

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 10/17/2018-10/25/2018*	
		FEI NUMBER 3006072852	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jerome A. Greene, Owner/Pharmacist			
FIRM NAME San Diego Compounding Pharmacy		STREET ADDRESS 5395 Ruffin Rd Ste 104	
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92123-1338		TYPE ESTABLISHMENT INSPECTED Producer of non-sterile 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 WE OBSERVED: OBSERVATION 1 Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.</p> <p>Specifically, equipment and utensils are cleaned; however, hazardous drugs were produced without providing adequate cleaning of work surfaces and utensils in that the use of a cleaning agent to inactivate any residues of hazardous drug material is not employed, which could potentially affect the safety, identity, strength, quality or purity of drug products manufactured using shared equipment.</p> <p>For example, the firm produces products such as BI-EST 5.5MG/GM HRT CREAM which involves the weighing of Estradiol in a hood. The firm's current cleaning includes only the use of (b) (4)</p>			
<p>*DATES OF INSPECTION 10/17/2018(Wed), 10/18/2018(Thu), 10/22/2018(Mon), 10/25/2018(Thu)</p>			
<p>Joey V Quitania Investigator Signed By: Joey V. Quitania -S Date Signed: 10-25-2018 09:50:22</p>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Santiago Gallardo Johnson, Investigator Joey V Quitania, Investigator		DATE ISSUED 10/25/2018
	<p>Santiago Gallardo Johnson Investigator Signed By: Santiago Gallardo Johnson -S Date Signed: 10-25-2018 08:49:14</p>		
<p>FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 of 1 PAGES</p>			