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	08/18/2014 - 08/25/2014 FEI NUMBER 3004600090

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. 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 WE OBSERVED:

Facilities and Equipment System

OBSERVATION 1

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

Specifically,

A. Your firm failed to conduct environmental monitoring of air, personnel and surface during daily production periods, within the ISO 7 clean room and ISO 5 laminar flow hoods used to prepare your sterile drug products. For example:

   a) During the period covering March 21st 2014 to June 19th 2014, no environmental monitoring of air, personnel, or surface was performed by your firm. During this period, an average number of [redacted] (b) (4) sterile formulations were compounded, filled and released from your facility per day.

   b) During the period of January 26th 2014 to March 19th 2014, no environmental monitoring of air, personnel, or surface was performed by your firm. During this period, approximately [redacted] (b) (4) sterile formulations were compounded, filled, and released from your facility per day.

B. Your firm does not monitor personnel and environmental bio-burden within your sterile processing facility during production periods. For example:

   a) Your firm does not perform microbiological sampling of personnel gowns worn by pharmacists and technicians that process drug products intended to be sterile in aseptic processing areas. On 8/18/2014, we reviewed environmental monitoring records that

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ademola O. Daramola, Investigator Binh T. Nguyen, Investigator	DATE ISSUED 08/25/2014

indicated results of finger tips sampling but no other portion of the operators (such as arms and chest) who performed aseptic manipulations was tested. Your chief operating officer stated that there were no other samples collected to monitor the microbial load of gowns worn by operators in the aseptic processing areas. Additionally, operators' finger-tips are tested [redacted] (b) (4) of aseptic process, not after production, and testing is not performed for microbial contamination at least daily but [redacted] (b) (4). The written procedure which guides the gloved fingertip sampling; AWI 4.30 titled "Area Work Instruction: Gloved Fingertip Sampling Procedure" does not have a defined frequency for sampling and testing of personnel finger tips as well as monitoring other areas such as arms, chests, and masks.

b) There are [redacted] (b) (4) ISO 5 LFH (laminar flow hood) located in ISO 7 area. These [redacted] (b) (4) LFH's are used on a [redacted] (b) (4) basis. However, your firm does not perform environmental monitoring of these LFH's at least on a [redacted] (b) (4) basis. Your firm performed environmental monitoring of work surfaces as follows per SOP AWI 1.60 titled "Area Work Instruction (AWI): Environmental Monitoring Procedure"

a. On 07/18/14, LFH [redacted] (b) (4) was surface-tested using [redacted] (b) (4)
b. On 07/25/14, LFH [redacted] (b) (4) was surface-tested using [redacted] (b) (4)
c. On 08/02/14, LFH [redacted] (b) (4) was surface-tested using [redacted] (b) (4)
d. On 08/09/14, LFH [redacted] (b) (4) was surface-tested using [redacted] (b) (4)
e. On 08/15/14, LFH [redacted] (b) (4) was surface-tested using [redacted] (b) (4)

SOP AWI 1.60, section 5.2 states "Samples are collected [redacted] (b) (4) using both [redacted] (b) (4) [redacted] (b) (4) media. Each type of media is used on [redacted] (b) (4): [redacted] (b) (4) [redacted] This SOP does not specify that each hood be tested at a certain frequency.

OBSERVATION 2

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

A. Storage of sterilized stoppers (inside ISO 8 room) and conditions of reuse may pose contamination risks. Previously sterilized rubber stoppers used as container closure for your

sterile products are loaded into totes and stored inside the ISO 8 ante room for upwards of (b) (4) [redacted]. The (b) (4) storage date is arbitrarily assigned with no scientific justification. Prior to use inside the clean room, the sterility and endotoxin of these stoppers are not verified. The tote bags are removed from the ante room and moved into the clean room, where the tote bag is opened under ISO 5. Once open, the bag is left open on the LAF work surface for (b) (4) [redacted] allowing the employee to make repeated retrieval of rubber stoppers from the bag based on the batch size of product being manufactured before resealing the bag and returned to the ISO 8 location. This process is repeated several times on different production days until the tote bag is emptied. The rubber stoppers are immediate contact surfaces for the sterile products and the process of opening the tote bag several times and picking out rubber stoppers before being stored under ISO 8 conditions may pose a contamination risk to the product. For example, this same lot of serum bottle stopper (b) (4) [redacted] was used in the capping of the following drug products.

