

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 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	<small>DATE(S) OF INSPECTION</small> 05/13/2013 - 05/22/2013*
	<small>FEI NUMBER</small> 3010116308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Peter H. Wolfe, Jr., Owner

<small>FIRM NAME</small> Total Pharmacy Services, Inc.	<small>STREET ADDRESS</small> 7806 Park Ave
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Houma, LA 70364	<small>TYPE ESTABLISHMENT INSPECTED</small> 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

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

Specifically,

- Smoke studies are not conducted under dynamic conditions and not videotaped.
- Surface and air monitoring of the ISO 5 environment are not conducted each day sterile drug products are produced. Currently, surface and air monitoring is conducted every (b) (4).
- Personnel monitoring (i.e. fingertip sampling) is not conducted each day sterile drug products are produced. Currently, you conduct fingertip sampling every (b) (4).
- Pressure differentials have not been monitored and documented since July 25, 2012.

OBSERVATION 2

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

Specifically,

- You have not qualified the (b) (4) for its intended use to demonstrate bacterial retentive and physical/chemical compatibility to sterilize injectable drug products made from non-sterile drug components.
- You do not have documentation to prove integrity testing is conducted or the results of each test of the (b) (4) (b) used for all injectable drug products made from non-sterile drug components.

OBSERVATION 3

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

Specifically, employees were observed to use non-sterile cloth gowns and face masks while producing sterile drug products.

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Claire M Minden, Investigator <i>Claire M. Minden</i>	<small>DATE ISSUED</small> 05/22/2013
---------------------------------	---	--

**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		05/13/2013 - 05/22/2013*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FBI NUMBER
TO: Peter H. Wolfe, Jr., Owner		3010116308
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	

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically,

- Media fills do not simulate actual production quantities and different size vials.
- Employees were observed to drop material directly onto the ISO 5 work surface without sanitizing each material with sterile isopropyl alcohol and rested their arms covered in a non-sterile gown directly on the work surface.

OBSERVATION 5

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

Specifically,

- Your procedure, "Cleaning and Maintenance of the Clean Room Facility" does not include instructions or frequency when the sporicidal ((b) (4)) agent is to be used. In addition, you do not document when you use the sporicidal agent in the LFH.
- You use non-sterile wipes to clean the ISO 5 environment before and after producing sterile drug products.

OBSERVATION 6

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

Specifically, sterility and endotoxin testing is not conducted on each batch of injectable drug products made from non-sterile drug products.

OBSERVATION 7

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, potency analysis is not conducted on any batch of injectable product made from non-sterile drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Claire M Minden, Investigator <i>CM</i>	05/22/2013

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 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	DATE(S) OF INSPECTION 05/13/2013 - 05/22/2013*
	FEI NUMBER 3010116308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Peter H. Wolfe, Jr., Owner

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

OBSERVATION 8

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

Specifically, you have no scientific data to support the three month beyond use date you assign for all injectable sterile drug products. In addition, you did not conduct any stability testing on any drug product you produce to determine an appropriate beyond use date.

OBSERVATION 9

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, you do not conduct any additional testing of raw materials used to produce sterile drug products. In addition, you have not qualified your suppliers to verify the Certificate of Analysis you receive with the raw material used to produce sterile drug products.

OBSERVATION 10

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically, since May 13, 2013, you did not investigate the complaint you received in April 2013 for the repackaged Avastin syringes you produced. In addition, your procedure, "Complaint Handling" does not include reporting serious adverse events to FDA.

OBSERVATION 11

Batch production and control records do not include a description of drug product containers and closures used for each batch of drug product produced.

Specifically, your formula sheets do not include the size of vial used or the quantity of vials filled for each batch of sterile drug products produced to allow for reconciliation in case of a recall.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Claire M Minden, Investigator	<i>Cmm</i>	DATE ISSUED
			05/22/2013

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."