DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	6/12/2023-7/5/2023* FEI NUMBER 3014391500

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Manuel G. Francia, Pharmcist-In-Charge (PIC)

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 I OBSERVED:

OBSERVATION 1

Failure to conduct post-use filter-integrity testing on filters used to sterilize drug products.

Specifically, your firm did not conduct post-use (b) (4) testing of the (b) (4) used in the production of the sterile finished drug products. For examples:

a. The (b) (4) used to aseptically fill (b) (4) vials of Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL lot AL-05112023 (b) (4), on 06/14/2023 was discarded in the trash without conducting the post-use (b) (4) testing by your filling pharmacist.

b. Post use (b) (4) testing were not performed for the following drug product lot as well:

i. Testosterone Cypionate 180mg/mL/Testosterone Propionate 20mg/mL, lot AL-03142023 (b) (4), Exp. Date 05/09/2023. This lot was used to fill approximately (b) (4) prescriptions that were dispensed to patients.

ii. Testosterone Cypionate 180mg/mL/Testosterone Propionate 20mg/mL, AL-04262023 (b) (4) Exp. Date 06/25/2023. Approximately (b) (4) prescriptions filled and dispensed to patients between 04/17/2023 – 05/30/2023.

iii. Papaverine/Phentolamine/Alprostadil 30mg/1mg/10mcg (Trimix) batch record lot AL-06082023 (b) (4) Exp. Date 07/07/2023, Rx: (b) (6), (b) (7)(C)

On 6/12/2023, your pharmacist stated that you do not do any (b) (4) testing on your Testosterone Cypionate180mg/mL/Testosterone Propionate 20mg/mL and Trimix drug products.

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EMPLOYEE(S) SIGNATURE
Ucheabuchi C Chudi-Nwankwor, Investigator

X Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi-nwankwor -S Date Signed: 07-05-2023 13:05:16

DATE ISSUED
7/5/2023

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OBSERVATION 2

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically,

a. Your media fill program is deficient in that your media fills are not representative of batch sizes and container types. Your media fills are performed in batch sizes of (b) (4) vials however your firm routinely prepares (b) (4) batches into 2mL and 5 mL vials of Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL. In addition, your firm perform sterile to sterile production of sterile eye drop filled in a 10mL plastic dropper which requires some manipulations to add the caps while assembling the sterile dropper after aseptic filling of the droppers. This process has not been simulated in your media fill.

b. Media fills do not capture the worst-case processing conditions such as the number of aseptic manipulations in the hood. For example, bulk drug product is routinely (b) (4) in the (b) (4) Hood using (b) (4) into the (b) (4) bottle part of the (b) (4) unit and stored inside the ISO 5 BSC hood pending contract testing lab results. This duration may take (b) (4). Bulk sample taken out of the ISO 5 BSC hood, through the ISO 7 hazardous (HD) cleanroom, into the non-HD ISO 7 cleanroom and reintroduced into an ISO 5 (b) (4) laminar flow hood (LFH) for filling operations. This process was not represented in you. media fill process for operators (b) (7)(C), and (b) (7)(C), (b). Your pharmacist stated that that the bulk (b) (4) step using (b) (4) in the production process for Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL was not included during the media fill.

OBSERVATION 3

Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted.

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Specifically, on 06/14/2023, I observed your sterile operator (b) (6), (b) (7) blocking first air by placing supplies to include a tray of (b) (4) vials, empty carton, bottle of bulk drug product and the Repeater (b) (4) Pump with its connecting power cord in front of the HEPA filter in the ISO 5 (b) (4) LFH, while aseptically (b) (4) and filling sterile drug product vials of Testosterone Cypionate 180mg/mL/Testosterone Propionate 20mg/mL lot AL05112023 (b) (4) between these supplies and the operator.

Vials used during the aseptic operations on 06/15/2023 were selected from the last row of the vial box in the ISO 5 (b) (4) LFH closest to the operator and filled behind the staged materials in the ISO LFH blocking First Pass air.

OBSERVATION 4

Use of a sporicidal agent in the facility's ISO 5 areas and classified areas was lacking.

Specifically, sporicidal agents were not used in your facility's ISO 5 classified aseptic processing area. Your firm's Pharmacist stated that he cleans and disinfects the ISO 5 BSC's and ISO 5 LFH with only (b) (4) Sterile pre- saturated wipes which were (b) (4) . The (b) (4) Sterile pre-saturated wipes consists of (b) (4) I observed this on 06/14/2023 and 06/15/2023 before and after the aseptic filling of Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL lot AL05112023 (b) (4) . The ISO 5 LFH hood located in the non-hazardous IV cleanroom was only wiped with Sterile (b) (4) wipes that were also sprayed with sterile (b) (4) These hoods have been used in the aseptic filling of approximately (b) (4) sterile drug products, including Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL, Vancomycin and Papaverine/Phentolamine/Alprostadil (Tri-Mix) between May 19th 2023 and June 13th 2023.

OBSERVATION 5

Use of non-sterile cleaning wipes in the ISO 5 area.

