DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	12/1/2022-12/9/2022* FEI NUMBER 3021451094

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Venus L. Hensley, Prescription Department Manager

FIRM NAME	STREET ADDRESS
Purformance Wellness Pharmacy LLC dba Seven Cells	600 Se Indian St Ste 3
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Stuart, FL 34997-5540	Producer of 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

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

Specifically,

a) Your firm does not use a strong oxidizer capable of deactivating hazardous drug products to prevent cross-contamination of work surfaces and non-dedicated, shared equipment used in the production of hazardous drug products containing testosterone, progesterone, estriol and/or estradiol.

b) Your firm has not established the use of (b) (4) is adequate to remove drug product residues to prevent contamination from shared equipment used in the production of hazardous drug products containing testosterone, progesterone, estriol and/or estradiol.

OBSERVATION 2

Non-microbial contamination was observed in your production area.

Specifically,

a) On 12/1/2022 during the initial walk through of the facility, I observed an unknown white powder-like substance on two separate (b) (4) capsule machines. According to your non-sterile technician (b) (6) no production of capsules occurred that day and the last time the machines were used to produce capsules were on 11/7/2022 to produce (b) (4) 25mg capsules and on 11/29/2022 to produce

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 12-09-2022 15: D: 5	12/9/2022

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Ivermectin 18mg capsules. Your (b) (4) capsules machines are not dedicated equipment and are used to produce hazardous drug products containing progesterone.

b) On 12/1/2022, I observed a white jar with a white screw cap top that had a yellowish unknown residue on the cap with a greasy oily texture placed in a cabinet used to store clean non-dedicated equipment ready for use in the production of your topical drug products (creams and gels) containing hazardous drug substances such as testosterone, progesterone, estriol and/or estradiol.

***DATES OF INSPECTION**

12/01/2022(Thu), 12/02/2022(Fri), 12/05/2022(Mon), 12/07/2022(Wed), 12/09/2022(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 12-09-2022 15: D: 5	12/9/2022

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."