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	1/10/2019-2/21/2019* FEI NUMBER 3014857565

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Natasha N. Vo, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Lifetime Value Pharmacy III Inc.	301 E 17th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Santa Ana, CA 92706-2804	Compounding Pharmacy

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

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

Specifically,

No remedial actions beyond routine cleaning procedures were taken by your firm to ensure the sterility of the ISO 5 classified area after an air sample collected within the ISO 5 LFH on 11/16/18 tested positive for Coagulase Negative Staphylococcus species (2 CFU/m^3). Potential impact to products that had been recently produced in the ISO 5 LFH was not assessed.

OBSERVATION 2

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

Specifically,

On 01/10/19, your firm's Pharmacist-in-charge (PIC) stated that she had performed sterile production of the injectable preparation (b) (4) vials (b) (4) and (b) (4) that morning after using a non-sterile concentrated germicidal detergent to clean her gloves in place of the sterile (b) (4) required by your procedures.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christopher R Czajka, Investigator X Christopher R Czajka Investigator Signed By: Christopher R. Czajka -S Date Signed: 02-21-2019 11:41:03	2/21/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	1/10/2019-2/21/2019* FEI NUMBER 3014857565

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Natasha N. Vo, Pharmacist in Charge	
FIRM NAME Lifetime Value Pharmacy III Inc.	STREET ADDRESS 301 E 17th St
CITY, STATE, ZIP CODE, COUNTRY Santa Ana, CA 92706-2804	TYPE ESTABLISHMENT INSPECTED Compounding Pharmacy

OBSERVATION 3

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.

Specifically,

No remedial actions were taken by your firm to ensure the sterility of the ISO 7 cleanroom area after the following events:

a) Two air samples collected from around the supply cart in the ISO 7 cleanroom on 08/09/17 tested positive for Coagulase Negative Staphylococcus species (total of 8 CFU/m^3).
b) A contact plate sample collected from the surface of the supply cart in the ISO 7 cleanroom on 03/07/18 tested positive for Bacillus species (1 CFU/25cm^2).
c) An air sample collected from around the supply cart in the ISO 7 cleanroom on 11/16/18 tested positive for Coagulase Negative Staphylococcus species (4 CFU/m^3).

OBSERVATION 4

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

Specifically,

a) On 01/11/19, I observed that the laminar flow filter in the ISO 5 Laminar Flow Hood (LFH) had a splattering of a dried red/brown substance over an approximately 8" x 4" area, with similar small splatters at other locations on the filter. Your Compounding Pharmacist stated that this was caused by an accident during production, but could not provide any information about how or when this accident may have happened, nor was she able to identify the substance.
b) On 01/11/19, I observed that the inside of the Plexiglas surface that forms the top of the ISO 5 LFH work area had a yellow residue on its surface.
c) On 01/11/19, I observed that the joints between the walls and ceiling of the ISO 5 LFH work space were lined

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christopher R Czajka, Investigator	X Christopher R Czajka Investigator Signed By: Christopher R. Czajka -S Date Signed: 02-21-2019 11:41:03	2/21/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	1/10/2019-2/21/2019* FEI NUMBER 3014857565

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Natasha N. Vo, Pharmacist in Charge	
FIRM NAME Lifetime Value Pharmacy III Inc.	STREET ADDRESS 301 E 17th St
CITY, STATE, ZIP CODE, COUNTRY Santa Ana, CA 92706-2804	TYPE ESTABLISHMENT INSPECTED Compounding Pharmacy

with an uncleanable porous foam material.

