

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	
<p>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.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1</p> <p>You produced hazardous drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.</p> <p>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.</p>			
<p>*DATES OF INSPECTION 12/06/2018(Thu), 12/07/2018(Fri), 12/17/2018(Mon)</p>			
<p>SEE REVERSE OF THIS PAGE</p>	<p>EMPLOYEE(S) SIGNATURE Linda Thai, Investigator</p>		<p>DATE ISSUED 12/17/2018</p>
		<p>Linda Thai Investigator Signed By: 1300149654 Date Signed: 12-17-2018 08:28:10</p> <p>X _____</p>	
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