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	2/23/2023-3/15/2023* FEI NUMBER 3008174851

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shahram Soroudi, Owner

FIRM NAME	STREET ADDRESS
Palisades Compounding Pharmacy	540 Palisades Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pacific Palisades, CA 90272	Producer of Non-Sterile Drugs

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

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

Specifically, the hood, utensils, mortar and pestle, unguator and other equipment used to produce hazardous products are not adequately cleaned, to include the deactivation of hazardous products, between batches to prevent cross-contamination.

For example, your firm dispensed prescriptions for Rx# (b) (6), (b) (7)(C), Progesterone (50 mg) capsules; Rx# (b) (6), (b) (7)(C), Progesterone (200 mg/gm) cream; Rx# (b) (6), (b) (7)(C), Estradiol (8 mg/gm) cream; Rx# (b) (6), (b) (7)(C), Bi-Estrogen (3.5 mg/gm) gel; Rx# (b) (6), (b) (7)(C), Testosterone (9 mg/gm) cream; Rx# (b) (6), (b) (7)(C) Testosterone (2 mg/gm) gel; Rx# (b) (6), (b) (7)(C) Estriol (2 mg/gm) cream; Rx# (b) (6), (b) (7)(C) Estriol (5 mg/gm) cream on your firm's equipment without using a deactivator between each product produced.

OBSERVATION 2

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, your firm used the following expired excipients in the production of the finished drug product with lot # 12262022@ (b) (4) produced on 12/26/2022 and filled on 1/18/2023 for Rx # (b) (6), (b) (7)(C) Benzocaine 20%/Lidocaine 10%/Tetracaine 10%" with an expiry/use by date of 06/26/2023:

a. (b) (4) Lot # (b) (4), expiration 12/25/2022

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Darren S Brown, Investigator X Darren S Brown Investigator Signed By 2001647750 Date Signed 03-15-2023 12 33 36	3/15/2023

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b(b) (4) , Lot # (b) (4), expiration 10/24/2022

***DATES OF INSPECTION**

2/23/2023(Thu), 2/27/2023(Mon), 2/28/2023(Tue), 3/03/2023(Fri), 3/09/2023(Thu), 3/10/2023(Fri), 3/15/2023(Wed)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Darren S Brown, Investigator

X Darren S Brown
Investigator
Signed By: 2001647750
Date Signed: 03-15-2023
12:33:36

DATE ISSUED
3/15/2023

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."