OBSERVATION 5

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

Specifically,

a) The disposable lab coats, hairnets, face masks, and shoe covers worn by your firm's personnel during sterile compounding operations are non-sterile, and are not sterilized in any way prior to performing sterile production.
b) An air hand dryer is installed next to the hand wash sink in the corner of the IOS 8 buffer room in a way that provides insufficient space to dry your hands without touching the dryer power cord or one of the facility walls. Using this dryer during gowning is required by your firm's SOP 404.4, active 08/10/13, titled "Hand Hygiene and Garbing".
c) On 01/10/19, I observed apparent dirt tracks on the floor of the ISO 8 buffer room, spanning the demarcation between the unclassified entryway and the ISO 8 classified area. The following day, I observed that the tracks were still visible despite daily mopping of the room required by your SOP 304.3, active 08/10/13, titled "Cleaning and Disinfecting of the Compounding Facility". On 01/11/19, I observed your Compounding Pharmacist walk from the ISO 8 classified portion of the buffer room which contained the tracks into the ISO 7 cleanroom without changing her shoe covers.

OBSERVATION 6

Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically,

On 01/11/19, I observed that one of the ceiling tiles in your ISO 7 clean room is not sealed to the adjacent metal bracket along one of its short edges. This tile is located approximately 10' from the opening to the ISO 5 area of the LFH.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christopher R Czajka, Investigator	X Christopher R Czajka Investigator Signed By: Christopher R. Czajka -S Date Signed: 02-21-2019 11:41:03	2/21/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	1/10/2019-2/21/2019*
	FEI NUMBER 3014857565

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Natasha N. Vo, Pharmacist in Charge	
FIRM NAME Lifetime Value Pharmacy III Inc.	STREET ADDRESS 301 E 17th St
CITY, STATE, ZIP CODE, COUNTRY Santa Ana, CA 92706-2804	TYPE ESTABLISHMENT INSPECTED Compounding Pharmacy

OBSERVATION 7

Non-sterilized and Non-depyrogenated equipment was used in sterile drug production.

Specifically,

On 01/10/19, I observed that the (b) (4) used to sterilize glassware used in sterile production displayed no qualification or calibration information. Your firm's Compounding Pharmacist stated that no qualification of the (b) (4) or validation of the sterilization methods had been performed.

OBSERVATION 8

Non-microbial contamination was observed in your production area.

Specifically,

On 01/11/19, I observed visible signs of contamination in your ISO 7 cleanroom:

a) Discoloration and dried fluids were observed over an approximate 8" x 4" area on the floor next to the back left corner of the ISO 5 LFH.
b) An approximately 4" long discolored mark was observed on the wall just above the floor behind the back right corner of the ISO 5 LFH.
c) An approximate 1" x 1/2" area of discoloration and a white fiber were observed on the front left corner of the LFH work surface, approximately 2" from the ISO 5 classified area.
d) Discolored spots were observed on the floor underneath all four wheels of the metal supply cart located adjacent to the powder hood.
e) Two dark grey scuff marks, measuring approximately 2" long and 6" long, were observed on metal brackets in the ceiling of the room.

OBSERVATION 9

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christopher R Czajka, Investigator	X Christopher R Czajka Investigator Signed By: Christopher R. Czajka -S- Date Signed: 02-21-2019 11:41:03	2/21/2019

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	1/10/2019-2/21/2019* FEI NUMBER 3014857565

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Natasha N. Vo, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Lifetime Value Pharmacy III Inc.	301 E 17th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Santa Ana, CA 92706-2804	Compounding Pharmacy

Your ISO 8 buffer room is equipped with an air-blowing hand dryer which may raise the air pressure in the room and adversely affect the pressure differential into the adjacent, higher pressure ISO 7 cleanroom. Your firm does not monitor pressure differential readings to determine the effect of the dryer on the differential between the ISO 8 buffer room and the ISO 7 cleanroom.

***DATES OF INSPECTION**
1/10/2019(Thu), 1/11/2019(Fri), 1/14/2019(Mon), 1/15/2019(Tue), 1/16/2019(Wed), 1/17/2019(Thu), 2/21/2019(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christopher R Czajka, Investigator	X Christopher R Czajka Investigator Signed By: Christopher R. Czajka Date Signed: 02-21-2019 11:41:03	2/21/2019