DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	09/08/2014 - 09/18/2014* FEI NUMBER 1000121499

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Joseph G. Bettinger, Owner and Compounding Specialist

FIRM NAME	STREET ADDRESS
Hieber's Pharmacy	3500 5th Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pittsburgh, PA 15213-3337	Producer of Sterile Drug 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 WE 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,

1. The firm has not validated the (b) (4) sterilization process by (b) (4) for injectable drug products. For example, Histamine Phosphate (PF) 2.75mg/ml Sterile Inj lot 07072014@18 and Histamine (with preservative) 2.75mg/5ml Sterile Inj lot # 07292014@6.
2. The firm has not validated the sterilization and depyrogenation processes for components such as vials and stoppers used in products such as Dexamethasone Sodium Phosphate (MDV) 16mg/ml Sterile Inj lot 06102014@7 and Mitomycin (0.02%) 0.2 mg/ml ophthalmic lot # 08112014@10.
3. The (b) (4) sterilization for producing batches of injectable product has not been validated. The (b) (4) has no documentation to qualify the (b) (4) used with regard to (b) (4) The firm has no documentation to (b) (4) the (b) (4) or bioburden quantity for formulations such as Cyanocobalamin (with preservative) 2000 mcg/ml Inj lot # 08192014@16 and Doxycycline 20mcg/ml inj lot # 06272014@22.

OBSERVATION 2

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

Specifically, there is no antimicrobial effectiveness testing data for injectable drug products containing preservatives, such as Cyanocobalamin 2000mcg/ml Inj lot 08192014@16.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Thomas E. Friel, Investigator Cynthia L. Rakestraw, Investigator	09/18/2014

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OBSERVATION 3

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

Specifically, sterility and endotoxin testing are not performed for all lots of injectable drug product. For example, Histamine Phosphate (PF) lot 2.75mg/ml Sterile Inj lot # 07072014@18 was released without sterility and endotoxin testing.

OBSERVATION 4

An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically, there is no data to support the beyond use dates assigned to compounded formulations. For example, there is no data to support the 120 day beyond use date for Histamine Phosphate (PF) 2.75mg/ml Sterile Inj lot # 07072014@18 and Histamine (with preservative) 2.75mg/5ml Sterile Inj lot # 07292014@6. The formulations are (b) (4) sterilized using (b) (4) [redacted]

OBSERVATION 5

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, it was reported that only (b) (4) [redacted] is tested for potency. Additionally, Histamine 2.75mg/ml Sterile Inj lot # 04152014@9 failed testing for potency at 2.187mg/ml. This batch was used to formulate Histamine 2.75mg/5ml Sterile Inj lot # 04152014@7 requiring a recall. No additional batches of Histamine Sterile Inj have been analyzed for potency to date.

*** DATES OF INSPECTION:**
09/08/2014(Mon), 09/09/2014(Tue), 09/10/2014(Wed), 09/11/2014(Thu), 09/12/2014(Fri), 09/18/2014(Thu)

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