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Specifically, on 06/14/2023 and 06/15/2023, before and during filling of bulk Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL lot AL05112023 (b) (4) respectively, your pharmacist transferred the non-sterile wipe with the lot number of the drug product inscribed on it from BSC ISO 5 in the HD ISO 7 cleanroom to the non-HD ISO 7 cleanroom and then into the ISO 5 LFH for filling into the final drug product vials that will be distribute for patient use. Per your pharmacist this drug product bulk was prepared on 05/11/2023 and had been placed on this same non-sterile wipe since then.

OBSERVATION 6

Smoke studies were inadequately performed under dynamic conditions.

Specifically, you presented a report for smoke studies conducted by your third party (b) (4) on 1/26/2023. The smoke study reported for ISO 5 LFH located in the ISO 7 Non-Hazardous IV buffer room does not appear to have been conducted under dynamic conditions. Your pharmacist stated that he was not involved in the (b) (4) hood smoke study but only demonstrated dynamic manipulation of the (b) (4) hood which is located in the ISO 7 Hazardous chemical buffer room. This ISO 5 hood in the Non-Hazardous IV buffer room has been used in the aseptic filling of approximately (b) (4) prescriptions of your sterile products from March to May 2023, to include the following but not limited products: Vancomycin 5% eye drop and Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL

OBSERVATION 7

Use of a disinfectant in a manner insufficient to achieve adequate levels of disinfection.

Specifically, the disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate level of disinfection. You are not waiting the required (b) (4) dwell time for the disinfectants used to sanitize your ISO 5 hoods where sterile products are compounded and ISO 7 buffer rooms. Your pharmacist stated that the disinfectants direction specifies waiting (b) (4) prior to wiping down.

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On 06/12/2023, I observed your technician (b) (7)(C), (b) perform (b) (4) cleaning of the ISO 7 Hazard chemical buffer room and the Non-Hazardous IV buffer room along with the ISO 5 Biological safety cabinet and the ISO 5 LFH located in the buffer rooms respectively. Your technician failed to adhere to the (b) (4) disinfectant times as detailed in your cleaning instruction. Disinfectant was used but immediately wiped down after application. Sterile Pre-saturated wipes (b) (4) sprayed with Sterile (b) (4) was used on the ISO 5 classified areas while (b) (4) Disinfectant was used on the floors but immediately wiped down after application. I observed that between May 19th 2023 and June 13th 2023 (b) (4) was used in the disinfection of your clean rooms which is a non-sporicidal agent.

OBSERVATION 8

Personnel infrequently sanitized gloves to prevent contamination.

Specifically, on 06/15/23, I observed operator (b) (7)(C), use his gloved hands to clean the bulk drug product spills on the (b) (4) area which is (b) (4) approximately three times using a previously used (b) (4) in the ISO 5 LFH. He immediately continued the aseptic filling of vials with Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL lot 05112023 (b) (4) without sanitizing his gloves.

OBSERVATION 9

HEPA filters are not sealed around the perimeter.

Specifically, the HEPA filters in the ISO 7 non-hazardous room were not properly sealed. The perimeter of the HEPA filter did not overlap to the ceiling. The HEPA filters are not adequately sealed to the ceiling and had gaps." This is a repeat observation.
The ISO 5 Laminar Air Flow Hood (LFH) used in the aseptic filling of Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL lot AL05112023 (b) (4) vials on 06/14/2023 and 06/15/2023 is situated in this room.

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OBSERVATION 10

The facility design was observed to allow the influx of lesser quality air into a classified area containing higher quality air.

Specifically, all material flows directly from an unclassified area into a negative pressure ISO 7 HD cleanroom in which sterile production occurs via (b) (4) . Additionally, material for the non-HD production is also brought in through this (b) (4) .

a. On 06/14/2023 and 06/15/2023 I observed the operator pass the sterile packaged vials of Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL lot AL05112023 (b) (4) , through to the unclassified area Non-Sterile Dry Lab through an unclassified material (b) (4) into the classified ISO 7 Hazardous Chemical Buffer cleanroom where compounding of aseptically manipulated drug products is conducted.

b. Additionally, microbial growth of 1 CFU/25cm2 was recovered from this (b) (4) in the last certification from January 26, 2023, Test Report: 230126-1000. Microbial identification was *Cladosporium species* which is a common fungus.

c. On 06/12/2023, I observed the weighing and mixing of non-sterile Bulk Dug substances Testosterone Cypionate, Testosterone Propionate, Cottonseed oil and Benzyl Alcohol and Benzyl Benzoate liquids in an unclassified area. This should be done in an ISO 8 environment. These unsterile components were used in manufacturing of Bulk Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL lot 06122023 (b) (4) which per your pharmacist will be used in sterile aseptic filling of vials after laboratory analysis.

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OBSERVATION 11

Use of processing aides not intended for pharmaceutical use in sterile drug production.

Specifically, your pharmacist stated that (b) (4) unit is used in the initial (b) (4) of Bulk Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL drug product. which is part of the production flow for the drug product. I observed this operation on 06/13/2022 during the bulk (b) (4) of Bulk Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/m lot 06122023 (b) (4) using the non-pharmaceutical grade (b) (4) unit. In addition the certificate of Quality (COQ) stated that "This product is not intended for use in direct patient care or diagnostic procedures".

***DATES OF INSPECTION**

6/12/2023(Mon), 6/13/2023(Tue), 6/14/2023(Wed), 6/15/2023(Thu), 6/16/2023(Fri), 6/26/2023(Mon), 7/05/2023(Wed)

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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."