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	07/16/2013 - 07/19/2013* FEI NUMBER 3010285019

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Alfonse J. Muto, Jr., Pharmacist

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 and cleaning and maintenance.

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, the ISO 7 (Class 10,000) conditions in the surrounding "buffer" area, and the ISO 8 (Class 100,000) conditions in the adjoining gowning room (anteroom) given the following design limitations and practices.

a. Smoke studies were not performed under dynamic 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 bench where sterile drug products are opened and manipulated, and to the rest of the ISO 7 clean room.

b. The entry way to the ISO 7 buffer room from the ISO 8 anteroom is through vinyl strip door curtains which do not cover approximately two (2) feet at the bottom of the entrance doorway.

c. The entry way to the ISO 8 anteroom from the surrounding unclassified area is through vinyl strip door curtains which do not cover approximately two (2) feet at the bottom of the entrance doorway.

OBSERVATION 2

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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The non-sterile gowning worn by employees entering the ISO 7 cleanroom is stored in the ISO 8 anteroom in an open plastic bag.

Non-sterile masks and non-sterile bonnets are used to cover the mouth and head of operators during sterile processing; allowing exposed facial skin over the critical ISO 5 laminar flow bench. Additionally, no goggles are used by those operators.

OBSERVATION 3

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

Specifically,

a. The work surfaces, inside the ISO 5 hood, are not tested for microbial contamination on a frequent basis. Environmental monitoring of the sterile processing area is performed by an outside contractor only every [redacted] (b) (4) by swabbing the surfaces. You claim that your firm performed this as well without stating the frequency; however you refused to provide documentation to support your claims.

b. Environmental monitoring for viable air counts in the ISO 5 zone is only performed [redacted] (b) (4) by an outside contractor. You claim that your firm performed this as well without stating the frequency; however you refused to provide documentation to support your claims.

c. Environmental monitoring for non-viable particulates in the ISO 5 zone is only performed every (b) (4) [redacted] (b) (4) by an outside contractor. You claim that your firm performed this as well without stating the frequency; however you refused to provide documentation to support your claims.

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OBSERVATION 4

Adequate exhaust systems or other systems to control contaminants are lacking in areas where air contamination occurs during production.

Specifically, the wall mounted Magnehelic Pressure Gauge, measuring the air pressure from the ISO 8 anteroom to the unclassified surrounding area, was registering at almost zero.

OBSERVATION 5

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. This beta-Lactam powder, which is contained in glass vials, is processed in the same ISO 5 hood as sterile non beta-Lactam drugs. You refused to provide your written procedures on how to clean a potential breakage of the glass vial and consequent powder spill.

OBSERVATION 6

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 [redacted] (b) (4) [redacted] to disinfect the ISO 5 hood sterile processing surfaces.

OBSERVATION 7

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 [redacted] (b) (4) orders, from lots processed in the past year. For the sterile drug products, the following testing was not performed:

a. There were no records provided upon our request to show assay or product identification testing for any of the sterile injectable or sterile ophthalmic drug products produced.

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b. Sterility testing for all drug products produced is not performed. Your firm claims to perform sterility testing in certain cases, however, no records were provided to us upon request. Additionally, the sterility test method that you stated is utilized, [redacted] (b) (4), has not been validated.

c. Endotoxin testing data is not available for any lot of sterile drug products produced. No records were provided to us upon our request.

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

OBSERVATION 8

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 up to 30 days for sterile drug products.

OBSERVATION 9

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically, the aseptic processing of sterile drug products has not been validated. No media fills/process simulations have been performed. You refused to produce any study reports to show otherwise.

OBSERVATION 10

Adequate lab facilities for testing and approval or rejection of drug products are not available to the quality control unit.

Specifically, visual checks of sterile drugs for clarity/discoloration or particulates/contaminants are not performed against a contrasting background.

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07/16/2013(Tue), 07/17/2013(Wed), 07/19/2013(Fri)

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