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	08/31/2015 - 09/10/2015* FEI NUMBER 3004578527

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David A. Nicoletti, R.Ph., President

FIRM NAME	STREET ADDRESS
Prescription Lab Compounding Pharmacy	6586 E Grant Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tucson, AZ 85715-3801	Producer of sterile drugs

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

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

Specifically, Environmental monitoring (b) (4) (b) (4) used to prepare sterile products is not conducted each day that sterile drugs are prepared. For example:

A. Non-viable particulate monitoring (b) (4) (b) (4) and in the surrounding ISO 7 buffer room is performed every (b) (4) by the vendor that certifies the (b) (4)
B. Viable air monitoring (b) (4) (b) (4) and in the surrounding ISO 7 buffer room is performed every (b) (4) by the vendor that certifies the (b) (4) .
C. Surface monitoring (b) (4) (b) (4) and the surrounding ISO 7 buffer room is performed (b) (4)
D. Personnel monitoring of the gloved fingertips is performed only (b) (4) .

OBSERVATION 2

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

Specifically, a solution of (b) (4) is used to clean the ISO 5 (b) (4) and the ISO 7 workbench.

OBSERVATION 3

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

Specifically, oil based products (b) (4) (b) (4) . The process (b) (4) have not been validated and no (b) (4) are placed in the (b) (4) (b) (4) product. For example:

a. Testosterone (70/30) Cypion/Enan 200mg/ml, lot number 08212015:93@32 was prepared on 8/21/2015. The

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Caryn M. Mcnab, Investigator Caryn McNab	09/10/2015

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product was (b) (4) and then (b) (4). In addition,

i. There is no validation study showing that these (b) (4) are adequate to render the product sterile.
ii. There is no (b) (4) used during the (b) (4) to confirm sterility.
iii. There is no record of the actual time (b) (4) of the (b) (4) during the processing period.

b. Testosterone Cypionate 200mg/ml Injection, lot number 08262015:94@75 was prepared on 8/26/15. The product was (b) (4). In addition,
i. There is no record of the (b) (4) time (b) (4) for this process.
ii. There is no validation study showing that the (b) (4) are adequate to render the product sterile.
iii. There is no (b) (4) used during the (b) (4) to confirm sterility.

OBSERVATION 4

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

Specifically, there is no stability data to support expiration dates applied to sterile drug products, for example:

a. Ascorbic Acid Preservative Free 500mg/ml Injectable, lot number 08252015:98@48 was prepared on 8/25/15 and assigned a beyond-use date (BUD) of 30 days refrigerated.
b. Glutathione Preservative Free 100mg/ml Solution for Inhalation, lot number 08292015:88@14 was prepared on 8/29/15 and assigned a BUD of 9/28/15 (30 days).
c. Tacrolimus Ophthalmic 0.02% Suspension for dogs, lot number 08142015:83@28 was prepared on 8/14/15 and assigned a BUD of 11/12/15 (90 days).

*** DATES OF INSPECTION:**
08/31/2015(Mon), 09/01/2015(Tue), 09/03/2015(Thu), 09/10/2015(Thu)

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	Caryn M. Mcnab, Investigator Caryn Mcnab	09/10/2015