DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Florida District 555 Winderley Place, Suite 200 Maitland FL 32751 (407) 475-4708 Fax: 407-475-4770 Industry Information: www.fda.gov/oc/industry	6/6, 7, 8, 9, 10, 13/ 2016
	FEI NUMBER 3007271263

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Vern Allen, RPh, Owner/President & CEO

FIRM NAME	STREET ADDRESS
PREMIER PHARMACY LABS INC.	8265 COMMERCIAL WAY
CITY, STATE AND ZIP CODE WEEKI WACHEE, FL, 34613	TYPE OF ESTABLISHMENT INSPECTED 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) (WE) OBSERVED:

1. Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure. Specifically,

a. Your firm has no procedures in place to describe the requirements and acceptance criteria for the HEPA Filters certification for ISO 5 areas available on site (ISO 5 Laminar Flow Hood and ISO 5 area), used for compounding operations, or evaluation of airflow pattern studies (smoke studies) reported as part of the (b) (4) certification process of all areas.

b. Airflow pattern studies (smoke studies) executed and included with the most recent certification exercise conducted in (b) (4) (reported to be conducted under similar conditions as to previous exercise conducted in (b) (4)) was found inadequate in that:

1) The video of the smoke studies conducted on (b) (4) for the ISO 5 (b) (4) laminar airflow working hood (LAFW) (b) (4) where the (b) (4) Machine is located showed non-unidirectional and turbulent air over the critical ISO 5 zone (b) (4) This turbulence was observed during (b) (4) and was due to the (b) (4) (b) (4) laminar air flow (b) (4) (b) (4) (b) (4) . Your firm failed to recognize the (b) (4) and poor air control and did not implement corrective and preventive action. A total of (b) (4) batches of various ophthalmic drug products have been produced in this equipment within the last 90 days.

2) Areas depicted in videos included (b) (4) and failed to include evidence of smoke pattern in the (b) (4) (ISO 5 Area), including at rest/ dynamic conditions of routine interventions such as (b) (4)

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2. Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.

Specifically, laminar air flow working hood (LAFW) (b)(4) is located (b)(4) Cleanrooms (b)(4) (b)(4) which is not a suitable location to prevent cross-contamination from personnel walking between rooms. During aseptic operations on 6/6/16, it was observed that the operator from Cleanroom (b)(4) walked between cleanrooms and behind the operator in LAFW (b)(4) numerous times while aseptic operations of injectable drug products were ongoing in LAFW (b)(4)

3. Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet each appropriate specification as a condition for their approval and release.

Specifically, SOP 820.4 "Particulate Testing, Visual Inspection and Reconciliation for Sterile Preparations" does not require 100% visual inspection of sterile injectable and ophthalmic drug products before release; instead (b)(4) (b)(4) is visually inspected. In addition, there are no criteria for acceptable levels of defects and the type and number of defects observed during visual inspection are not always documented in the batch record at the time of performance. For example, on 6/6/16 upon inspection of the batch record of quarantined Proparacaine unit dose 0.5% solution, lot PRO060216NWAB, repackaged on 6/2/16 and pending test results, we found a leaking vial and a vial with a red fiber that were segregated as defective on 6/2/16; however, the batch record only documented a visual inspection of (b)(4) of which (b)(4) passed. There was no investigation or documentation of 100% visual inspection of the rest of the vials to ensure similar defects were not present (product was (b)(4) (b)(4) Machine).

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

Specifically, the (b)(4) (b)(4) was not properly qualified during installation to determine appropriate (b)(4) and is not maintained at appropriate intervals to ensure proper performance. A failed media fill on (b)(4) and CAPA 15004, 1/15/15, issued for leaking (b)(4) did not identify adequate corrective and

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preventive action and a surface sample of 13 CFUs (spec (b) (4)) on the equipment on 9/12/15 was not investigated.

5. Approved drug product containers are not retested or reexamined as appropriate for identity, strength, quality and purity after storage for long periods and exposure to conditions that might have an adverse event with subsequent approval or rejection by the quality control unit.

