DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	7/8/2019 - 8/1/2019
	FEI NUMBER 3010006900

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mark J. Badria, Pharmacists in Charge/Co-Owner

FIRM NAME	STREET ADDRESS
Southern California Compounding Pharmacy, LLC	11125 Flintkote Avenue Suite F
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
San Diego, CA 92121	Producer of Sterile and Non-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
Personnel and environmental monitoring conducted within the ISO 5 Environments on a (b) (4) frequency are deficient.

Specifically, your firm does not perform growth promotion for each batch of media purchased or use a positive control when conducting (b) (4) gloved finger assessment and surface sampling. Your firm conducts gloved fingertip test and surface sampling as part of the compounding personnel qualification.

OBSERVATION 2
Gowning and aseptic practices are deficient.

Specifically, during the aseptic operation for Rx # (b) (6) on 7/10/19, we observed operator's head enter the ISO 5 Laminar Airflow Workstation (LAFW) during aseptic operations with exposed skin on forehead and cheeks. In addition, operator's skin was exposed at the ankle during aseptic operations and lower back skin was exposed during (b) (4) cleaning of the ISO 7 Buffer room.

OBSERVATION 3
The firm's cleaning and disinfecting procedure in the aseptic processing area are deficient.

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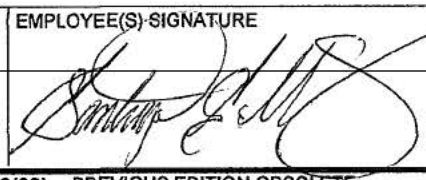
	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
SEE REVERSE OF THIS PAGE		Santiago Gallardo Johnson, Investigator	08/01/2019

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Specifically,
Your firm uses non-sterile wipes sprayed with (b) (4) to wipe components prior to introduction into the ISO 5 Laminar Airflow Workstation (LAFW) and to clean ISO 5 LAFW counter top where the sterile drug products are prepared. On 7/10/19, during sterile compounding of Rx #(b) (6) operator was observed moving items staged on the ISO 7 buffer room storage table to the ISO 5 LAFW without first sanitizing the items with (b) (4)

In addition, your firm utilizes the following non-sterile products to clean the ISO 5 LAFW:
(b) (4)

OBSERVATION 4
Smoke study conducted on 6/21/2019 to determine unidirectional airflows in ISO 5 LAFW was inadequate.

Specifically, the smoke study failed to adequately simulate dynamic conditions and did not provide adequate coverage to demonstrate unidirectional air flow during routine operations. ISO 5 LAFW is where the firm produces all its sterile drug products.

OBSERVATION 5
Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, sampling plans, and test procedures designed to assure drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, finished non-sterile drug products are not tested for the presence of microorganisms, for example: Ketoprofen 20%/Lidocaine 10%, lot no. 07419K20L10A, submitted for (b) (4) process validation sample did not include a test for the presence of microorganisms.

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	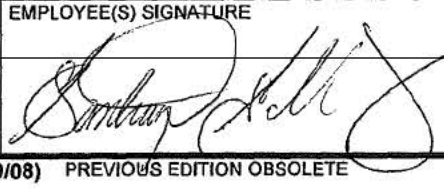	Santiago Gallardo Johnson, Investigator	08/01/2019