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	09/15/2014 - 10/07/2014* FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Paul K. Yamamoto, Vice President Operations

FIRM NAME	STREET ADDRESS
Leiter's Compounding	17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95119	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 WE OBSERVED:

OBSERVATION 1

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

Specifically, per your SOP 4.040, entitled Use, Validation and Maintenance of the [redacted], dated Effective Date of 07/14/14, your firm failed to perform validation studies of the [redacted] sterilization and/or depyrogenation cycles using the [redacted].

- Section 9.7.1 provides procedures and parameters for the performance qualification for the [redacted] validation of [redacted] sterilization to include sterilization [redacted] at [redacted].
- Section 9.7.2 [redacted] validation for glassware depyrogenation is deficient in that it does not specify the [redacted] for glassware depyrogenation.

1. Your firm has not used the [redacted] for production runs to monitor the effectiveness of the method of sterilization being used since the start of your operation on 07/21/2014. Additionally, there is a failure to perform real-time assessment of sterilization [redacted] such as [redacted] to verify that the set [redacted] have been met.

   A. The review of the [redacted] of Use, Maintenance, and Cleaning for the [redacted] revealed the following examples of *OFFICE USE* sterile injectable and ophthalmic suspensions that were [redacted] sterilized since 07/21/2014:

AMENDMENT 1

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	Anh Lac, Investigator Alicia K. Mckinsey, Investigator	10/08/2014

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- 500 ml Glycerin 99.5% Preserved Ophthalmic Suspension, lot 08132014@72
- (b) (4) (10ml) vials Phenol 5% in Almond Oil Injection Injectable, lot 08092014@7
- (b) (4) (10ml) vials Hydroxyprogesterone Caproate Injection, lot 08202014@28. This product lot failed the sterility testing.
- [redacted] (b) (4), that were used in the production of Hydroxyprogesterone Caproate Injection, lot 08202014@28

OBSERVATION 2

The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the identity, strength, quality, and purity of drug products.

Specifically, finished product certificates of analysis from your contract laboratory references methods MIC-SOP-0016, USP <71> Sterility Tests, and USP <85> Endotoxin Testing. These procedures and associated data could not be evaulated and verified for adequacy and reproducibility because your contract laboratory refused to provide any analytical worksheets, documentation, procedures, or methods associated with their results.

Examples include but are not limited to the following finished product certificate of analysis which state:

- Bevacizumab 2.5mg/0.1mL injection, lot number 08202014@73, 74, 76 sterility testing method MIC-SOP-0016 used: "Does not meet all the requirements for sampling and/or method suitability specified in USP <71>."
- Phenol 5% in almond oil injection, lot number 08092014@7 sterility testing method MIC-SOP-0016 used: "Does not meet all the requirements for sampling and/or method suitability specified in USP <71>". Additionally, USP <85> used for endotoxin testing but could not be verified for adequacy or reproducibility.

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- Lidocaine/Phenylephrine 1%/1.5% injection, lot number 08152014@64 sterility testing method USP <71> and endotoxin testing method USP <85> used but could not be verified for adequacy and reproducibility.
- Hydroxyprogesterone Caproate 250mg/mL injection, lot number 08192014@27 sterility testing method USP <71> and endotoxin testing method USP <85> used but could not be verified for adequacy and reproducibility.

OBSERVATION 3

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. Your firm has not established a written procedure describing the system for reprocessing batches that do not conform to specifications and the steps to ensure the reprocessed products will conform with all established specifications and standards.

B. The review of your [redacted] (b) (4) of Use, Maintenance, and Cleaning for the [redacted] (b) (4) revealed that the following [redacted] (b) (4) sterilization [redacted] (b) (4) of sterile drug products were "reran" without evaluating the impact of re-sterilization on product quality.
   - [redacted] (b) (4) (10ml) vials of Hydroxyprogesterone Caproate Injection, lot 08192014@27 were initially sterilized on 08/19/2014; on 08/20/2014, this product lot was indicated to be "reran".
   - [redacted] (b) (4) (10ml) vials of Hydroxyprogesterone Caproate Injection, lot 08202014@28 were initally sterilized on 08/20/2014; on 08/21/2014, this product lot was indicated to be "reran".

~~Procedures prescribing a system for reprocessing batches to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics are not written and followed.~~

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OBSERVATION 4

The labels of your firm's drug products observed by FDA do not contain information required by section 503B(a)(10) of the Act.

Specifically, the following but not limited to drug product labels do not contain the statement "This is a compounded drug," and the date that the drug was compounded:

- Cefuroxime 1 MG/0.1ML Intravitreal Injection Solution
- Moxifloxacin 0.1MG/0.1ML Ophthalmic
- Papaverine 12MG/Phentolamine 1MG/ProstaglandinE1 10MCG/ML Injectable Solution
- Lidocaine/Phenylephrine PF 1%/1.5% Injectable
- Glycerin 99.5% Preserved Ophthalmic Suspension
- Vanomycin 1MG/0.1ML Intravitreal Injection Solution
- Phenylephrine HCL 2.5% PF Ophthalmic
- Phenol 5% In Almond Oil Injection, 10ML Injectable
- Acetyl Cysteine 10% Opthalmic Solution, 10ML
- Sodium Phosphate 4MEQ NA/ML 3 MM P/ML Injection Solution
- Amphotericin 10 MCG/0.1ML Intravitreal Injection

The following but not limited to drug product labels do not contain the statement "Office Use Only":

- Cefuroxime 1MG/0.1ML Inravitreal Injection Solution
- Glycerin 99.5% Preserved Ophthalmic Suspension
- Phenol 5% In Almond Oil Injection, 10ML Injectable
- Sodium Phosphate 4MEQ NA/ML 3 MM P/ML Injection Solution

The following but not limited to drug product labels do not contain the quantity or volume:

- Glycerin 99.5% Preserved Ophthalmic Suspension
- Sodium Phosphate 4MEQ NA/ML 3 MM P/ML Injection Solution

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*** DATES OF INSPECTION:**
09/15/2014(Mon), 09/16/2014(Tue), 09/17/2014(Wed), 09/18/2014(Thu), 09/22/2014(Mon), 09/23/2014(Tue), 09/24/2014(Wed), 09/25/2014(Thu), 09/29/2014(Mon), 10/07/2014(Tue)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."