U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations II
4040 N. Central Expressway
Suite 900
Dallas, TX 75204

www.fda.gov

Via UPS
Return Receipt Requested

09/23/2019

Dr. Irit Weiser
CEO
Institute for Food Microbiology and Consumer Goods Ltd.
9, Derekh Ha-Shalom
Nesher, 3665112
Israel

Dear CEO Weiser:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Institute for Food Microbiology and Consumer Goods Ltd., FEI:3009891907, located at 9, Derekh Ha-Shalom, Nesher, IL from 07/22/2019 - 07/24/2019. FDA has determined that the inspection classification of this facility is "no action indicated" ('NAI')[1]. Based on this inspection, this facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP).

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of NAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by the appropriate CDER or CVM review office. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact Lolithia L Lett via telephone at 404-669-4566 or email at Lolitha.Lett@FDA.HHS.GOV.

Sincerely,
Lareese K. Thomas -S

Digitally signed by Lareese K. Thomas -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000359724, cn=Lareese K. Thomas -S
Date: 2019.10.02 17:41:59 -04'00'

LaReese Thomas, Supervisory Investigator
Office Pharmaceutical Quality Operations II

[1] See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm223231.htm.