DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	12/2-12/4/19 & 12/6/19
	FEI NUMBER 3014853350

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Paul W. Franck, Owner & Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Avenue Pharmacy Inc. dba Pathway Pharmacy	202-A SW 17th Street
CITY, STATE AND ZIP CODE Ocala, FL 34471	TYPE OF ESTABLISHMENT INSPECTED Producer of 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) (WE) OBSERVED:

Observation 1: Non-microbial contamination was observed in your production area.

Specifically, on 12/3/19, within the firm's Non-Sterile Suite, Lab (b) (4) Hood (b) (4) ((b) (4) hood), the vent directly over the working surface was observed visually un-clean and to contain an unknown white powder residue. According to your firm's Pharmacy Technician ((b) (6) she has never cleaned the vent during routine cleaning of the Hood. Your firm's Pharmacy Technician stated since October 2019 to December 4, 2019 she has only produced non-sterile drug products (chemotherapeutic, hazardous and non-hazardous) within Lab (b) (4) Hood (b) (4) (approximately (b) (4) batches of non-sterile drug products were produced). Examples of non-sterile drugs produced on 11/7/19 are as follows:

• Fluorouracil 5%/Calcipotriene .005% (2323) Cream (Chemotherapy drug), lot #11072019@2, BUD: 12/7/19 (Produced at 12:43pm) and dispensed under (b)(6) on 11/9/19;

• Biest (50/50) 0.04MG/Progesterone 2MG/Testosterone 0.15MG/0.5ML (2346) Cream (Hazardous drug), lot #11072019@7, BUD: 12/7/19 (Produced at 3:44pm) and dispensed under (b)(6) on 11/7/19;

• T3 30MCG/T4 100MCG E4M (2425) Capsules (non-hazardous drug), lot #11072019@4, BUD: 5/5/20 (Produced at 4pm) and dispensed under (b)(6) on 11/8/19.

Observation 2: Your firm produced drugs while construction is underway in an adjacent area without adequate controls to prevent contamination of the production environment and product.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Jessica L. Pressley	Jessica L. Pressley, Investigator	12/6/19

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Specifically, during the current FDA Inspection from 12/2-12/4/19 & 12/6/19, on-going construction of the (b) (4) (b) (4) Room was observed in an adjacent area nearest to the pharmacy where prescriptions are filled and dispensed and across the hall from the non-sterile suite where drug products were being produced. Adequate controls to prevent contamination of the production environment and product are not in place as the facility has one HVAC system allowing for the potential influx of particulates to be transferred into the pharmacy and production area. In addition, the doors leading to the construction area were left open.

Observation 3: 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, on 12/2/19, during the production of T3 35MCG/T4 35MCG E4M, lot #12022019@3, 180 Days BUD, the API, Riboflavin USP (Vitamin B2), 0.03 g was weighed on Scale (b) (4)), dated 9/17/19 (calibrated range: (b) (4)), therefore outside the calibrated range.

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	Jessica L. Prassley	Jessica L. Prassley, Investigator	12/6/19