

**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 4/20/2016-5/9/2016*
	FEI NUMBER 3012266548

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael A. Pavlovich, Pharm. D. , President

FIRM NAME Professional Partners, Inc./ Westcliff Compounding Pharmacy	STREET ADDRESS 1901 Westcliff Dr. Ste. 3A
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CITY, STATE, ZIP CODE, COUNTRY Newport Beach, CA 92660-5505	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs
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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

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

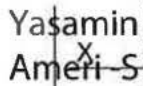
Specifically, your firm

- does not have a written procedure to test containers and closures to ensure that they are pyrogen free:
- has not conducted studies to show that sterile products' container/closures that are purchased non-sterile and sterilized by your firm are free of pyrogen after sterilization.
- has not established written procedure for washing and depyrogenating of container and closures used to hold sterile Testosterone hormone pellets. Currently, glass vials and (b) (4) caps are (b) (4) and then (b) (4).

OBSERVATION 2

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

Specifically, your firm has not conducted any validation study to show that (b) (4) is adequate to sterilize Testosterone hormone drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Yasamin Ameri, Generic Drug User Fee Amendments (GDUFA)	 <p>Digitally signed by Yasamin Ameri-S DN: cn=US, o=US Government, ou=FDA, ou=People, ou=Yasamin Ameri-S, o=9-2342, 2.5.4.2.1.20030010001111, 001565915 Date: 2016.05.09 13:51:49 -0700</p>	DATE ISSUED 5/9/2016

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OBSERVATION 3

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, your firm has produced and distributed approximately (b) (4) sterile Testosterone hormone pellets in various strengths since January 6, 2016 without testing for endotoxin prior to distribution of the product.

OBSERVATION 4

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

Specifically,

- SOP Nos. 19.004, Environmental surface and air testing and 16.009, LAFW (Laminar Flow Workbench) and (b) (4) are deficient in that they require that viable air and surface samples to be taken on (b) (4) basis for ISO 5 (b) (4) instead of production days.
- Your firm also failed to perform routine environmental monitoring for March and April of 2016 on (b) (4) (ISO 5). The (b) (4) was used for compression of Testosterone pellets prior to (b) (4) sterilization.

OBSERVATION 5


Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, the firm does not follow SOP No. 6.001 titled "Glassware-cleaning", for cleaning of (b) (4) SOP No. 6.001, section A.2, "Water-insoluble"; states: (b) (4)

(b) (4)

(b) (4)

On April 25, 2016, I observed that the technician wiped the (b) (4) which was used in production of Testosterone Hormone pellets lot # 04252016@5, with (b) (4)

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(b) (4)) and put them inside the common dishwashing sink in "(b) (4) Compounding room". This sink is used for (b) (4).

Technician (b) (7)(C), (b) (6) stated that (b) (7)(C), (b) (6) used non-sterilized (b) (4) for sanitization of the containers prior to use. (b) (7)(C), (b) (6) also explained that (b) (7)(C), (b) (6) sprayed the items with (b) (4) and let them (b) (4), (b) (4).

The same (b) (4) is used for (b) (4) of potent (Testosterone, Progesterone, Estradiol, etc.) and non-potent (Lidocaine, Baclofen, etc.) drug products.

OBSERVATION 6

Written records are not always made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically, the firm has no written procedure to conduct investigation on unexplained discrepancies. For example, firm rejects some pellets after sterilization for Testosterone lots # 03302016@4, 01142016@18, 02092016@5, and 02012016@4; but failed to conduct any investigation to determine the cause for the rejection.

OBSERVATION 7

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, there is no written stability testing program to support the Beyond Use Date (BUD) of drug products. For example, sterile Testosterone hormone drug products are assigned with six months expiration date without a six months stability data on sterility.

OBSERVATION 8

The calibration of instruments , apparatus and recording devices is not done at suitable intervals in accordance with an established written program.

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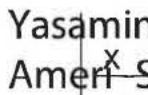
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Specifically,

- SOP Nos.: 6.013, (b) (4) "Balance Cleaning and Maintenance"; 6.013.01, (b) (4) "Balances"; 6.013.02, (b) (4) "Balance"; and 6.013.03, (b) (4) "Balance" requiring balances to be calibrated with (b) (4) at least (b) (4) and recorded on a balance Calibration log on are not followed. Firm uses only (b) (4) for calibration of all balances.
- Your firm uses none-calibrated equipment and instruments for processing and measuring of the processes. The following pieces of equipment were used by your firm without calibration:
 - o (b) (4) used for sterilization of Testosterone hormone pellets
 - o (b) (4) on incubator used for incubation of (b) (4) (b) (4)) and contact plates (personnel fingertip samples)
 - o (b) (4) used for verification/calibration of (b) (4) balance
 - o (b) (4) used for monitoring (b) (4) cleanrooms (ISO 5 and 7).

***DATES OF INSPECTION**

4/20/2016(Wed),4/21/2016(Thu),4/22/2016(Fri),4/25/2016(Mon),4/26/2016(Tue),4/27/2016(Wed),4/28/2016(Thu),4/29/2016(Fri),5/09/2016(Mon)

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