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	08/31/2015 - 09/23/2015* FEI NUMBER 3010750417

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ernesto R. Samuel, President & CEO

FIRM NAME	STREET ADDRESS
Pharmaceutic Labs, LLC.	15 Walker Way
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Albany, NY 12205-4945	Outsourcing Facility

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 I OBSERVED:

OBSERVATION 1

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

Specifically, certifications were not performed under dynamic conditions to verify that operators, processing equipment or activities of the ISO 7 Clean Rooms do not alter or impede the unidirectionality of air from the HEPA filters in the ISO 5 laminar flow hoods, nor the ISO 5 (b) (4) where drug products are aseptically processed.

OBSERVATION 2

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

Specifically, sterile drug products are aseptically manipulated by the clean room operators who were observed wearing goggles that were sterilized via (b) (4) . Validation of the sterilization of the multi-use goggles was inadequate as it only consisted of the (b) (4)

OBSERVATION 3

Test procedures relative to appropriate laboratory testing for sterility are not written.

Specifically, SOP #OP.PL.348, Quality Control Sample, states that (b) (4) . The number of units at the (b) (4) are not defined as they are (b) (4).

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	Chad N. Thompson, Investigator Chad N. Thompson	09/23/2015

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OBSERVATION 4

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

Specifically,

a. Visual inspection is not performed on 100% of repackaged sterile syringes of Avastin (bevacizumab) 25 mg/mL against a contrasting background, for product contamination prior to distribution.

b. A procedure is not established to train and qualify personnel that conduct manual visual inspection for the presence of particles and contaminants.

c. Procedure #QC.PL.701, Material Acceptance, indicates that (b) (4) Your firm has not created a specification sheet to be used during incoming receiving of Avastin (bevacizumab).

OBSERVATION 5

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, the laboratory (b) (4) that is used as the black background during visual inspection was observed to have many white scratches. The (b) (4) is not a uniform black background necessary to visually inspect repackaged sterile syringes of Avastin (bevacizumab).

OBSERVATION 6

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

Specifically, your firm does not have stability data to support the 90 day Beyond use Date for the storage of repackaged Avastin (bevacizumab) drug product at 5°C within (b) (4) syringes.

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*** DATES OF INSPECTION:**
08/31/2015(Mon), 09/01/2015(Tue), 09/02/2015(Wed), 09/03/2015(Thu), 09/08/2015(Tue), 09/14/2015(Mon), 09/23/2015(Wed)

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