DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	10/1/2024-10/4/2024* FEI NUMBER 3010810839

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul W Franck, Pharmacist & Owner

FIRM NAME	STREET ADDRESS
Avenue Pharmacy Inc dba Pathway Pharmacy	202 Sw 17th St Ste A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34471-8138	Producer of Non-Sterile Drug Products

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,

1. Your firm's contract testing laboratory identified five potency failures (spec (b) (4)%) for the following finished drug product and bulk lots which were used in the production of finished drug product batches.

   Testosterone 2mg/mL cream lot # 06102024@(b) (4) (produced on 6/10/24) = 85.5%, BUD: 12/7/24 was dispensed to a patient on (b) (4) (QTY (b) (4)).

   Liothyronine (T3) bulk lot #06122024@(b) (4) = 77.3% (produced on 6/12/24), BUD: 12/9/24. This bulk product was used to produce (b) (4) finished product lots that were dispensed to patients.

   Levothyroxine (T4) bulk lot #06032024@(b) (4) = 121.8% (produced on 6/3/24), BUD: 11/30/24. This bulk product was used to produce (b) (4) finished product lots that were dispensed to patients.

   Levothyroxine (T4) bulk lot #04172024@(b) (4) = 148.3% (produced on 4/17/24), BUD: 10/14/24. This bulk product was used to produce (b) (4) finished product lots that were dispensed to patients.

   Liothyronine (T3) bulk lot #08072024@(b) (4) = 84.4% (produced on 8/7/24), BUD: 2/3/25. This bulk product was used to produce (b) (4) finished product lots that were dispensed to patients.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica P Mcalister, Investigator	X Jessica P Mcalister Investigator Signed By: Jessica L. Mcalister -S Date Signed: 10-04-2024 11:02:15	10/4/2024

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2.According to your firm's pharmacy technician your Hazardous Rooms' HVAC unit has been down since 6/24/24 and your firm failed to ensure the temperature and humidity within the room were adequately controlled while drug products are produced and stored. On 10/2/24, your temperature within the room was observed to be 26.3 ▫ C.

In addition, your firm stores hazardous bulk drug substances which require a controlled environment, gelatin bulk capsules (b) (4) specs: (b) (4) ▫ C and (b) (4)% RH) and finished product Progesterone Capsules (produced on 6/25/24, BUD: 12/22/24) which could potentially be affected by the lack of temperature and humidity controls.

OBSERVATION 2

Contamination was observed in your production area and areas adjacent to production areas.

Specifically,

1.On 10/1/24, I observed (b) (4) AC units within your firm's Hazardous Room that contain white powder residue and dust which could potentially lead to product contamination. Your pharmacy technician had an open container of Testosterone Cream, 4mg/g, lot #09302024@(b)(4 BUD: 12/29/24 on the countertop adjacent to (b) (4) AC unit.

In addition, white powder residue was observed on ALL surfaces (refrigerator, countertops, Bulk Drug Substance containers, etc.) of your Hazardous Room.

2.Your pharmacy technician was observed placing her soiled gloved index finger inside of the finished product Testosterone Cream, 4mg/g, lot #09302024@(b)(4 BUD: 12/29/24 to remove residual product from the container.

3.On 10/1/24 and 10/2/24, I observed a blue ripped towel which appears un-clean in the hazardous

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hood. Your pharmacy technician stated she uses the towel to wipe her gloved hands and powder accumulation within the hood.

4. On 10/1/24, I observed both Non-Hazardous (b) (4) Hoods with discolored and chipped painted grates. Your firm failed to initiate corrective actions and instead continued to utilize the hoods to produce drug products.

***DATES OF INSPECTION**

10/01/2024(Tue), 10/02/2024(Wed), 10/04/2024(Fri)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Jessica P Mcalister, Investigator

Jessica P Mcalister
Investigator
Signed By: Jessica L. Mcalister -S
Date Signed: 10-04-2024
11:02:15

X

DATE ISSUED

10/4/2024

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."