DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Los Angeles District 19701 Fairchild Irvine, CA 92612 949-608-2900 Industry Information: www.fda.gov/oc/industry	10/17, 20/16; 11/01,02,07,15/16
	FEI NUMBER 3006072852

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jerome A. Greene, Owner/ Pharmacist

FIRM NAME	STREET ADDRESS
San Diego Compounding Pharmacy	5395 Ruffin Rd., Suite 104
CITY, STATE AND ZIP CODE San Diego, CA 92123	TYPE OF ESTABLISHMENT INSPECTED Producer of non-sterile and sterile 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 (I) (WE) OBSERVED:

OBSERVATION 1

The (b) (4) is not always conducted for each lot of sterile drug products. Sterile drug products are produced by the firm from non-sterile API via (b) (4) under aseptic processing. There is no (b) (4) sterilization of finished drug products. The firm does not always conduct (b) (4) used to produce sterile drug products.

For example, Testosterone Cypionate 200mg/mL, Lot# 06/16/2016:0816 was produced via (b) (4) and aseptic processing. There was no evidence that testing was conducted to (b) (4) During the inspection, the firm discontinued the production of sterile drug products indefinitely.

OBSERVATION 2

The firm has not demonstrated that the aseptic filling and closing operations are adequate to produce sterile drug products. Specifically, there have been no media fill process simulations performed in the firm's cleanroom and ISO Class 5 Hood. During the inspection, the firm discontinued the production of sterile drug product indefinitely.

OBSERVATION 3

Room air pressure differentials are not monitored during each production of aseptically processed sterile drug products. The firm's cleanroom suite and ISO Class 5 Hoods used to produce sterile drug products lack gauges or other devices to measure and/or monitor the air pressure differentials. Air pressure differentials are only measured and recorded (b) (4) During the inspection, the firm discontinued the production of sterile drug products indefinitely.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	JQuitania	Joey V. Quitania, Investigator	11/15/2016