DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	6/20/2017-6/23/2017
	FEI NUMBER 3010987875

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alec Gillies , General Manager

FIRM NAME	STREET ADDRESS
Buffalo Pharmacies Inc	6035 Transit Rd
CITY, STATE, ZIP CODE, COUNTRY East Amherst, NY 14051-1803	TYPE ESTABLISHMENT INSPECTED Producer of Sterile & Non-Sterile Drug Product

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

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

Specifically, your firm failed to establish a gowning procedure and aseptic processes that reduces the possibility of chemical and microbial contamination of compounded products manufactured in the ISO 5 laminar flow hood.

(a) On 6/20/17, we observed the compounding technician re-use a gowning jacket between multiple product compound preparations. As per the technician, your firm uses only one gown jacket during the daily routine compounding processes and disposes of it at the end of the day.

(b) On 6/20/17, we observed the compounding technician donning gloves inside the ISO 5 laminar flow hood, exposing the product contact surface areas to exposed skin.

(c) On 6/20/17, we observed the compounding technician introducing unfiltered air into a sterile bottle of Tacrolimus vet product through a syringe in order to create positive pressure.

OBSERVATION 2

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

Specifically, you have not performed media fills that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rachael A Moliver, Investigator Jose O Hernandez, Investigator 6/23/2017 X Rachael A Moliver Rachael A Moliver Investigator Signed by: Rachael Moliver -S	6/23/2017

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

Specifically,
(a) Cleaning wipes used in the ISO 5 aseptic processing area are not sterile. Your firm is currently using the non-sterile wipes, (b) (4) for the sanitization of the ISO 5 laminar flow hood surface areas.
(b) Sporicidal agents are not used in your facility's cleanroom and ISO 5 area. Currently, your firm uses non-sterile, (b) (4) for the disinfection of the ISO 5 laminar flow hood surface areas.

OBSERVATION 4
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,
(a) You do not conduct viable and non-viable monitoring of the ISO 5 and ISO 7 areas during dynamic processes. You do not possess the necessary equipment to conduct such testing, nor is it performed by an outside contractor. Currently, your firm only performs non-viable monitoring of the ISO 5 and ISO 7 areas during (b) (4) conditions, (b) (4)
(b) You do not perform smoke studies under dynamic conditions to demonstrate and assure proper air flow patterns in the ISO 5 laminar flow hood area.

OBSERVATION 5
Adequate ventilation is not provided.

Specifically,
(a) Your firm failed to provide adequate positive air pressure and air changes of the ISO 8 anteroom in connection to the hallways; thus, allowing the possibility of environmental contaminants to enter the ISO 8 area, as per the Cleanroom Certification Report from February 16, 2017. This is an ongoing issue, for which your firm doesn't monitor the pressure differentials and the air changes on a routine basis.

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(b) Your firm failed to provide adequate negative pressure and air changes of the ISO 8 capsule room in connection to the hallways; thus, allowing the possibility of powder products to leave the ISO 8 area, as per the Cleanroom Certification Report from February 16, 2017. This is an ongoing issue, for which your firm doesn't monitor the pressure differentials and the air changes on a routine basis.

OBSERVATION 6

Routine calibration and inspection of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

(a) You have not calibrated or maintained the (b) (4) Incubator, (b) (4) (b) (4) since the purchase of the equipment. This equipment is used for the incubation of (b) (4) (b) (4) after (b) (4) monitoring of the ISO 7 cleanroom.

(b) You have not calibrated the (b) (4) Model (b) (4) originally calibrated March 2013, since the purchase of this equipment. This equipment is used to test the (b) (4) of your sterilizing (b) (4) used in the processing of compounded sterile drug products.

6/23/2017

X Jose O Hernandez

Jose O Hernandez
Investigator
Signed by: Jose O. Hernandez-guzman -S

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