DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	10/12/2022-10/21/2022* FEI NUMBER 3021032578

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Payam (nmi) Zarrabizadeh, Owner

FIRM NAME	STREET ADDRESS
Rx Unlimited Pharmacy	16673 Roscoe Blvd
CITY, STATE, ZIP CODE, COUNTRY North Hills, CA 91343-6109	TYPE ESTABLISHMENT INSPECTED Producer of Nonsterile and 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

Your company has not demonstrated that (b) (4), (b) (4) or germicidal/sporicidal cleaning solutions used to clean (b) (4) hoods, equipment, and utensils in your hazardous drug compounding areas (b) (4) are capable of deactivating hazardous drug substances to prevent cross-contamination.

Since July 12, 2022, your company dispensed approximately (b) (4) patient prescriptions from drug products produced in your hazardous compounding area. For example, you dispensed the following compounded drug products:

- BI-EST (80:20) 2.G mg/ml/Progesterone 200mg/ml/Testosterone 0.5mg/ml Cream (Lot# 10192022@(b) (4) BUD03/18/2023)
- Estriol (E3) 4mg/ml/Estradiol (E2) 2 mg/ml cream (Lot#10192022@(b) (4) BUD03/18/2023)
- Hydroquinone 8%/ Hydrocortisone 1%/ Tretinoin 0.5% (New Night Cream) Cream (Lot# 10192022@(b) (4) BUD 11/18/2022)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jolanna A Norton, Investigator Gunneet Kaur, Investigator	X Jolanna A Norton Investigator Signed By: Jolanna A. Norton -S Date Signed: 10-21-2022 17:50:21	10/21/2022

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OBSERVATION 2

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

Your company failed to perform any testing (microbial and analytical) of (b) (4) generated through your (b) (4) system. This (b) (4) is used as (b) (4) in the production of (b) (4) non-sterile drug products and in the production of (b) (4). Furthermore, your company's (b) (4) system has not been qualified and validated and no documented maintenance has been performed on it.

Since May 2022, your company produced (b) (4) drug product formulations (nasal spray, oral suspension, oral and topical solutions) using (b) (4) as an ingredient. In the last three months your company dispensed (b) (4) patient prescriptions with (b) (4) as an ingredient. For example you dispensed the following compounded drug products :

-Misoprostol 0.0024%/Diphenhydramine HCl 0.1%/Lidocaine HCl 1% Oral Rinse ((b) (4)) 0.0024%/0.1%/1% Suspension (Lot# 09212022@(b) (4) BUD:10/01/2022)

-Finasteride Foam 0.2% (Lot# 09262022@(b) (4) BUD: 10/26/2022)

-Misoprostol 0.0024%/Diphenhydramine HCl 0.1%/Lidocaine HCl 1% Oral Rinse ((b) (4)) (Lot# 09082022@(b) (4) BUD:09/18/2022)

-Minoxidil 6%/ Finasteride 0.2%/ Bimatoprost 0.03% Topical Solution (Lot# 07252022@(b) (4) BUD: 08/24/2022)

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-Minoxidil 10%/ Bimatoprost Topical Solution (Lot#09262022@(b)(4) BUD:10/26/2022)
-Oxytocin 10 Units/0.1 ML Nasal Spray ((b) (4)) (Lot# 09282022@(b)(4) BUD:10/28/2022)
-Minoxidil 6%/ Finasteride 0.2% Topical Solution (Lot# 09262022@(b)(4) BUD: 10/26/2022)

OBSERVATION 3

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

On October 17, 2022, during gowning we observed the sterile coverall worn by a technician come into contact multiple times with the handwashing sink located in the ISO 8 Ante Room of your non-hazardous sterile suite. The technician failed to change the coverall before entering the ISO 7 Compounding Area and before performing aseptic sterile (b) (4) of compounded injection drug product: Bi-Mix Injection (Phentolamine Mesylate/Papaverine) (1 mg/30 mg)/ml Solution, Lot 10172022@(b)(4) BUD 12/1/2022.

OBSERVATION 4

Vermin was observed in an area immediately adjacent to your production area.

Specifically,

Your firm failed to adequately control pest activity in your facility.

A: On 10/12/2022, during a walkthrough of your facility, we observed insect activity on a (b) (4) mat at the entrance to the hazardous compounding area.

B: On 10/13/2022, we observed a flying insect in the dispensing area adjacent to non-sterile

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compounding area. On this day, we observed your non-sterile technician produce non-hazardous non-sterile Diazepam 5 MG/ Baclofen 10 mg Base (b) (4) Suppository ((b) (4)) Lot 10132022@[(b) (4)] BUD 4/11/2023.

Drug producing/holding area should be free of pest activity to prevent drug product contamination.

***DATES OF INSPECTION**

10/12/2022(Wed), 10/13/2022(Thu), 10/14/2022(Fri), 10/17/2022(Mon), 10/18/2022(Tue), 10/20/2022(Thu), 10/21/2022(Fri)

X Gunneet Kaur
Investigator
Signed By: 2003283692
Date Signed: 10-21-2022 17:50:53

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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."