



May 29, 2018

Robin Smith Hoke, President and CEO  
Leiter's Enterprises, Inc. dba Leiter's  
17 Great Oaks Blvd.  
San Jose, CA 95119-1359

Dear Ms. Hoke:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Leiter's Enterprises, Inc. dba Leiter's, located at 17 Great Oaks Blvd., San Jose, CA 95119-1359, from June 7, 2017, to June 15, 2017, by the U.S. Food and Drug Administration (FDA).

When the Agency concludes that an inspection is "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, please contact William Millar, Compliance Officer, at (510) 337-6896.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven Porter", is centered below the word "Sincerely,".

CDR Steven E. Porter, Jr.  
Director, Division of Pharmaceutical Quality Operations IV

SP:wvm

Enclosure: EIR

Division of Pharmaceutical Quality Operations IV  
19701 Fairchild Road, Irvine, CA 92612  
Telephone: (949) 608-2900  
Fax: (949) 608-4417  
[www.fda.gov](http://www.fda.gov)