

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 8/26/2019-9/9/2019* FEI NUMBER 3006078531
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey A. Barris, President

FIRM NAME Pacifica Pharmacy	STREET ADDRESS 23560 Madison St
CITY, STATE, ZIP CODE, COUNTRY Torrance, CA 90505-4708	TYPE ESTABLISHMENT INSPECTED Compounding Pharmacy

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 work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

The cleaning of hazardous drug product is not adequate. Your firm's cleaning between compounded products included only a wipe down of the compounding area/compounding hood with (b) (4). Your firm could not provide evidence that (b) (4) cleaned the hazardous drugs compounded at your firm. Additionally, you could provide no evidence that the detergents used to wash utensils and equipment remove the hazardous drug products you work with. The compounding area/compounding hood, utensils, and equipment are shared amongst all products (both hazardous drugs and non-hazardous drugs) at your pharmacy. Hazardous drugs compounded at your firm include Chloramphenicol, Methimazole, Diethylstilbestrol, Leflunomide, Estradiol, Apomorphine, Tretinoin, Oxytocin, Fluconazole, and Finasteride.

Your firm did not provide adequate cleaning of the (b) (4) hoods used to compound all hazardous drugs and non-hazardous drugs with (b) (4) ingredients. On 8/26/2019, I observed particle build up on the wires and the power strip located in the back of hood serial number (b) (4). The wires and power strip are kept less than a foot from areas with open containers during compounding. On 8/26/2019, the balance in hood serial number (b) (4), which used to weigh (b) (4) ingredients for compounding, had a buildup of material. These items were not removed during that day of compounding.

OBSERVATION 2

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Bryan A Galvez, Investigator	Bryan A Galvez Investigator Signed By: 2001972293 Date Signed: 09-09-2019 14:32:13 X _____	DATE ISSUED 9/9/2019

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Specifically,
Your firm used an expired ingredient to compound several topical prescriptions. Vitamin A Palmitate in Almond Oil lot (b) (4) expired on 01/01/2019. Additionally, this lot of Vitamin A's label indicates that it should be stored refrigerated. The Vitamin A was held at room temperature. This Vitamin A was used in the compounding of 21 prescription products in the last three months.

***DATES OF INSPECTION**
8/26/2019(Mon), 8/28/2019(Wed), 8/29/2019(Thu), 9/04/2019(Wed), 9/09/2019(Mon)

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