DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	02/18/2014 - 03/06/2014* FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Paul K. Yamamoto, R.Ph., Vice President of Operations

FIRM NAME	STREET ADDRESS
Leiter's Cambrian Park Drugs, Inc., dba Leiter's Pharmacy	1700 Park Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95126-2033	Producer of Sterile Drug Products

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

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, your firm did not provide any data to demonstrate that your product, Brilliant Blue G D2O 0.025%, is sterile and/or pyrogen free.

a. The sterility testing performed by the contract laboratory consist of: Aerobic and Anaerobic Bacteria, and Fungi (Mold and Yeasts). Your firm provided no data to demonstrate that the test method is suitable for your sterile drug product, Brilliant Blue G D2O 0.025%. In addition, the Certificate of Analysis from your contract laboratory indicates that the sterility testing "does not meet all the requirements for sampling and/or method suitability specified in USP <71>" which ensures the specific product tested for sterility did not give a false negative result due to product inhibition.

b. Your firm has not established the specification for endotoxin product release testing for Brilliant Blue G D2O 0.025%. According to your Laboratory Manager, as long as the associated Certificate of Analysis are provided from the contract laboratory, the finished product lots are approved and released for distribution irrespective of the endotoxin test results. She stated that she assumes the contract laboratory would only sends Certificate of Analysis with acceptable results.

OBSERVATION 2

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

Specifically,

a. Your firm's SOP 2.030, entitled Sterile Compounding Personnel Qualification, Version 1.0, dated, effective date of 03/01/09, requires each employee shall be evaluated on his or her designated aseptic process a minimum of every six

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months. During the review of your firm's media fill personnel qualification for the Baxa Repeater Pump operation, one operator has not been qualified for the Baxa Repeater Pump operation. Brilliant Blue G D2O 0.025%, lot 10222013@3, indicates a total of (b) (4) vials were filled or "punched out" by this operator.

b. Your firm's SOP 9.200, entitled Baxa Repeater Pump Media Fills (Aseptic Process Validation), 1 L Filled as 1 ML, Version 1.0, dated, effective date of 07/17/13; requires media fills to be conducted in the same manner and same quantity as product would be with the Baxa Repeater Pump. The media fill qualification records do not document the identification of the hood used for the non-dedicated Baxa Repeater Pump that can moved and used in any of the five ISO 5 hoods that are stationed in the Cleanroom and none of the records documented the number of operators that worked in the Cleanroom at the time of the media fill. According to your management, four operators are allowed in the Cleanroom at the same time.

OBSERVATION 3

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

a. Your firm's SOP 3.030, entitled Environmental Monitoring of the Cleanroom Facility, Version 4.0, dated, effective date of 01/10/2014, section 9.5.2.1, states that the surface sampling of Class 100 (ISO 5) hoods shall be taken with each compounding assignment daily. During the review of your environmental monitoring program, surface sampling of the direct sterile compounding area and fingertips were not performed on January 28-31, 2014 and February 6-7, 2014 due to lack of TSA contact plates in stock. Brilliant Blue G D2O 0.025%, lot 01292014@11, was filled or "punched out" on 01/31/2014.

b. Your firm's SOP 9.100, entitled Required Garb For Cleanroom Facility Access, Version 2.0, dated, effective date of 11/18/13, section 10.1, outlines personnel must remove all makeup and jewelry prior to entering the laboratory facility. During the inspection on 02/18/14, one operator in the cleanroom was observed to have eye make-up without eye covers while filling or "punching out" sterile injectable drug product, PAP 12MG/Prost 10 MCG/ML lot 02182014@1.

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	Anh Lac, Investigator Henry K. Lau, Investigator	03/06/2014

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OBSERVATION 4

Failure to reject any lot of components that did not meet the appropriate written specifications for identity, strength, quality, and purity.

Specifically,

a. Your firm manufactured and distributed six lots of Brilliant Blue G D2O 0.025% using the expired raw ingredient, Sodium Phosphate Monobasic Monohydrate, lot 132517 with an expiry date of 06/01/2013. The six lots include the following:

- Brilliant Blue G D2O 0.025%, lot 07032013@13
- Brilliant Blue G D2O 0.025%, lot 08092013@24
- Brilliant Blue G D2O 0.025%, lot 09262013@1
- Brilliant Blue G D2O 0.025%, lot 10222013@3
- Brilliant Blue G D2O 0.025%, lot 11252013@2
- Brilliant Blue G D2O 0.025%, lot 01292014@11

b. Your assessment, entitled Review of Impact of Utilizing Sodium Phosphate, Monobasic, Monohydrate in the formula ID 10662 Brilliant Blue, in Six Lots Produced in 2013 after 06/01/2013, dated, 02/20/14 is deficient for failure to perform comprehensive investigation as well as extend the investigation to other products. You have not assessed the quality impact of the Beyond Use Date for the Brilliant Blue G D2O 0.025% product that used the expired raw ingredient. You disposed the expired Sodium Phosphate Monobasic Monohydrate lot 132517 without further testing.

