DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	8/23/2021-8/27/2021* FEI NUMBER 3014391500

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael J. Kellihan, PharmD & Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
New Vitalis Pharmacy LLC dba New Vitalis Pharmacy	4139 Cadillac Ct Ste 201
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Louisville, KY 40213-1578	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

Vermin was observed in an area immediately adjacent to your production area.

Specifically, on 08/24/2021, the Pharmacist-in-Charge stated the ISO 7 cleanroom was clean and ready for compounding use. While you were producing Testosterone Cypionate 180mg/Testosterone Propionate 20 mg/ml in 1 ml vials, lot 08242021@901, two apparent dead flies were noted on the floor; one behind the ISO 5 hood and one near the trash can which is positioned directly beside the right side of the ISO 5 hood.

OBSERVATION 2

Non-microbial contamination was observed in your production area.

Specifically, on 08/24/2021, the Pharmacist-in-Charge stated the ISO 7 cleanroom was clean and ready for compounding use. While you were producing Testosterone Cypionate 180mg/Testosterone Propionate 20 mg/ml in 1 ml vials, lot 08242021@901, the following were observed in the ISO 7 cleanroom:

- Black specs of apparent debris were observed on the floor throughout the ISO 7 cleanroom.
- (b) (4) tape reading "RESTRICTED AREA" was tapped on the floor by the door and was observed to be peeling and bubbling up with apparent build-up of black residue on the peeling tape.
- The ceiling has apparent black residue built-up around (b) (4) HEPA filters.

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EMPLOYEE(S) SIGNATURE
Lauren N Howard, Investigator
Carl A Huffman, Investigator

X Carl A Huffman
Investigator
Signed By: Carl A. Huffman -S
Date Signed: 08-27-2021
14:22:13

DATE ISSUED
8/27/2021

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OBSERVATION 3

Personnel conducted aseptic manipulations in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically, in the vertical airflow ISO 5 hood you were observed hand-stoppering Testosterone Cypionate 180mg/Testosterone Propionate 20 mg/ml in 1 ml vials, lot 08242021@901, after the vials were filled, while your hand and forearm were over the exposed sterile injectable product vials.

OBSERVATION 4

HEPA filters were not sealed around each perimeter to the support frame.

Specifically, HEPA filters are not sealed in the ISO 7 cleanroom identified as the (b) (4) room where sterile compounding occurs. One of the HEPA filters was observed having a corner hanging loose from the ceiling. Additionally, the entire (b) (4) ceiling in the ISO 7 cleanroom is caulked along all the seams and the caulk appears to be jagged and rough with pieces that could potentially fall off. There is also a (b) (4) sprinkler head located directly above the ISO 5 hood where sterile compounding occurs.

OBSERVATION 5

Personnel did not disinfect to prevent contamination.

Specifically, while you were producing Testosterone Cypionate 180mg/Testosterone Propionate 20 mg/ml in 1 ml vials, lot 08242021@901, you did not disinfect your gloves when you re-entered the ISO 5 hood after collecting a vial rack and bag of stoppers. You also did not wipe down the bag of stoppers with your (b) (4) sterile wipes when transferring from a lesser air quality to a higher air quality prior to introduction in the ISO 5 hood.

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	Lauren N Howard, Investigator Carl A Huffman, Investigator	X Carl A Huffman Investigator Signed By: Carl A. Huffman -S Date Signed: 08-27-2021 14:22:13	8/27/2021

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In addition, you were observed continuing to use the (b) (4) (b) (4) (b) (4) compounded solution and fill the 1 ml vials) after the tip of the (b) (4) touched the benchtop inside the ISO 5 hood for Testosterone Cypionate 180mg/Testosterone Propionate 20 mg/ml in 1 ml vials for lot 08242021@901.

Lastly, on 08/24/2021 while you were producing the sterile drug product Testosterone Cypionate 180mg/Testosterone Propionate 20 mg/ml in 1 ml vials, lot 08242021@901 in your ISO 5 hood, we observed vials and stoppers being used that according to the Pharmacist-in-Charge had been stored uncovered in the ISO 5 hood since 08/19/2021.

OBSERVATION 6

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

Specifically, your mask was not covering your nose while producing Testosterone Cypionate 180mg/Testosterone Propionate 20 mg/ml in 1 ml vials for lot 08242021@901, a sterile injectable drug product. Additionally, you attempted to fix the mask twice using your sterile gloved hand and did not sanitize your gloved hand while continuing compounding activities.

OBSERVATION 7

You produced hazardous drugs without providing adequate cleaning of utensils to prevent cross-contamination.

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Specifically, you have inadequate cleaning for your non-dedicated (b) (4) Blender, which blends active pharmaceutical ingredients such as progesterone and melatonin. You are currently using non-pharmaceutical grade detergents to clean equipment used in pharmaceutical compounding.

***DATES OF INSPECTION**
8/23/2021(Mon), 8/24/2021(Tue), 8/25/2021(Wed), 8/27/2021(Fri)

X Lauren N Howard
Investigator
Signed By: Lauren N. Howard -S
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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."