DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	12/10/2013 - 12/16/2013* FEI NUMBER 3010285019

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Alfonse Muto, Sr., Owner

FIRM NAME	STREET ADDRESS
Pine Pharmacy and Home Care Products Center, Inc.	5110 Main Street
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Williamsville, NY 14221	Sterile Drug Producer

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

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, your firm lacks adequate environmental monitoring data to support that the capabilities of its cleanroom can maintain ISO 5 (Class 100) conditions at the laminar flow hood (LAFW) and the biological safety cabinet (BSC), the ISO 7 (Class 10,000) conditions in the surrounding "buffer" area, and the ISO 7 conditions in the adjoining gowning room (anteroom) and adjoining storage room and the "powder hood" in the ISO 7 anteroom.

Smoke studies were not performed under actual processing conditions to verify that operators and processing equipment do not alter or impede the unidirectional cascade of air from the HEPA filters to the ISO 5 laminar flow benches where sterile drug products are opened and manipulated, and to the rest of the ISO 7 clean room.

OBSERVATION 2

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

Specifically, sterile drug products are aseptically manipulated by the cleanroom operators who wear non-sterile gowns, non-sterile glasses/goggles, non-sterile footwear, non-sterile facial masks, etc. The only apparell that are sterile are the operator's gloves. The operator's face and head are not fully enclosed and allows exposed facial skin and hair over the critical ISO 5 laminar flow areas.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	James A. Liubicich, Investigator James A. Liubicich Karen L. Kosar, Investigator Karen L. Kosar	12/16/2013

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OBSERVATION 3

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

Specifically, for the newly constructed clean room that became operational on 11/18/2013 and the previous clean room per SOP 7.4 Environmental Monitoring of the Clean Room:

a. Environmental monitoring for viable air counts in the ISO 5 zone is only performed (b) (4) by an outside contractor.

b. Environmental monitoring for non-viable particulates in the ISO 5 zone is only performed every (b) (4) by an outside contractor.

c. The work surfaces, inside the ISO 5 hoods, are not tested for microbial contamination on a frequent basis. Environmental monitoring of the sterile processing area surfaces is performed only (b) (4)

OBSERVATION 4

The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

Specifically, there are no separate facilities, for processing operations, to prevent contamination from beta-Lactam non-penicillin drugs, such as Ceftazidime ophthalmic drops or Ceftazidime Intravitreal Injection. This beta-Lactam powder, which is contained in glass vials, is processed in the same ISO 5 hoods as sterile non beta-Lactam drugs. There is no assurance that a potential breakage of the glass vial and consequent powder spill would not contaminate other sterile drug products.

OBSERVATION 5

Equipment and utensils are not sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, non-sterile wipes are either sprayed with (b) (4) to disinfect the ISO 5 hood sterile processing surfaces.

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OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm has distributed approximately (b) (4) orders, from lots processed in 2013. For the sterile drug products, the following testing was not performed:

a. Assay or product identification testing is not done for all of the sterile injectable or sterile ophthalmic drug products produced.

b. Sterility testing for all drug products produced is not performed. Your firm performs sterility testing in certain cases, as for Avastin syringes.

c. Endotoxin testing data is not available for almost all sterile drug products produced. Some sterile products such as Methylobalamin vials are tested for endotoxins.

d. There is no antimicrobial effectiveness testing data for sterile drug products containing preservatives, such as fluphenazine and protamine zinc insulin injectable.

OBSERVATION 7

An adequate number of batches of each drug product are not tested nor are records of such data maintained to determine an appropriate expiration date.

Specifically, you produce injectable drug products, sterile ophthalmic solutions and other drug products. The beyond use dates assigned to the drug products are not supported by stability studies conducted by your firm. There is no assurance, with the lack of appropriate scientific data, that your sterile drug products will remain sterile or maintain potency throughout the expiry period. You solely rely on published literature or vendor supplied information to establish beyond use dates. Examples are Avastin in BD Tuburculin Syringes for 180 days refrigerated and Methylcobalamin in 0.3ml short needle (BD) for 90 days.

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OBSERVATION 8

Results of stability testing are not used in determining expiration dates.

Specifically, prescription # (b) (6) for Cyclosporin 1% Ophthalmic, sterile veterinary drug, the processing record shows an ingredient used - Adjuvants Stock for Cyclosporin (a) eye drop with an expiration date of 12/24/13. The Beyond Use Date assigned to this prescription order was for 180 days to March 2, 2014 which is over two months past the expiration date of the aforementioned ingredient used in preparing this order.

OBSERVATION 9

Employees are not given training in the particular operations they perform as part of their function.

Specifically, surface samples of the ISO 5 LAFW and BSC along with other clean room surfaces are placed onto contact plates. Also, gloved fingertip samples are also placed onto the agar surface of the contact plate. CFUs are subsequently read by the firm's personnel who have not been trained in determining that nor is there any written procedure on how to perform it.

*** DATES OF INSPECTION:**
12/10/2013(Tue), 12/12/2013(Thu), 12/13/2013(Fri), 12/16/2013(Mon)

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