DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	7/25/2017-8/4/2017* FEI NUMBER 3012080718

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gerard E. O' Hare , Owner and President

FIRM NAME	STREET ADDRESS
Jeffreys Drug Store	1 N Central Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Canonsburg, PA 15317-1301	Producer of sterile and non-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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, certification activities for the ISO 5 classified areas are inadequate in that the ISO 5 classified areas were not certified under dynamic conditions, and smoke studies were either inadequate or not performed.

For example,

a) Certification of the laminar hood (b)(4) , model #(b)(4), serial # (b)(4)), conducted on 7/21/16 was not performed under dynamic conditions and no smoke study was performed.

b) Certification of the laminar hood ((b)(4) model #(b)(4), serial # (b)(4)) conducted on 9/12/16 does not include complete documentation of the smoke study, which is limited to a written statement with minimal details of the results, and does not contain details of how the study was performed and under what conditions.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Lisa B Orr, Investigator

X Lisa B Orr
Investigator
Signed By: 2001665590
Date Signed: 8/4/2017

DATE ISSUED
8/4/2017

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c) Certification of the (b) (4)(b) (4) (b)(4), model #(b) (4), serial #(b) (4) conducted on 11/30/16, was not performed under dynamic conditions and no smoke study was performed. In addition, no viable air or surface sampling was performed.

d) Certification of the laminar hood ((b)(4), model #(b)(4), serial # (b)(4)) conducted on 5/9/17 was not performed under dynamic conditions and no smoke study was performed. In addition, the (b) (4) was not evaluated under dynamic conditions.

OBSERVATION 2

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

Specifically, the firm does not perform media fills and has no procedures for conducting media fills.

OBSERVATION 3

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

Specifically,

a) non-sterile cleaning solution, (b)(4) brand (b) (4), is used to clean the interiors of the ISO 5 laminar hood and the ISO 5 (b) (4)(b) (4) including the work surfaces.

b) non-sterile wipes are used for applying the cleaning and disinfecting agents inside the ISO 5 (b)(4)(b)(4) and the ISO 5 laminar hood, including the work surfaces.

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lisa B Orr, Investigator X Lisa B Orr Investigator Signed By: 2001665590 Date Signed: 8/4/2017	8/4/2017

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Gerard E. O' Hare , Owner and President

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7/25/2017(Tue),7/26/2017(Wed),7/27/2017(Thu),7/28/2017(Fri),7/31/2017(Mon),8/01/2017(Tue),8/02/2017(Wed),8/03/2017(Thu),8/04/2017(Fri)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Lisa B Orr, Investigator

X Lisa B Orr
Investigator
Signed By: 2001665590
Date Signed: 8/4/2017

DATE ISSUED
8/4/2017

U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Date: September 14, 2017

Gerard E. O' Hare
Jeffreys Drug Store
1 N Central Ave
Canonsburg, PA 15317-1301

Subject: System Notification

Dear Gerard E. O' Hare,

We are notifying you that due to a technical error related to a software update, the FDA Form 483 you received recently inadvertently included a sentence meant only for medical device firms. That statement says, "Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

This statement refers to quality system requirements applicable only to medical device establishments, but was inadvertently included on certain Form 483's issued to non-device establishments for a brief period of time. Please note that the statement has no bearing on the inspection observations themselves, which remain applicable as of the date that you were issued the Form FDA 483.

Should you have any questions, please send to AskORAIT@fda.hhs.gov.

Sincerely,

Lisa Creason
Director, Office of Information Systems Management
Office of Regulatory Affairs
Food and Drug Administration