301 East 17th Street, Santa Ana, CA, 92706. During the inspection, the investigator noted deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on February 21, 2019. FDA acknowledges receipt of your facility's response, dated March 12, 2019. Additionally, FDA acknowledges your firm's statements that you have voluntarily ceased production of sterile and non-sterile compounded drug products. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].[1]

Specific violations are described below.

[1] 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 503A of the FDCA.

Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road, Irvine, CA 92612-25006
Telephone: (949) 608-2900
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B. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator observed that:

1. The classified areas had difficult to clean, particle generating and visibly dirty equipment and surfaces, including spattering of a dried red/brown substance and yellow residue on the plexiglass inside the ISO 5 classified Laminar Airflow Hood (LFH). There was also not easily cleanable porous foam material between the walls and ceiling of the ISO 5 LFH.

2. There were unsealed, loose ceiling tiles and recessed lights in the ISO 7 clean room, approximately 10 feet from the opening to the ISO 5 LFH, where your firm compounded sterile drug products. These gaps may allow for the accumulation of viable and non-viable particles that could render your drug products adulterated.

3. There was nonmicrobial contamination, including dried fluids and dirt tracks on the floor in your ISO 8 buffer room and ISO 7 production area, near the ISO 5 LFH where your firm compounded sterile drug products and the powder hood where your firm compounded non-sterile drug products.

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.

C. Corrective Actions

We have reviewed your firm's response to the Form FDA 483. We acknowledge that you voluntarily ceased production of sterile and non-sterile drug products. If you decide to resume sterile and/or nonsterile compounding, we request that you inform the FDA.

You did not address observations related to the insanitary conditions, for example:

1. Your response did not provide corrective actions for the unsealed, loose ceiling tiles and recessed lights in the ISO 7 clean room.

2. Your firm did not provide documented corrective actions for the visibly dirty and difficult to clean areas within your ISO 5 LFH, ISO 7 clean room and ISO 8 buffer room.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A.

FDA strongly recommends that if you decide to resume production of sterile drugs, your management first undertake a comprehensive assessment of operations including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

D. 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 the violations identified above 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 if you have taken any specific steps to correct the violations cited in this letter, or you may inform us that you do not intend to resume sterile or non-sterile compounding operations. If you intend to resume sterile or non-sterile compounding operations in the future, please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above violated the FDCA, include your reasoning and any supporting information for our consideration. In addition to taking appropriate corrective actions, you should notify this office fifteen (15) working days prior to resuming sterile or non-sterile compounding operations in the future.

Your written notification should reference unique identifier **CMS 607601** and sent via email to ORAPHARM4_RESPONSES@fda.hhs.gov, or mail to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food and Drug Administration
19701 Fairchild Road
Irvine, CA 92612

If you have questions regarding the content of this letter, please contact William V. Millar, Compliance Officer, by telephone at (503) 671-9711 Ext. 30, or by email at william.millar@fda.hhs.gov.

Sincerely,

Katherine E. Jacobitz -S

Digitally signed by Katherine E. Jacobitz -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300153047, cn=Katherine E. Jacobitz -S
Date: 2020.09.22 16:08:09 -07'00'

CAPT Katherine E. Jacobitz
Acting Director, Division of Pharmaceutical Quality Operations IV

SP: wm

FEI 3014857565