Date made	Quantity	Product	Lot #
(b) (4) [redacted]	(b) (4) [redacted]	Nandrolone Decanoate Oil Injection 100mg/ml	B717389
		Hydroxyprogesterone Caproate 250mg/ml	B041214A
		Progesterone in Ethyl Oleate 50mg/ml	B041314A
		Progesterone in Ethyl Oleate 50mg/ml	B050714A
		Hydroxyprogesterone Caproate 250mg/ml	B052314R
		Hydroxyprogesterone Caproate 250mg/ml	B071714A
		Progesterone in Ethyl Oleate 50mg/ml	B071814A

B. Your firm does not perform closure container integrity test to verify that your products are adequately protected from leaks and ingress of microorganisms. For example, your firm uses a (b) (4) [redacted] seal your finished product vials.

OBSERVATION 3

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, your clean room design is deficient to prevent product contamination. For example:

A. The air exhaust vents located in your ISO 7 and ISO 8 cleanrooms open into a non-classified area of the facility. On 8/18/2014, we observed that the modular clean rooms have air exhaust vents located on the base of the wall. The air vents open directly to the unclassified

environment surrounding the clean room, increasing the potential for air exchanges between the ISO 7 and ISO 8 cleanrooms and the non-classified environment, and an influx of contamination from the unclassified area of low air quality into the clean room due to the lack of proper air pressurization (there is no pressure differential monitoring between the classified and unclassified areas as well as between ISO 7 and ISO 8 areas). Additionally, there is no program in place for pest monitoring at the facility.

B. The exhaust vents located in the ISO 7 cleanroom were partially blocked by a metal table, obstructing air flow/return. On 8/18/2014, we observed that the air vents exhaust located on the base of the wall directly opposite the laminar flow hood inside your ISO 7 clean room were obstructed by a silver colored metal table which held tote bags and sterile components used in the production of your sterile drug products. The blockage of the air exhaust vents may pose a potential risk of airflow turbulences inside the [redacted] (b) (4) ISO 5 laminar flow hoods located inside this ISO 7 clean room.

C. Your firm failed to calibrate the [redacted] (b) (4) pressure gauges; [redacted] (b) (4) used to monitor air pressure of ISO 7 and ISO 8 clean rooms.

D. There is no documented unidirectional air flow between ISO 5 work benches where aseptic manipulation of drug products occurs and room spaces classified as ISO 7 areas. Additionally, smoke studies conducted on March 20th 2014 show turbulent and stagnant air within ISO 5 areas used to sterilize and fill drug product unit containers.

OBSERVATION 4

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

Specifically, The frequency of cleaning and disinfection of your cleanroom is inadequate for the operations being performed. Your firm compounds an average of [redacted] (b) (4) of sterile drug products daily but the clean rooms (walls and floor) are only cleaned [redacted] (b) (4) with non-sterile germicidal solutions such as [redacted] (b) (4). Your firm does not use any sporicidal cleaning agent to clean the ISO 5 environment. Per the Quality Assurance Director, the [redacted] (b) ISO 5 hoods are cleaned with [redacted] (b) (4) on at least [redacted] (b) (4) compounding batch but the

firm does not have any cleaning procedure for ISO 5 hood in place yet.

OBSERVATION 5

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

A. Your firm has not conducted equipment qualification to show that [redacted (b) (4)] used to sterilize rubber stoppers and [redacted (b) (4)] used to de-pyrogenate glassware achieve appropriate log reduction of microbes. Your firm does not use any BI (biological indicator) during the sterilization of glassware and closure (rubber stoppers). [redacted (b) (4)] sterilization of finished products by [redacted (b) (4)] is done at [redacted (b) (4)], while glassware and rubber stoppers are sterilized in the [redacted (b) (4)] for [redacted (b) (4)]. Your firm only conducts [redacted (b) (4)] of the [redacted (b) (4)] (not [redacted (b) (4)]) using [redacted (b) (4)].