Specifically, the (b) (4) sterile plastic vials (droppers) used for ophthalmic drug products are received in a (b) (4) (b) (4) containing (b) (4)) which is re-sealed (b) (4) if all vials are not used within a batch (range in size from approximately (b) (4) . However, your firm did not establish an acceptable re-use date of opened vials and lacked test data to ensure the vials remain sterile during handling with gloved hands and in the re-sealed bag which is stored in an ISO 7 area. In addition, your firm failed to protect empty vials from particulates generated by using (b) (4) within the ISO 5 area.

6. There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. Specifically,

a. CAPA 15038, (b) (4) , was issued for failed media fill Lot (b) (4) reported during the qualification of one employee for (b) (4) but failed to include a complete evaluation of machine parameters to ensure the reported failure was not associated to operating parameters and failed to include a comprehensive evaluation of impacted product (b) (4) with the same equipment. The investigation report describes that 5 unit vials (single dose droppers) were found leaking during the post-filling manual inspection, but no additional evaluation of the (b) (4) parameters was performed and the root cause was determined to be inadequate equipment use and maintenance.

b. CAPA 15004, 1/15/15, was issued to describe the investigation of leaking units observed during the inspection of dispensed Vigamox 0.5% Lot VIG121714NUHM, Tetracaine Hydrochloride. The investigation describes the root cause as a (b) (4) , but no additional information is included to determine the impact to other lots processed in the same machine or evaluate the qualification of the equipment for use.

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c. CAPA 16011, 4/13/16, was issued for the investigation of a failed potency test result (91% or close to the limit of (b)(4) for Brilliant Blue Lot BBL040416SVAB. No documented evidence was available with the CAPA report to describe the investigation process conducted on site prior to the release of the lot , which included a (b)(4) (b)(4) of the lot, laboratory investigation and re-analysis.

d. CAPA 16019, 4/13/16, was issued for the investigation of a failed potency test result (117% or above specification of (b)(4) for Vancomycin Lot VAN041216IJHM. No documented evidence was available with the CAPA report to describe the investigation process conducted on site prior to the release of the lot, which included a (b)(4) of the lot, laboratory investigation and re-analysis.

e. Investigation reports for excursions in Environmental Monitoring (EMI) samples (fingertips) collected during compounding operations were not fully documented or include timely and effective corrective/preventive actions. EMI reports 10, 11,13,14,26 issued during May-June 2015 failed to include a timely implementation of corrective and preventive actions, complete evidence for the identification of the microorganism, or evaluation of trend that would effectively prevent the recurrence of the events. All investigation reports describe out of limit results from 2-6 CFUs and describe the need to reinforce training to employees, without a timeframe for implementation to prevent recurrence.

f. Complaint events identified on site as Quality Related Event Reports (QRE) as described in SOP 120.4, Corrective Action Preventive Action and Complaints, are not logged formally to ensure that all initial reports of events that could be evaluated as complaints are received and formally documented for evaluation. QREs include events reported by clients to the firm for evaluation and may include incorrect product in container, incorrect drug name, incorrect drug quantity or compound quality issues, among others.

7. Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals. Specifically,

a. Certificates of Analysis received on site for non-sterile Bulk Drug Substances and evaluated in accordance with

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procedure 450.5, Receipt ,Storage and Handling of Materials, are not reviewed to ensure the manufacturer is registered with FDA.

b. Procedure 401.2, Vendor Qualification, approved for the qualification of vendors who supply active pharmaceutical ingredients, product components, and sample analysis for compounded products does not include a complete supplier qualification program. The procedure requires the (b) (4) for the qualification of a vendor, but does not require documented evidence of the information included with the (b) (4) (such as evidence for FDA registration and evidence of compliance with 21 CFR 211) or require an on-site audit at a regular frequency.

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

a. SOP 324.2, Operation and Maintenance of (b) (4), used for glassware depyrogenation activities via validated (b) (4), does not define responsibilities and steps to be conducted for the execution of the (b) (4), intervention by (b) (4) described during this inspection, evaluation of the (b) (4) by the Quality Unit, documentation of (b) (4) obtained, and fails to include a timely review as the procedure requires a weekly review of executed (b) (4).

b. SOP 322.3, Operation and Maintenance of (b) (4) used for sterilization of compounded product and materials used in routine operations via validated (b) (4) does not define responsibilities and steps to be conducted for the execution of the (b) (4), intervention by (b) (4) described during this inspection, evaluation of the (b) (4) (initially by operators) and the Quality Unit, and fails to include a timely review as the procedure requires a (b) (4) review of executed (b) (4).

