DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food & Drug Administration US Custom House, Room 900 200 Chestnut Street, Philadelphia PA 19106 (215) 597-4390 Industry Information: www.fda.gov/oc/industry	02/01,02,03,04,05,09/2016
	FEI NUMBER 3012080718

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Gerard O'Hare, RPH, Owner

FIRM NAME	STREET ADDRESS
Jeffreys Drug Store	1 North Central Avenue
CITY, STATE AND ZIP CODE Canonsburg, PA 15317	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation-1
Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, no potency, sterility, endotoxin is performed for the following preservative free sterile injectables:
a. Testosterone Cypionate and Testosterone Propionate Injectable doses 200mg, 50mg, 20ml, with 90 day before use date (BUD) at room temperature
b. Methylcobalamin Injectable dosage 25mg/ml with 30 day before use date (BUD) refrigerated temperature
c. Trimix Injectable 20ml with 30 day before use date (BUD) at refrigerated temperature

Observation-2
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, the following deficiencies were identified related to the firm's environmental and personnel monitoring program:
a. The firm conducts personnel monitoring (b) (4) (b) (4) Operator gloves are not sampled at least daily.
b. No environmental samples are taken during production of the following sterile injectables: Testosterone Cypionate and Testosterone Propionate, Methylcobalamin and Trimix.

Observation-3
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.
Specifically,
a. Uncovered vials of (b) (4) located in the anteroom (ISO 6).
b. Unlabeled black cover vial tips were left within the LAF Hood (ISO 5).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Anita R. Michael Lisa B. Orr	Anita R. Michael, Investigator Lisa B. Orr, Investigator	02/09/2016

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c. Trashcan located in the anteroom classified as ISO6 was blocking the air movement from the classified area (ISO 6) to the non-classified area.
d. The plastic separation flaps were observed with dirt and grime leading from the anteroom into the clean room (ISO 6) housing the LAF Hood (ISO 5).
e. No smoke studies have been performed in the ISO 5 area.

Observation-4
There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, for the following products no stability testing is performed:
a. Testosterone Cypionate and Testosterone Propionate Injectable doses 200mg, 50mg, 20ml, with 90 day before use date (BUD) at room temperature
b. Methylcobalamin Injectable dosage 25mg/ml with 30 day before use date (BUD) refrigerated temperature
c. Trimix Injectable 20ml with 30 day before use date (BUD) at refrigerated temperature

Observation-5
Clothing of personnel engaged in the processing, packing, and holding of drug products is not appropriate for the duties they perform.

Specifically, gowning apparatus are not received sterile. For example, booties, hair covers, masks, hair nets are not sterile. Additionally, on 02/02/2016 9:59 AM, a compounding pharmacist was observed preparing non-sterile Benazepril 4 mg/mL suspension, Lot 020216-111121, Rx # (b) (4), (b) (6) without a lab coat.

Observation-6
Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition. Specifically,

a. The plastic separation flaps were observed with dirt and grime leading from the anteroom into the clean room (ISO 6) housing the LAF Hood (ISO 5).
b. A large storage shelf located next to the cleanroom blocking airflow from cleanroom to unclassified area.

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	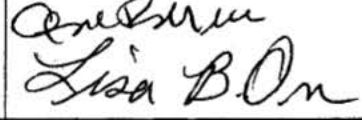	Anita R. Michael, Investigator Lisa B. Orr, Investigator	02/09/2016

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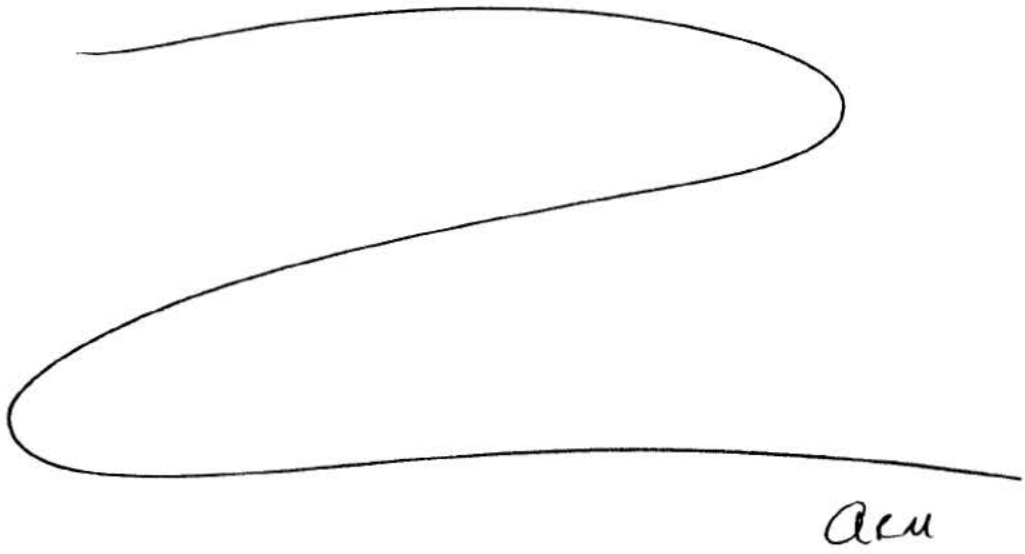
Observation-7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions. Specifically, for cleaning and sanitizing the classified areas agents (b) (4) and (b) (4) are used and are non-sporicidal disinfectants.

Observation-8

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product. Specifically, (b) (4) is used to clean the (b) (4) and the (b) (4).



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