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	5/11/2021-6/7/2021*
	FEI NUMBER 3012937475

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Henry Shiu, PIC and Owner

FIRM NAME	STREET ADDRESS
Front Door Pharmacy, LLC dba Pure Pharmacy (Pure Pharmaceuticals)	8973 Interchange Dr
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77054-2513	TYPE ESTABLISHMENT INSPECTED Sterile Drug Producer

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

Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product.

Specifically, during the visual sterile production observation of the finished sterile drug product, P105 (PAP30MG/ PHE1MG/ PGE10MCG), Lot # 051321@(b) (4) Expiry 7/16/21 being performed by the pharmacy PIC, the following conditions were observed:

A. Reaching over filled sterile (b) (4) unstopped vials to fill empty vials.
B. Placed a tray of empty vials awaiting filling in between the HEPA filter and the vials undergoing (b) (4) (b) (4) /filling, resulting in an interruption of 1st air for the vials being processed the ISO 5 LAFU.

OBSERVATION 2

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that prove a challenge to aseptic operations.

Specifically, your pharmacy fail to provide an adequate justification for your facility's media fill program in order to simulate aseptic production operations for the worst-case activities and conditions. For example, your firm's media fill program documented within procedure, Conduct High Risk Media Fill Test, PURE_SOP 3.9.6 Conduct High Risk Media Fill Test fail to represent actual aseptic production practices, which include the stopper placement and affixing the (b) (4) to the vial. **Repeat Observation**

OBSERVATION 3

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	Camerson E Moore, Investigator	Camerson E Moore Investigator	6/7/2021

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Houston, TX 77054-2513	Sterile Drug Producer

Environmental monitoring was not performed in your aseptic processing areas.

Specifically, environmental Monitoring and measurement frequency of microbiological contamination (viable/non-viable monitoring) of the air in the ISO 5 zone is inadequate. Your pharmacy fail to establish a viable monitoring program during sterile drug production within the ISO 5 LAFU. Additionally, during a review of your pharmacy's cleanroom re-certification for VIABLE Report 1.27.2021, which documents the (b) (4) assessment of air, and Surface contaminates within ISO 7 and ISO 8 Ante-room, fail to include the ISO 5 LAFU.

OBSERVATION 4

The use of sporicidal agents in the cleanrooms and ISO 5 classified aseptic processing area was inadequate.

Specifically, your firm failed to validate the sporicidal agent, (b) (4) Sporicidal Disinfectant Cleaner for its intended use within the cleanroom and aseptic production processing area. **Repeat Observation**

OBSERVATION 5

Your facility design allowed the influx of poor-quality air into a higher classified area.

Specifically, your firm air returns are adjacent to your HEPA filters in the ceiling of the ISO 8 Anteroom and ISO 7 Cleanroom (b) (4) used in the production of sterile drugs. Your pharmacy fail to provide records and/or documents (smoke study) in support of adequate air circulation in the prevention of an influx of poor quality air into a higher classified area. **Repeat Observation**

OBSERVATION 6

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

Specifically, your pharmacy produces the non-sterile hazardous drug, Testosterone Cream 100 mg/mL and Estradiol 0.1MG/GM Cream without adequate segregation, deactivation, and adequate cleaning program to prevent cross-contamination. All non-sterile compounded drugs are compounded in the same designated drug production area without adequate cleaning requirements. Your firm's hazardous material SOP, Hazardous Material_4.9.6, Handling Hazardous Material - Pharmacy procedure failed to include cleaning requirements to deactivate hazardous drug products and components. Your pharmacy technician report you firm uses dish detergent to wash and allow to (b) (4). Equipment is wiped using (b) (4) **Repeat Observation**

OBSERVATION 7
ISO-5 classified areas were not certified under dynamic conditions.

Specifically, unidirectional airflow was not verified under operational conditions. Your firm's clean room re-certification reports tests dated 1/27/2021, 8/5/2020, 2/12/2020, and 8/15/2019 were documented as being performed in dynamic conditions. On 5/24/2021, PIC reported no aseptic production simulation was performed at the time of any of the documented cleanroom and ISO 5 aseptic production processing areas during re-certifications. **Repeat Observation**

***DATES OF INSPECTION**
5/11/2021(Tue), 5/12/2021(Wed), 5/13/2021(Thu), 5/14/2021(Fri), 5/24/2021(Mon), 5/25/2021(Tue), 5/26/2021(Wed), 5/27/2021(Thu), 6/07/2021(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator	Camerson E Moore Investigator	DATE ISSUED 6/7/2021

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."