DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	10/14/2014 - 10/17/2014 FEI NUMBER 3004600090

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Glen A. Olsheim, Chief Financial Officer

FIRM NAME	STREET ADDRESS
California Pharmacy & Compounding Center	4000 Birch St Ste 120
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Newport Beach, CA 92660-2258	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 WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Thorough investigations were not conducted for complaints received by your firm. For example:

A. One patient adverse drug event (ADE) complaint was received by your firm from a Physician's office on 9/4/2014 for repackaged Avastin syringes. Documentation states that patient received Avastin injection 1.25mg/0.05ml with lot (b) (6) on 8/26/2014 but developed endophtalmitis associated with the Avastin injection. No documentation could be provided that the compounding records were reviewed or that other related lots prepared during this time period were investigated.

B. On 5/16/2014, three patient adverse drug events complaints, with ADE log #: ADE-1, ADE-2, and ADE-3 were received due to patient's use of Bevacizumab (Avastin) 1.25mg/0.05ml lot (b) (6). According to the ADE reports, Bevacizumab (Avastin) 1.25mg/0.05ml with lot (b) (6) was implicated in endophtalmitis; necessitating surgery to restore patients' vision. The same lot of Avastin was administered to the three patients on separate visits. Your firm did not investigate the connection between Avastin 1.25mg/0.05ml lot (b) (6) and the adverse events.

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	Ademola O. Daramola, Investigator Binh T. Nguyen, Investigator Liming Zhang, Investigator	10/17/2014

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OBSERVATION 2

Written records of investigations into the failure of a batch or any of its components to meet specifications do not include the conclusions and follow-up.

Specifically,

Microbial growths were observed in the following areas or during personnel monitoring:

Employee's left glove growth on 10/17/14 (1 cfu)
Employee's sterile face shield growth on 10/01/14 (3+cfu)
Employee's sterile gown growth on 10/01/14 (3 cfu)
Employee's sterile face shield growth on 10/02/14 (result: "fail"- no cfu count was recorded)
Employee's sterile face shield growth on 10/07/14 (2 cfu)
Employee's sterile gown growth on 10/07/14 (1 cfu)
Employee's sterile gown growth on 10/09/14 (2 cfu)

There were no investigation reports completed for the positive test results. You did not conduct any microbial identification to understand the normal flora of cleanroom surfaces, personnel, and environment.

Additionally, root cause corrective actions or preventive actions were not implemented, which is a deviation from your firm's written procedure #AWI 4.30 Rev A titled "Area Work Instruction (AWI): Gloved Fingertip Sampling Procedure," effective date 10/8/14, page 5, section 5.4.3 which states as follows: "(b) (4) "

5.4.3.1 "(b) (4) "
5.4.3.2 "(b) (4) "

According to section 5.4.2 of the the firm's procedure #AWI 4.30 Rev A titled "Area Work Instruction (AWI): Gloved Fingertip Sampling Procedure,", the "action level guidelines are per USP<797>" as follows:

ISO 5 environment: >3 cfu

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ISO 7 environment: N/A
ISO 8 environment: N/A

There is no alert level guideline specified in the procedure #AWI 4.30 Rev A titled "Area Work Instruction (AWI): Gloved Fingertip Sampling Procedure."

OBSERVATION 3

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically,

Your firm lacks adequate controls for printing labels, issuing labels, examining issued labels, and reconciliation of used labels to prevent mix-ups.

For example,

A. Your firm does not maintain a written and approved procedure describing the steps and practise of label printing, issuance, examination, and reconciliation of the labels for your sterile and non-sterile compounded drug products.

B. The results of the examination of labeled products were not documented in the batch production or control records. Specifically, there is no documentation of the review of each unit by the pharmacist of finished product after compounding prior to release and distribution. The review of labeled syringes prior to distribution for Bevacizumab (Avastin) lots B101414A, B101314, B100714, B101214, and B100114 was not documented.

C. Drug product labels are not stored under secure and access-restricted locations to avoid mix-ups. Specifically, half-used booklets of labels for Avastin lot B101414A and Avastin lot B101314 were observed stored in the open on a table within the production room unmonitored.

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