

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702	DATE(S) OF INSPECTION 12/10/2018-12/19/2018*
	FEI NUMBER 3003434972

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

FIRM NAME Leiter's Enterprises, Inc.	STREET ADDRESS 17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY San Jose, CA 95119-1359	TYPE 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 OBSERVED:  
OBSERVATION 1**

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

Your firm's management of the building monitoring system alarms lacks adequate quality control review. There are no time frames established in your firm's procedures to ensure alarms are reviewed in a timely manner and quality control is not required to review alarm acknowledgements to ensure alarms are handled appropriately and do not impact drug products.

**OBSERVATION 2**

Employees engaged in the processing of a drug product lack the training required to perform their assigned functions.

Specifically,

During routine visual inspections of filled drug products, an operator is not required to take a break unless they have been inspecting for (b) (4). An operator may inspect (b) (4) units for (b) (4) before taking a (b) (4) break. Your firm

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Ashar P Parikh, Investigator	Ashar P Parikh Investigator Signed by Ashar P. Parikh -S Date Signed 12-19-2018 13:09:08 X	DATE ISSUED 12/19/2018

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currently qualifies the visual inspectors if they can pass (b) (4) visual inspection qualifications of (b) (4) identifying at least (b) (4) % of the units with defects. This is inadequate to ensure an operator is capable of detecting drug product units with defects visible particulates during the entire (b) (4) visual inspection process.

**OBSERVATION 3**

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

Specifically,

Your firm does not routinely clean the wheels of chairs and rolling carts in your ISO 7 cleanroom. The carts are moved throughout the cleanroom during operations as observed during aseptic processing on December 12, 2018. Your firm's SOP 3.020 "Cleaning and Disinfection of ISO 7 and ISO 8 Areas" has no requirement for the technicians to clean the chair and cart wheels.

**\*DATES OF INSPECTION**

12/10/2018(Mon), 12/11/2018(Tue), 12/12/2018(Wed), 12/13/2018(Thu), 12/14/2018(Fri),  
12/19/2018(Wed)

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