B. Your firm has not validated sterilization method used to sterilize glass vials and rubber stoppers used in the storage of sterile drug products to ensure sterility of glass vials and rubber stoppers.

Quality System

OBSERVATION 6

Clothing of personnel engaged in the manufacturing, processing, and holding of drug products is not appropriate for the duties they perform.

Specifically, gowning for sterile operation is inadequate in that

A. Non-sterile face masks, hair nets, and shoe covers are worn during aseptic processing of sterile drug production in the ISO 5 horizontal laminar air flow hoods.

B. Street scrubs are worn covered with sterile gown but the scrubs are still exposed during production of sterile products.

C. There are no sterile goggles worn during production of sterile products.

D. There is facial skin exposure during production of sterile products.

E. Employees can bring cell phones and head phones to listen to media during production of sterile products.

For example,

a) On 8/18/2014, we observed your Pharmacist ([redacted (b)(6)]) and Pharmacy technicians ([redacted (b)(6)]) during aseptic processing (compounding and filling) of sterile human drugs (Bevacizumab 2.5mg/0.1ml PFS syringe; lot #B081814) inside the ISO 7 cleanroom and ISO 5 laminar flow hood, wearing non-sterile glasses (without goggles), non-sterile face masks, and non-sterile hair nets. We also observed [redacted (b)(6)] had [redacted (b)(4)] head phones (worn beneath non-sterile hairnet) connected by wires to a cell phone (stored in plastic bag) placed inside the hood (within 6 inches from the hood's edge) to listen to media.

b) On 8/18/2014, the employees ([redacted (b)(6)]) had their forehead, eyebrows, eyelashes, and neck region exposed during aseptic processing (compounding and filling) of sterile human drugs (Bevacizumab 2.5mg/0.1ml PFS syringe; lot #B081814). During the performance of this sterile operation, they had their foreheads inside the ISO 5 laminar flow hoods where there was no physical barrier between their exposed skin or the non-sterile face masks and the open 10 ml Bevacizumab glass vials on the LFH work surface.

c) On 8/18/2014, we observed that the employees' ([redacted (b)(6)]) street clothes were protruding from under the gowns worn during the aseptic processing of sterile Bevacizumab 2.5mg/0.1ml PFS syringe; lot #B081814, inside the ISO 7 cleanroom and ISO 5 laminar flow hoods.

d)On 8/18/2014, we also observed that the employees ([redacted (b)(6)]) entered the cleanroom and engaged in the aseptic production of sterile Bevacizumab 2.5mg/0.1ml PFS syringe; lot #B081814 while wearing shoe covers over their shoes; the shoe covers were donned inside a non-classified area of the facility.

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OBSERVATION 7

Written records are not made of investigations into unexplained discrepancies.

Specifically, your firm failed to document internal investigation of three cases of product leakage in transit during shipment for sterility tests. For example,

1. On 5/14/2014, one sample of Oxytocin Nasal Spray 360 iu/ml solution (sterile); lot #B051414B leaked during transit to the sterility testing laboratory;

2. On 07/01/2014, one sample of Oxytocin Nasal Spray (Investigational study IND # 100,860) 120 iu/ml solution; lot AB062614 was found to have leaked out during transit to the sterility testing laboratory;

3. On 07/01/2014, one sample of Oxytocin Nasal Spray (Investigational study) 120 iu/ml solution; lot RB062614 was found to have leaked out during transit to the sterility testing laboratory.

According to the chief operating officer and quality control specialist, your firm conducted an in house investigation to find the root cause of the leaks, from the investigation; the firm determined the root cause and implemented corrective action. However, there is no written documentation of the steps involved in the investigation, the corrective action and effectiveness checks of the corrective action taken.

