

**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 3/27/2017-4/21/2017*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Glen A. Olsheim , Chief Operating Officer		FEI NUMBER 3004600090
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 Outsourcing Facility	

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 OBSERVED:

OBSERVATION 1

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition and free of infestation by rodents, birds insects, and other vermin.

Specifically,

- Your firm failed to take measures to protect against infestation by insects. From 2/26/2016 to 10/10/2016 you had 23 deviations in which your environmental monitoring samples were contaminated with fly larvae in the firm's incubator. I observed 5 glue traps in the ISO-8 room and saw what appeared to be dead insects inside the traps.
- The horizontal working surface of ISO-5 classified hood (b) (4) is constructed of laminated particle board which is not easily cleanable and risks harboring microorganisms. The underside of the horizontal working surface of (b) (4) hoods is exposed particle board. The edges of the laminated working surface of hood (b) (4) are separating, creating an area that could harbor microorganisms. This edge is approximately 15 inches from the aseptic processing area of the hood.
- The cabinets in the ISO-8 room are constructed of laminated particle board with exposed particle board surfaces, which are porous and can harbor microorganisms.
- Particle board dust was observed in the ISO-8 room next to the (b) (4)
- The (b) (4) for your scale is housed in a wooden box stored in the ISO-8 room which is not easily cleanable.

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- Your firm stores a wooden stool in the ISO-8 room. Plastic totes were placed on the stool prior to entering ISO-7 room.

OBSERVATION 2

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

- Your firm's return vents in the ceiling of the ISO-8 classified room are located next to the HEPA filters.
- I observed perforations in the ceiling of the ISO-7 room which may allow unfiltered air to enter this room. For example...
 - (b) (4) are protruding through a hole in the ceiling. The edges of the hole are not smooth surfaces which could be easily cleaned.
 - The hole in the ceiling for wiring of (b) (4) camera has caulking which is peeling away.
- Inside the ISO-7 room there is wiring for the thermostat located at the exit above the door which has been held to the ceiling with clear plastic tape.
- There is carpet and broken linoleum tile at the entrance on the inside of the ISO-8 classified room.
- There is an unused doorway with a plywood door in the ISO-8 room which leads to a non-classified space. The plywood door is difficult to clean. Your firm has used blue

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painters tape to seal a gap above the plywood door.

- The walls of the ISO-8 room are constructed of drywall. Drywall dust was observed shedding from a hole in the drywall of the ISO-8 room. The hole is approximately 2 feet from the plywood door.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

- In the ISO-7 room your firm utilizes non-sterile (b) (4) and non-sterile (b) (4) which they refill with sterile (b) (4). Your firm could not provide assurance that the contents of these (b) (4) remain sterile. The (b) (4) are used in the ISO-5 hoods to (b) (4). The filled (b) (4) are stored in the ISO-5 hoods during production.
- I observed one area in the firm's ISO-8 classified room approximately 3 inches wide by 8 feet deep between the back wall of the ISO-7 room and the ISO-8 room that has stains on the floor, is not clean, and has what appear to be latex gloves, dust and dead insects on the floor.
- I observed dust on the top of the storage cabinet in the back of the ISO-8 room.

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

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Specifically,

The firm has conducted smoke studies under dynamic conditions in the (b) (4) which were not adequate. The study was only conducted (b) (4) (b) (4)

During the study the (b) (4)

Also the (b) (4)

The firm did not conduct a smoke study of the ISO-7 classified room as a whole.

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Your firm failed to investigate a discarded vial in your media fill for the preparation of Lidocaine HCl/ Phenylephrine HCl (P-F) 1%/1.5% Injectable on 3/24/2016 Lot Number (b) (4)

OBSERVATION 6

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

The materials section of your firm's batch records do not accurately capture the materials used during production. The wrong number and or type of (b) (4) used in the production of Lidocaine HCl/ Phenylephrine HCl (P-F) 1%/1.5% Injectable have been recorded in the materials section of your firm's (b) (4) Worksheets.

OBSERVATION 7

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Employees are not given training in the particular operations they perform as part of their function and written procedures required by current good manufacturing practice regulations.

Specifically, your firm does not have a written standard operating procedure for training personnel on reading environmental monitoring plates. Your firm does not keep records of employees trained to read environmental monitoring plates.

***DATES OF INSPECTION**

3/27/2017(Mon),3/28/2017(Tue),3/29/2017(Wed),3/30/2017(Thu),3/31/2017(Fri),4/03/2017(Mon),4/05/2017(Wed),4/06/2017(Thu),4/07/2017(Fri),4/13/2017(Thu),4/14/2017(Fri),4/19/2017(Wed),4/21/2017(Fri)

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