

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

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 8/27/2018-9/7/2018*
	FEI NUMBER 3014391500

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

FIRM NAME New Vitalis Pharmacy LLC dba New Vitalis Pharmacy	STREET ADDRESS 4139 Cadillac Ct, Suite 201
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CITY, STATE, ZIP CODE, COUNTRY Louisville, KY 40213-1578	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-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 released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess. Specifically,

Your firm produced finished Testosterone Cypionate 200MG/ML in Grapeseed Oil lots AL-07192018@906 and AL-08072018@901 using apparent food-grade Grapeseed oil supplied by (b) (4) (b) (4) and labeled by the manufacturer as "Caution: Dietary Supplement." According to your firm's batch record,

- Your firm produced (b) (4) finished vials of lot AL-07192018@906 using Grapeseed Oil, lot 1801260072. For example, the shipping record shows that a vial of lot AL-07192018@906 was delivered to RX (b) (6) in (b) (6) on 08/22/18.
- Your firm produced (b) (4) finished vials of lot AL-08072018@901 using Grapeseed Oil, lot 1801260072. For example, the shipping record shows that a vial of lot AL-08072018@901 was delivered to RX (b) (6) in (b) (6) on 08/29/18.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Bei Y He, Investigator	DATE ISSUED 9/7/2018 Bei Y He Investigator Signed By 2001678494 Date Signed 09-07-2018 10 11 58 X _____

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Visual inspection of finished drug products prior to distribution is not adequately performed. Specifically,

Your firm (b) (4) sterilized Testosterone Cypionate 200 MG/ML in Grapeseed Oil injectable lots AL-07192018@906 and AL-08072018@901 at (b) (4)°C for (b) (4) minutes, respectively on 07/24/18 and 08/07/18. Your firm stated that 100% visual checks are performed on each lot prior to labeling and dispensing or distribution to your patient. However, your firm does not utilize any black or white box or additional lighting source to examine for visible particulates, cloudiness, and/or discoloration in the finished vials.

For example:

- Your firm produced (b) (4) finished vials from lot AL-07192018@906. Your firm shipped a vial from this lot to RX (b) (6) in (b) (6) on 08/22/18.
- Your firm produced (b) (4) finished vials from lot AL-08072018@901. Your firm shipped a vial from this lot to RX (b) (6) in (b) (6) on 08/29/18.

OBSERVATION 3

Non-sterile, low-shedding wipes are used to cleaned the ISO 5 hoods. Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Bei Y He, Investigator	Bei Y He Investigator Signed By: 2001878494 Date Signed: 09-07-2018 10:11:58 X	DATE ISSUED 9/7/2018

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On 08/27/18, I observed non-sterile wipes ((b) (4), (b) (4)) in the ISO 7 clean room. Your firm stated that these non-sterile wipes utilized during the routine cleaning of the ISO 5 hoods.

***DATES OF INSPECTION**

8/27/2018(Mon), 8/28/2018(Tue), 8/29/2018(Wed), 8/30/2018(Thu), 8/31/2018(Fri), 9/04/2018(Tue), 9/05/2018(Wed), 9/07/2018(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Bei Y He, Investigator	Bei Y He Investigator Signed By: 2001878494 Date Signed 09-07-2018 10:11:58 X _____	DATE ISSUED 9/7/2018