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	08/02/2016 - 08/31/2016* FEI NUMBER 3004600090

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Glen A. Olsheim, Chief Operating 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	503B 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

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

Specifically,
1) Media fills conducted within the ISO 5 Laminar Flow Hoods are inadequate. For example:
a) They do not simulate the worst case scenario in your process to include the longest production times or human interventions as required in the Work Instruction WI-101-003-003. Your media fill matrix identified that Bevacizumab PFS production has the filling process for (b) (4) . The media fills completed on (b) (4) and thus they did not meet your maximum filling time.
b) You did not include gram negative bacteria and your in house representative isolates in the growth promotion challenge.
c) You used (b) (4) instead of (b) (4) for media fill of Lidocaine HCL/Phenylephrine HCL (P-F) 1%/1.5% Injection as required in the Media Fill Logged Formula Worksheet.
d) You failed to include vials/syringes that were rejected for particulates or physical defects during the media fill incubation.
2) Smoke studies conducted on (b) (4) to determine unidirectional airflow in ISO 5 (b) (4) Laminar Flow Hoods were not performed under dynamic conditions and did not provide assurance that the HEPA-filtered unidirectional airflow covering the working area under working conditions and no ingress of ISO 7 air into ISO 5 working area. The smoke studies failed to include components/equipment i.e. (b) (4) , and movements of an operator in/out of ISO 5/7 area during the production.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Linda Thai, Investigator	08/31/2016

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OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, there is no scientific rational to support your personnel monitoring program can provide adequate assurance for your aseptic processing of drug products. The personnel monitoring samples (i.e. around(b) (4)) were taken (b) (4)

OBSERVATION 3

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, the (b) (4) certifications for ISO 7 and ISO 8 area conducted on (b) (4) failed to include HEPA filter leak testing for the filters located in ISO 7 and ISO 8 room.

OBSERVATION 4

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, you failed to follow the written SOP No. P-101-002-C, Process Controls - Sterile Operations, that requires bacteria endotoxin to be performed (b) (4) There were no documents to indicate that the bacteria endotoxin test was conducted for the following drug products:

1) Vancomycin Ophthalmic (Intravitreal) 1 mg/0.1 mL Syringe.
2) Ceftazidime Intravitreal 2.25 mg/0.1 mL (PFS).

OBSERVATION 5

1) The labels of your outsourcing facility's drug products do not include information required by section 503B (a) (10) (A) and (B). Specifically, the following information is not found on some of your drug product labels:

- The national drug code (NDC) number is not on your drug product labels. Labels for

the following drug products do not contain an NDC number:

- Dexamethasone SOD PHOS 16mg/ml (PF) Sol.
- Lidocaine 1% Phenylephrine 1.5% P-F 1ml SDV
- Bevacizumab/Dexamethasone 1.25mg/1mg/0/1ml Injection
- Vancomycin PF 1mg/0.1ml (SDV) Sol.
- Progesterone 100mg Canola Oil Cap

- The statements, "This is a compounded drug," "Not for resale," and "Office use only".

Examples of drug products that do not contain this information:

- Alteplase 10mcg/0.1ml PF
- Lidocaine 1% Phenylephrine 1.5% P-F 1ml SDV
- Vancomycin 1mg/0.1ml Inj in NaCl 0.9%

- The lot or batch number is not on the product label for Testosterone PLO 4mg/ml Gel and Progesterone 100mg Canola Oil Cap.

- The statement, "Office use only" is not on the product label for Cefuroxime 1mg/0.1ml in 0.9% NaCl Oph Injection 1ml vial.

- A list of active and inactive ingredients, identified by established name and the quantity or proportion of each.

Examples of drug product labels that do not contain this information:

- Bleomycin 0.75U/.075ml Injection
- Alteplase 10mcg/0.1ml PF
- Lidocaine 1% Phenylephrine 1.5% P-F 1ml SDV
- Dexamethasone 16mg/ml in 0.9% NaCl
- Vancomycin 1mg/0.1ml Inj in NaCl0.9%
- Cefuroxime 1mg/0.1ml in 0.9% NaCl
- Testosterone PLO 4mg/ml Gel
- Progesterone 100mg Canola Oil Cap

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Furthermore, the following information is not found on the container labels for the drug products you produce.

- The route of administration:

Examples of container labels that do not contain this information:

- Bleomycin 0.75UNITS/.075ml Sol
- Alteplase (TPA) 10mcg/0.1ml (PFS) Sol
- Lido/Phenylephrine 1% /1.5% (PF) (SDV) Sol
- Dexamethasone SOD Phos 16mg/ml (PF) Sol
- Vancomycin PF 1mg/0.1ml (SDV) Sol
- Cefuroxime 10mg/ml Sol
- Triamcinolone Acetonide 4mg/0.1ml PFS PF Sol

1) Your outsourcing facility has not submitted a report to FDA identifying products compounded during June 2015 to December 2015 as required by section 503B(b)(2)(A).

*** DATES OF INSPECTION:**
08/02/2016(Tue), 08/03/2016(Wed), 08/04/2016(Thu), 08/05/2016(Fri), 08/08/2016(Mon), 08/09/2016(Tue), 08/10/2016(Wed), 08/11/2016(Thu), 08/31/2016(Wed)

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