DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	2/25/2019-3/18/2019* FEI NUMBER 3012937475

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Henry Shiu, PharmD, Pharmacist-In-Charge & Owner

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

Personnel engaged in aseptic processing were observed with exposed skin.

Specifically, on 3/6/2019, your pharmacist was observed with exposed skin while compounding the sterile drug, P-105 Lot # 030719@1 BUD 9/7/19, Qty. (b) (4) vials @ 10ml (b) (4) vials sent to contract laboratory for testing and (b) (4) vials dispensed - Rx (b) (6) dated 3/13/2019 & Rx (b) (6) dated 3/14/2019). Your pharmacist sterile gloves failed to extend over the sleeves of the gown worn.

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 media fill program fails to simulate aseptic production operations for the worst-case activities and conditions within your firm's aseptic processing operations. For example, your firm's media fill aseptically simulates manipulating (b) (4) vials. However, the pharmacy maximum compound compound batch size is (b) (4) vials for the compounded sterile drug, P-105.

OBSERVATION 3

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	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 03-18-2019 13:45:13	3/18/2019

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Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

Specifically, on 3/7/2019 during the aseptic processing of the sterile produced drug, P-105 Injection Lot # 030719@1 BUD 09/07/19, Qty. (b) (4) vials @ 10mL, your pharmacist was observed exiting the ISO 5 processing area, performing a task in the ISO 7 Cleanroom (b) (4) and re-entering the ISO 5 Aseptic processing area multiple times without re-sanitizing gloves upon re-entry. Prior to donning gloves, the skin of the pharmacist hands was completely exposed inside ISO 5 hood prior to sterile compounding P-105 Injection, Lot # 030719@1, BUD 09/07/19.

OBSERVATION 4

Equipment and materials or supplies were no disinfected prior to entering the aseptic processing area.

Specifically, on 3/6/2019 the following conditions were observed:

A. While compounding the sterile drug, P-105 Lot # 030719@1 BUD 9/7/19, Qty. (b) (4) vials @ 10ml, your firm's pharmacist failed to disinfect non-sterile (b) (4) drug components, Phentolamine Mesylate USP, Mannitol (D) USP, and Papaverine HCL, prior to removal from where weighed and staged on the stainless-steel table in ISO 8 Anteroom, and prior to entry into the ISO 5 aseptic processing area.
B. The (b) (4) mixer was observed within the ISO 5 Hood with foreign residue on its outer surface. Your firm's pharmacist failed to disinfect the mixer prior to placing it into the aseptic compounding area.
C. Your firm's stool, in the ISO 7 Cleanroom (b) (4) used by your pharmacist, during aseptic processing, is covered with a material which cannot be adequately disinfected.

OBSERVATION 5

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Disinfecting agents used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, your firm pharmacist was observed using an unlabeled bottle non-sterile (b) (4) to disinfect the ISO 5 Hood aseptic processing surfaces. Unlabeled bottles of non-sterile (b) (4) were found in the pharmacy's ISO 8 Anteroom, ISO 7 Cleanroom[(b) (4)]

OBSERVATION 6

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

Specifically, your firm failed to validate the use of (b) (4), surface disinfectant decontaminant cleaner, as a sporicidal agent used in your firm's clean room and aseptic processing area.

OBSERVATION 7

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 firm 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.

OBSERVATION 8

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Laboratory test equipment used in the preparation and testing of collected samples are inadequate.

Specifically, your firm uses a (b) (4) Model (b) (4) for the incubation of (b) (4) collected media-fills. The unit fail to have adequate temperature and relate humidity controls to perform and control these environmental conditions.

OBSERVATION 9

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

Specifically, your firm produces the non-sterile hazardous drug, Testosterone Cream 100 mg/mL 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.

OBSERVATION 10

ISO-5 classified areas were not certified under dynamic conditions. Specifically, unidirectional airflow was not verified under operational conditions.

Specifically, your firm's clean room re-certification tests dated (b) (4) (b) (4) were documented as being performed in dynamic conditions. On 2/27/2019, the pharmacy contract clean room certifier was asked if he recertifies the clean room while pharmacy is performing media fills and/or compounding actual sterile drug products. He reported no, he simulates motion in the clean room compounding area and documents as being in a dynamic state. Pharmacist

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reported no medial fills and/or drug compounding occurred during any of the clean room re-certifications.

OBSERVATION 11

The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically, during a walk-through on 2/25/2019, foreign particulate matter was observed in ISO 7 production area on top of (b) (4) which was not in service, adjacent to the ISO 5 Hood.

***DATES OF INSPECTION**

2/25/2019(Mon), 2/26/2019(Tue), 2/27/2019(Wed), 2/28/2019(Thu), 3/01/2019(Fri), 3/06/2019(Wed), 3/18/2019(Mon)

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