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	6/7/2017-6/15/2017* FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher F. Zuccarelli , Chief Operating Officer

FIRM NAME	STREET ADDRESS
Leiter's Enterprises, Inc. dba Leiter's	17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95119-1359	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

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

Specifically, while observing Pharmacy Technician (b) (6) gowning on June 8, 2017, I observed him touching his non-sterile hairnet multiple times with sterile gloves while tying his face mask. The technician proceeded to adjust the nose clamp on the mask and don a sterile hood and sterile gown without sanitizing his hands. He touched the front of his mask, the zipper area on the front of the gown, and the sleeves of his gown with his compromised gloves thus compromising these areas of his gown.

In addition, after washing his hands prior to gowning, Operator (b) (6) was observed dripping water on the gowning room floor (Room (b) (4) while walking from the sink to the location where the drying wipes were located, approximately 8 feet away.

OBSERVATION 2

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

Specifically,

On 6/7/2017, I observed the aseptic filling of two lots of CTP (Cyclopentolate HCl 1%, Tropicamide 1%, Phenylephrine HCl 2.5%) being performed in ISO 5 laminar flow hoods (b) (4) in Room (b) (4)

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	Ashar P Parikh, Investigator	X	6/15/2017

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A. I observed Pharmacy Technicians (b) (6) reach into the ISO 5 laminar flow hood to remove filled and capped CTP bottles multiple times without sanitizing their hands. The needle used to fill subsequent bottles of CTP was exposed in the ISO 5 laminar flow hood approximately one foot away from where the Technicians were observed reaching into the hood.

B. Your firm's operators were observed cleaning multiple sides of the ISO 5 laminar flow hood using the same wipe. Your firm's SOP 3.022, "(b) (4) ' states to '(b) (4) (b) (4) "

C. I observed your firm's viable and non-viable sampling equipment was placed directly next to the (b) (4) and at least 8-10 inches away from where the CTP was being filled into dropper bottles near the middle of the hood. The sampling does not provide meaningful evaluation of the conditions of the aseptic area and operators.

D. The personnel and environmental monitoring performed by your Operators was inadequate. The operators were observed taking direct contact surface samples by dropping the contact plate from a few inches above the surface and picking up the plate after 2-3 seconds.(b) (4) (b) (4) as required per your firm's SOP 3.030, "Environmental Monitoring". In addition, gloved fingertip sampling is inadequate. The Operators only sample the very edges of their finger tips on the surface contact media plate. Furthermore, Operator(b) (6)was observed taking contact surface samples and gloved fingertip samples using unlabeled media plates. The samples were taken and the plates were not immediately labeled. The unlabeled samples were then placed on a cart outside of the ISO 5 laminar flow hood while the Operator proceeded to work on other tasks.

E. The media fills/process simulations performed for products aseptically filled into 15mL dropper bottles, such as CTP, are not representative of the most challenging conditions. Your firm manufactures finished drug products consisting of (b) (4) with 1mL fill in 15mL dropper bottles and (b) (4) of 10mL fill in 15mL dropper bottles. Currently your operator qualification media fill batch sizes consist of (b) (4) each which is not representative of finished drug product batch sizes and fill volumes.

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OBSERVATION 3

Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other drug products that may have been associated with the specific failure or discrepancy.

Specifically, your firm failed to reject lots #12152016-0093 and 12152016-0094 of CTP (Cyclopentolate 1%, Tropicamide 1%, and Phenylephrine 2.5%) drug product that did not meet the specification for the (b) (4) The two lots of CTP were released and distributed prior to receiving OOS results for (b) (4) You did not contact the customer to notify them of the OOS results or recall these two lots of drug products.

***DATES OF INSPECTION**

6/07/2017(Wed),6/08/2017(Thu),6/09/2017(Fri),6/12/2017(Mon),6/13/2017(Tue),6/14/2017(Wed),6/15/2017(Thu)

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