DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION				
1431 Harbor Bay Parkway	12/10/2018-12/19/2018*				
Alameda, CA 94502-7070	FEI NUMBER				
(510)337-6700 Fax: (510)337-6702	3003434972				
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED					
Christopher F. Zuccarelli, Chief Operating Officer					
FIRM NAME	STREET ADDRESS				
Leiter's Enterprises, Inc.	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

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,

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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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Ashar P Parikh, Inv	estigator	Ashar P Parith Investigator Signed by Ashar P. Parith -S Signed 12-19-2018 13 09 08	DATE ISSUED 12/19/2018
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