



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration

**CENTER FOR DRUG EVALUATION AND RESEARCH**

Office of Manufacturing and Product Quality  
Division International Drug Quality  
International Compliance Branch  
10903 New Hampshire Avenue  
Building #51, Room 4220  
Silver Spring, MD 20993

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July 17, 2013

Dr. Irit Weiser  
CEO and Owner  
Institute for Food Microbiology and Consumer Goods Ltd.  
9 Ha'Shalom Rd  
PO Box 291  
Nesher, Israel 36601

Reference: FEI 3009891907

Dear Dr. Weiser:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your Microbiological testing facility in Nesher, Israel by Investigator Leonard H. Lavi during the period of June 11 – 12, 2013.

Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practice (CGMP).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at [http://www.fda.gov/cder/drls/registration\\_listing.htm](http://www.fda.gov/cder/drls/registration_listing.htm)

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

David S. Jones  
Compliance Officer  
Division of International Drug Quality

Enclosure: EIR