

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100	DATE(S) OF INSPECTION 6/10/2019-6/17/2019* FEI NUMBER 3015414747
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Vickilee K. Einhellig, CEO
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FIRM NAME Professional Pharmacy Services Inc dba Good Day Pharmacy	STREET ADDRESS 1749 Main St Unit D
CITY, STATE, ZIP CODE, COUNTRY Longmont, CO 80501-7441	TYPE ESTABLISHMENT INSPECTED Non-Sterile Drug Manufacturer

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 highly potent drugs without providing adequate containment, segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

Equipment, work surfaces, and utensils are used for the production of hormonal products as well as non-hormonal products. Inadequate cross-contamination precautions are established to protect drug products produced on these shared surfaces at the Good Day Longmont location as well as the Good Day Fort Collins location. You have failed to demonstrate that the use of the dish washer and manual cleaning operations (soap and water) are adequate to mitigate cross-contamination of products made on site. Non-dedicated equipment, utensils, and work surfaces include the (b) (4) hood, compounding counter adjacent to the hood, glass stirrers, metal spatulas, glass mortar and pestle, mesh sieves, (b) (4) capsule machines, unguator and mixing blades, ointment mill, troche mold, stir bars, and beakers.

a. On 6/4/2019 you made the following hormone containing prescription products and non-hormone containing prescription products with mixed use equipment, utensils, and workstations:

- Testosterone 10mg Mini Troche Rx (b) (6), (b) (4) troches
- Progesterone 100mg IR Capsule Rx (b) (6), (b) (4) capsules
- BIEST (50:50) 0.1mg/gm (b) (4) 01.mg/gm cream Rx (b) (6), (b) (4)
- Progesterone 75mg SR #1 75mg Capsule Rx (b) (6), (b) (4) capsules

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Zachary A Bogorad, Investigator	Zachary A Bogorad Investigator Signed By: Zachary A. Bogorad-S Date Signed: 06-17-2019 09:57:06 X _____	DATE ISSUED 6/17/2019

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- Enrof 20mg/Prednisolone 5mg/Ursodiol 80mg/ml Oral Suspension Rx (b) (6), (b) (4)
- Prazosin 0.5mg Capsule Rx (b) (6), (b) (4)
- Ranitidine 30mg/mL Glycerin Oral Suspension Rx (b) (6), (b) (4)
- Clonidine 0.1mg/mL Oral Suspension Rx (b) (6), (b) (4)

b. On 6/7/2019 you made the following hormone containing products and non-hormone containing products with mixed use equipment, utensils, and workstations (b) (4), (b) (4) hood and compounding counter adjacent to the hood):

- Estradiol 5mg/gm Cream Rx (b) (6), (b) (4)
- Estradiol 15mg/gm Cream Rx (b) (6), (b) (4)
- Biest (80:20) 1.45mg/ Pregnenolone 65mg/ Progesterone 200mg/ Testosterone 0.65mg Sugar Free Troche Rx (b) (6), (b) (4) roches
- Testosterone 16% (160mg/gm) Cream Rx (b) (6), (b) (4)
- Gabapentin 50mg #3 Capsule Rx (b) (6), (b) (4) capsules
- Omeprazole 2mg/ml Oral Suspension Rx (b) (6), (b) (4)

OBSERVATION 2

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

Specifically, your pharmacy makes non-sterile prescription drug products using purchased (b) (4) (b) (4) including (b) (4) and (b) (4)/grocery store brands. You have never reviewed or collected certificates of analysis or established specifications to ensure that (b) (4) used is appropriate for pharmaceutical production operations. Examples of products produced with purchased (b) (4) include:

A. Triamcinolone 0.5% Oral Rinse liquid suspension, Rx (b) (6) made on 6/11/2019, (b) (4) BUD 6/25/2019

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B. Losartan 2.5mg/mL (Orasweet) suspension, Rx (b) (6) made on 2/11/2019, (b) (4) BUD 3/11/2019

***DATES OF INSPECTION**

6/10/2019(Mon), 6/11/2019(Tue), 6/13/2019(Thu), 6/17/2019(Mon)

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