9. The written stability testing program is not followed.

Specifically, your firm failed to follow SOP 890.1 "503B Beyond Use Dating" in that no stability studies or literature research was provided to support the 90-days or 6 months BUDs assigned to compounded injectable drug products and re-packaged ophthalmic drug products in single-use dose containers.

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10. Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A). Specifically, the following products were compounded and not identified on your report dated 12/31/15:

- Hydrocodone Bitartrate 10 mg capsules
- Lidocaine 40mg/ml/Epinephrine 0.5 mg/ml/Tetracaine 5mg/ml 3 ml syringe
-Promethazine 25mg/0.5 ml TD Gel 1 ml syringe
-Butalbital 50mg/ml/Codeine 30 mg/ml capsules
-Vancomycin 250 mg/5ml 5 ml syringe

11. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Specifically, the following information is not found on your drug product labels:

a) The statements "This is a compounded drug" and "Not for resale". Examples of product labels that do not contain this information:
- Progesterone/Estradiol/Estriol/Testosterone 25mg/0.5mg/1.5mg/1mg/mL Cream in syringe
- Progesterone/Estradiol/Estriol/Testosterone 60mg/0.5mg/0.5mg/0.5mg/mL Cream in syringe
- Progesterone SL 10 mg tablets
- DHEA (Dehydroepiandrosterone) 12 mg capsules

b) The date the drug was compounded and list of active and inactive ingredients are not found on your product labels. Examples of drug product labels that do not contain this information include:
- Progesterone/Estradiol/Estriol/Testosterone 25mg/0.5mg/1.5mg/1mg/mL Cream in syringe
- Progesterone/Estradiol/Estriol/Testosterone 60mg/0.5mg/0.5mg/0.5mg/mL Cream in syringe
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	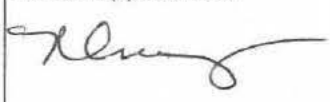	Noreen Muniz, Drug Investigator CAPT Ileana Barreto-Pettit, Drug Investigator	06/13/2016

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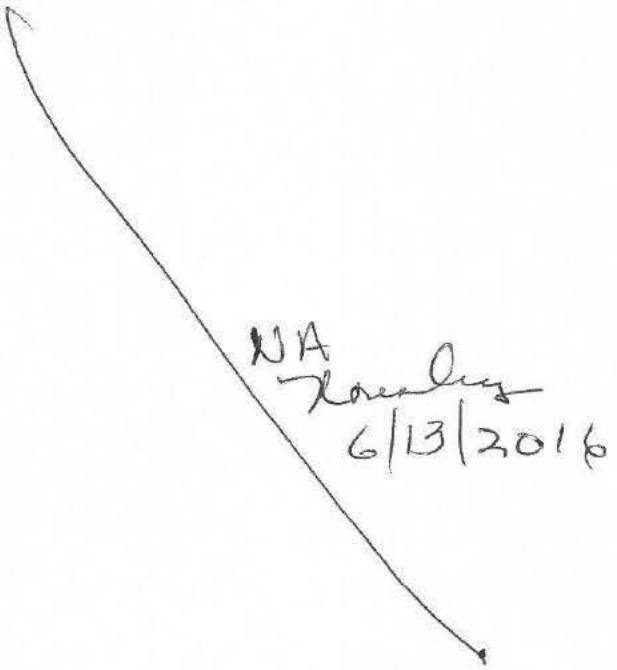
c) Furthermore, the following information is not found on the container labels for the drug products you produce: Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088. Examples of container labels that do not contain this information include:
- Progesterone/Estradiol/Estriol/Testosterone 25mg/0.5mg/1.5mg/1mg/mL Cream in syringe
- Progesterone/Estradiol/Estriol/Testosterone 60mg/0.5mg/0.5mg/0.5mg/mL Cream in syringe
- Progesterone SL 10 mg tablets
- DHEA (Dehydroepiandrosterone) 12 mg capsules



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