DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/23/2014 - 09/30/2014* FEI NUMBER 3010116308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Peter H. Wolfe, Jr., Owner

FIRM NAME	STREET ADDRESS
Total Pharmacy Services, Inc.	7806 Park Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houma, LA 70364	Producer of Sterile Products

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 validation of the sterilization process.

Specifically,

a) You have not qualified the (b) (4) to demonstrate (b) (4) to sterilize drug products made from non-sterile drug components. The (b) (4)

b) Smoke studies are not conducted under dynamic/operational conditions.

c) Media fills have not been performed since January 2014 and only include the 10 ml size vials used in sterile production.

OBSERVATION 2

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

Specifically,

a) You do not perform personnel and environmental monitoring each day sterile products is made.

b) Your growth promotion testing for environmental sampling (b) (4)) is not based on a scientific method.

OBSERVATION 3

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

Specifically, you were observed to put on protective apparel in a non-classified area and continue to perform aseptic operations without any further actions to protect drug products from contamination which does not follow your written procedure or proper aseptic procedures. In addition, the mask and head cover you wear is not labeled to be sterile or non-

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Claire M. Munden	09/30/2014

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."

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shedding.

OBSERVATION 4

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

Specifically, you have insufficient scientific data including preservative effective testing to support the three month beyond use date you assign for Testosterone Cypionate and Hydroxyprogesterone injectable sterile drug products.

OBSERVATION 5

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

Specifically, you do not perform sterility and endotoxin analysis on each batch/lot of sterile drug products made from non-sterile drug products.

OBSERVATION 6

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, you do not analyze each batch/lot of drug product for potency prior to dispensing as a prescription.

*** DATES OF INSPECTION:**
09/23/2014(Tue), 09/24/2014(Wed), 09/30/2014(Tue)

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