Laboratory System

OBSERVATION 8

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

Specifically,

A. Your firm does not have a written and approved employee training procedure to guide your technicians during conduct of sterile aseptic processes including frequency of training. There are no employee training logs documenting how and when each employee was trained in aseptic processes.

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B. There is also no training procedure for employees to perform 100% visual inspection checks of sterile drug products.

OBSERVATION 9

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

Specifically, your firm does not conduct sterility testing for Nandrolone Decanoate Oil Injection 200mg/ml solution (non-sterile to sterile process using non-validated [redacted (b) (4)]), a patient specific product with BUD of 3 days.

OBSERVATION 10

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

Specifically, your firm's practice of visual inspection is deficient as follows:

A. Your firm's product inspection process is deficient in that you do not perform 100% visual checks, against a contrasting background of your sterile liquid formulations prior to release. Per the Pharmacist in Charge (PIC), about [redacted (b) (4)] of the finished products are visually inspected. Your firm has not established a written procedure for performing products visual checks.

B. On 8/19/2014, during a demonstration of visual check by your pharmacist ([redacted (b) (6)]), I observed that the employee shook the vials when inspecting them for particulate matter and fungal growth.

OBSERVATION 11

Results of stability testing are not used in determining expiration dates.

Specifically, your firm fialed to conduct preserative content testing for your sterile finished products at the time of release. For example:

A. Thirty three (33) different sterile formulations containing [redacted (b) (4)] preservative and fourteen (14) different sterile formulations containing [redacted (b) (4)] preservative were released without performing preservative content testing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Ademola O. Daramola, Investigator Binh T. Nguyen, Investigator BTN	08/25/2014

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Products using [redacted] (b) (4) as preservative:

Product	Risk	Preservative (b) (4)	BUD
Vancomycin opthalmic 14mg/ml lot B718067 (1)	Sterile to sterile	[redacted]	9 days
DMSO/Glutathione 1.25% opthalmic lot B713477 (1)	Non-sterile to sterile		3 days
Voriconazole opthalmic 10mg/ml lot B721598	Sterile to sterile		9 days
Vancomycin opthalmic 14mg/ml lot B718067 (2)	Sterile to sterile		9 days
Mometasone Nasal 600mcg/2.5ml lot B721084	Non-sterile to sterile		3 days
Voriconazole opthalmic 10mg/ml lot B720846	Sterile to sterile		9 days
EDTA opthalmic 2% lot B720464	Non-sterile to sterile		3 days
DMSO/Glutathione 1.25% opthalmic lot B713477 (2)	Non-sterile to sterile		30 days
Voriconazole opthalmic 10mg/ml lot B720406	Sterile to sterile		9 days
Vancomycin opthalmic 14mg/ml lot# B718067 (6/10/2014)	Sterile to sterile		9 days
Vancomycin opthalmic 14mg/ml	Sterile to sterile		9 days

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lot B720223			
Vancomycin opthalmic 15mg/ml lot B719847	Sterile to sterile	[redacted] (b) (4)	9 days
Voriconazole opthalmic 10mg/ml lot B719498	Sterile to sterile		9 days
Voriconazole opthalmic 10mg/ml lot B719607	Sterile to sterile		9 days
Voriconazole opthalmic 10mg/ml lot B719498	Sterile to sterile		9 days
Vancomycin opthalmic 15mg/ml lot B718067(3) 5/17/14	Sterile to sterile		9 days
Interferon Alfa 2B opthalmic lot B710261	Non-sterile to sterile		14 days
Dexamethasone opthalmic 0.1% lot B050714B	Non-sterile to sterile		14 days

In addition to the eighteen products depicted in the above table, fifteen product lots were also compounded using [redacted] (b) (4) as a preservative.

