

**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 12/6/2018-12/17/2018*
		FEI NUMBER 3004600090
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Ian M Kuemerle, Owner		
FIRM NAME California Pharmacy & Compounding Center	STREET ADDRESS 4000 Birch St Ste 120	
CITY, STATE, ZIP CODE, COUNTRY Newport Beach, CA 92660-2258	TYPE ESTABLISHMENT INSPECTED Producer of 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 containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

Specifically, your firm produces hormone drug products and uses (b) (4) cleaning solution to clean the equipment and utensils. There is no assurance that (b) (4) cleaning solution removes any residues of hazardous drug materials of the working surface and utensils which could potentially affect the safety, identity, quality, or purity of drug products produced using shared equipment. For example, your firm produces hormone drug products such as Estradiol Sublingual 0.5 mg/0.05 ml Drop, Progesterone E4M 50 mg Capsule, Testosterone 2% (b) (4), Estradiol/Progesterone Versabase 0.5 mg/25 mg/ml, Testosterone Versabase 10%, and Testosterone base (yam) Troche, and any other hormone drug products.

***DATES OF INSPECTION**

12/06/2018(Thu), 12/07/2018(Fri), 12/17/2018(Mon)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Linda Thai, Investigator Mariza M Jafary, Compliance Officer (Region/District)	Linda Thai Investigator Signed By: 1000140954 Date Signed: 12-18-2018 15:10:26 X _____	DATE ISSUED 12/18/2018