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	2/23/2022-3/4/2022*
	FEI NUMBER 3010681729

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dana (nmi) Madievsky, Owner and Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Expert Compounding Pharmacy	6744 Balboa Boulevard
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lake Balboa, CA 91406	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 cleaning of utensils to prevent cross-contamination.

Specifically,

Your firm has not taken adequate steps to ensure the procedures for cleaning non-product dedicated utensils used in drug manufacturing operations effectively remove all contaminants. The procedure used by your firm to clean non-product dedicated utensils used for hormone drug production does not include a deactivating agent to prevent cross-contamination of residues from prior production operations between hormone drug lots. Your firm has released and distributed numerous lots of drug products without ensuring they have not been cross contaminated with residues from other hormone products, including but not limited to the following:

- Testosterone (b)(4)% gel, (b)(4) gm, lot 02222022:76, exp 08/14/22, exp 08/21/22, compounded 02/22/22 to fill Rx (b) (6)
- Estradiol/Estriol/Progesterone/Testosterone (b) (4) mg/gm cream, (b)(4) gm, lot 02212022:09, exp 08/20/22, compounded 02/21/22 to fill Rx (b) (6)

OBSERVATION 2

Non-microbial contamination was observed in your production area.

Specifically,

a) The ceiling of your (b) (4) Room, which is used to manufacture drug products containing

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	Christopher R Czajka, Investigator	X Christopher R. Czajka Investigator Signed By: Christopher R. Czajka -S Date Signed: 03-04-2022 14:10:50	3/4/2022

hormones, contains two air inlet vents, one of which was visibly covered with apparent dust build-up on 02/24/22. That same day, I observed the manufacture of the following drug product lots in the (b) (4) Room while air could be felt actively being blown into the room through the vents:

- Liothyronine (T3)/Methocel (Veg) (b)(4) mcg capsules, (b)(4) units, lot 02232022:96
- Progesterone (b)(4) mg per (b)(4) mL drops, (b)(4) mL, lot 02232022:24
- Estradiol (b) mg/Estriol (b) mg/Progesterone (b)(4) mg/Testosterone (b) mg per gm cream, (b)(4) gm, lot 02242022:63
- Progesterone (b)(4) mg suppositories, (b)(4) units, lot 02242022:42

b) The ceiling of the general compounding area in your facility consists of tiles made of an uncleanable porous (b) (4) material suspended by a (b) (4) grid framework. On 02/23/22 I observed build-up of dirt and foreign materials on both the (b) (4) tiles and (b) (4) grid in areas above and around the compounding stations used in non-hormone drug manufacturing operations. That same day, I witnessed the compounding of the following drug product lots in two of these areas, with components of each exposed to the ceiling above during weighing and transfer steps:

- Gabapentin (b)(4) mg capsules, (b) (4) units, lot 02232022:13
- Lidocaine (b)(4)%/Tetracaine (b)%% ointment, (b) (4) gm, lot 02232022:16

OBSERVATION 3

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

Specifically,

a) Your firm uses non-pharmaceutical grade (b) (4) in the production of non-sterile drug products.

b) Your firm does not perform analytical or microbiological testing of this component to determine whether the (b) (4) meets the specifications for (b) (4), USP.

OBSERVATION 4

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Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

Your firm does not perform quality control testing on finished drug products to ensure their identity, strength, purity, and quality prior to lot release. Your firm has released and distributed numerous lots of drug products without testing to ensure safety and efficacy, including but not limited to the following:

- Lidocaine/Tetracaine (b) (4) % LT microsomal base cream, (b) (4) kg, lot 05062021:64, exp 11/02/21, compounded 05/06/21 to fill Rx (b) (6) (non-patient specific)
- Benzocaine/Lidocaine/Tetracaine (b) (4) % microsomal base cream, (b) (4) kg, lot 05072021:72, exp 11/03/21, compounded 05/07/21 to fill Rx (b) (6) (non-patient specific)
- Doxycycline (vet) (b) (4) mg/mL suspension, (b) (4) mL, lot 11292021:39, exp 05/28/22, compounded 11/29/21 to fill Rx (b) (6) (non-patient specific)

OBSERVATION 5

Laboratory controls do not include determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of components used in the manufacture, processing, packing, or holding of drug products.

Specifically,

Your firm does not perform any analytical testing of incoming raw materials used in the manufacturing of drug products to ensure they conform to requirements for identity, strength, purity, and quality. Your firm has released and distributed numerous lots of drug products without ensuring the components in them are fir for use, including but not limited to the following:

- Lidocaine/Tetracaine (b) (4) % LT microsomal base cream, (b) (4) kg, lot 05062021:64, exp 11/02/21, compounded 05/06/21 to fill Rx (b) (6) (non-patient specific)

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OBSERVATION 6

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing and processing.

Specifically,

a) Your firm does not document actual weights and measurements of components used in the manufacture of drug products on the Logged Formula Worksheets which serve as batch records for drug product lots.

b) Your firm does not document the specific pieces of equipment used in the manufacture of drug products, including analytical balances and (b) (4) mixing machines.

Due to these practices, your firm has released and distributed numerous lots of drug products for which you do not have records documenting the actual amounts of the components or specific pieces of equipment that were used to manufacture them, including but not limited to the following:

- Lidocaine/Tetracaine (b) (4) % LT microsomal base cream, (b) (4) kg, lot 05062021:64, exp 11/02/21, compounded 05/06/21 to fill Rx (b) (6) (non-patient specific)
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***DATES OF INSPECTION**

2/23/2022(Wed), 2/24/2022(Thu), 2/25/2022(Fri), 3/01/2022(Tue), 3/04/2022(Fri)

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