OBSERVATION 5

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically but not limited to the following, your firm has never performed finished product potency testing on Brilliant Blue G D2O 0.025%. Between November 2011 and January 2014, 14 lots of Brilliant Blue G D2O 0.025% manufactured and distributed by your firm were not tested for potency.

Examples include:

- Brilliant Blue G D2O 0.025%, lot 12132012@19, (b) (4) vials were distributed
- Brilliant Blue G D2O 0.025%, lot 04052013@27, (b) (4) vials were distributed
- Brilliant Blue G D2O 0.025%, lot 10222013@3, (b) (4) vials were distributed

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- Brilliant Blue G D2O 0.025%, lot 11252013@2, (b) (4) vials were distributed

OBSERVATION 6

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

Specifically, your firm has no scientific data to justify the assigned Beyond Use Date for 180 days at room temperature for your preservative free sterile drug product, Brilliant Blue G D2O 0.025%. The formulation identified in the literature article source for the Beyond Use Date provided during the inspection is not equivalent to the formulation of Brilliant Blue G D2O 0.025%. The formulation identified in the literature composed of (b) (4), Brilliant Blue G powder and (b) (4) (b) (4) for injection) while your formulation indicated (b) (4) ingredients, including (b) (4) are used in the manufacturing of Brilliant Blue G D2O 0.025%.

OBSERVATION 7

Reserve samples for drug products are not retained for one year after the expiration date of the drug product.

Specifically, your firm does not maintain retention samples for any finished drug products intended For Office Use and anticipatory dispensing. In addition, your firm has not established a written protocol for retention samples.

OBSERVATION 8

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of manufacturing of the drug product.

Specifically, your firm does not perform calculations for theoretical and actual yields for finished products. Your established batch yield limit of ± 10% does not require investigation when excursions occur. Formula Worksheets (batch records) for Brilliant Blue G D2O 0.025% outside the ± (b) (4) limit do not include the investigation and reconcilation of any loss volume.

For example,

- Lot 12132012@19 listed starting quantity at (b) (4), however, a total of (b) (4) vials were filled.
- Lot 02082013@13 listed starting quantity at (b) (4), however, a total of (b) (4) vials were filled.
- Lot 10222013@3 listed starting quantity at (b) (4), however, a total of (b) (4) vials were filled.
- Lot 11252013@2 listed starting quantity at (b) (4), however, a total of (b) (4) vials were filled.

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OBSERVATION 9

The master production and control records are deficient in that they do not include complete manufacturing, control, and instructions.

Specifically,

a. Your firm does not consistently document the name/lot number including but not limited to equipment used in the processing of your sterile finished drug product, Brilliant Blue G D2O 0.025%.

For example,

- Lot 02082013@13 does not include documentation of the type and lot number of the [redacted] (b) (4) used during the third (b) (4) step, the lot number of the sterile (b) (4), or the lot number of the sterile (b) (4) used in the transferring of the (b) (4) finished product to the individual vials.
- Lot 08092013@24 does not include documentation of the type and lot number of the [redacted] (b) (4) used during the third (b) (4) step, the lot number of the sterile (b) (4), or the lot number of the sterile (b) (4) used in the transferring of the (b) (4) finished product to the individual vials.

b. The Formula Worksheet for Brilliant Blue G D2O 0.025% does not include the complete step by step instructions for operators to perform the manufacturing process.

For example,

- Brilliant Blue G D2O 0.025% is manufactured in (b) (4) steps. [redacted] (b) (4) The Formula Worksheet does not indicate when and who performed each of the (b) (4) steps.

* **DATES OF INSPECTION:**
02/18/2014(Tue), 02/19/2014(Wed), 02/20/2014(Thu), 02/21/2014(Fri), 02/24/2014(Mon), 02/25/2014(Tue), 02/27/2014(Thu), 03/06/2014(Thu)

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