Products using [redacted] (b) (4) as preservative:

Product	Risk	Preservative	BUD
Nadrolone Decanoate 100mg/ml inj lot B717389	Non-sterile to sterile	[redacted] (b) (4)	90 days
Hydroxyprogesterone caproate in castor oil lot B041214A	Non-sterile to sterile		180 days
Progesterone in ethyl oleate lot B041314A	Non-sterile to sterile		90 days

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EMPLOYEE(S) SIGNATURE
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Binh T. Nguyen, Investigator

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Progesterone in ethyl oleate lot B050714A	Non-sterile to sterile	[redacted] (b) (4)	90 days
Hydroxyprogesterone caproate in castor oil lot B052314R	Non-sterile to sterile		180 days
Hydroxyprogesterone caproate in castor oil lot B071714A	Non-sterile to sterile		180 days
Progesterone in ethyl oleate lot B071814A	Non-sterile to sterile		90 days
Progesterone Cypionate 120mg/3mg/ml inj lot B717688	Non-sterile to sterile		3 days
Nadrolone Decanoate 200mg/ml inj lot B720802	Non-sterile to sterile		3 days
Phosphatidylcholine/Deoxycholic acid inj 5%/4.2% lot B720839	Non-sterile to sterile		3 days
Phosphatidylcholine/Deoxycholic acid inj 5%/4.2% lot B720838	Non-sterile to sterile		3 days
Testosterone cypionate 120mg/3mg/ml inj lot B717688	Non-sterile to sterile		3 days
Testosterone propionate 200mg/ml inj lot B720246	Non-sterile to sterile		3 days
Nadrolone Decanoate 200mg/ml inj lot B720024	Non-sterile to sterile		3 days

Production System

OBSERVATION 12

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

Specifically, media fill simulations are deficient:

A. They do not simulate the worst case scenario in your sterile process, including the retrieval of

sterile rubber stoppers from sterile tote bags opened for [redacted] (b) (4) in the LFH and the capping process.

B. Additionally, your media fills do not simulate acceptable hold times including the maximum length of production times.

OBSERVATION 13

Procedures for the preparation of master production and control records are not followed.

Specifically, your firm's logged formulation worksheet (LFW) documenting the production steps of Hydroxyprogesterone caproate 250mg/ml injectable was not followed during the compounding. Your firm's technicians used [redacted] (b) (4) located inside the ISO 8 ante room to [redacted] (b) (4) before transferring it to the ISO 5 laminar flow hood in the ISO 7 clean room for filling. The LFW states that "all procedures shall be performed in a laminar flow hood clean air workstation within a cleanroom, utilizing aseptic technique."

Packaging and Labeling System

OBSERVATION 14

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

Specifically, your firm's label procedure SOP 8.00, Effective Date 07/18/14 titled "Standard Operating Procedure: Labeling, Storage, Shipment and Disposal Procedure" is deficient in that it fails to address label issuance, identification, storage, handling, sampling, and reconciliation. In actual practice, any pharmacist can print out a number of labels for use.

OBSERVATION 15

The labels of your outsourcing facility's drug products do not include information required by section 503B (a)(10)(A)and (B).

Specifically, the labels affixed to your firm's drug products do not include the statements, "This is a compounded drug," "Not for resale," and "Office Use Only." The labels affixed to the drug products

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also do not include the following required information: name, address, phone number of your outsourcing facility; dosage form and strength; statement of quantity or volume, as appropriate; date drug was compounded; expiration date; and storage and handling instructions.

Furthermore, neither the drug product label nor the container from which the individual units of the drug are removed for dispensing or administration include a list of inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

In addition, the container from which the individual units of the drug are removed for dispensing or administration do not contain the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 <http://www.fda.gov/medwatch and 1-800-FDA-1088>.

Labels for the following drug products do not contain all of the required information described above:

i. Vancomycin Intravit 1MG/0.1ML Sol.
ii. Bevacizumab/Dexameth 1.25MG/1MG/0.1ML Sol.
iii. Proparacaine Opth 0.05% Sol
iv. Bevacizumab 1.25MG/0.05ML Sol.
v. Ceftazidime Intravit 2.25MG/0.1ML Sol

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."