



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 4234  
Silver Spring, MD 20993

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August 13, 2014

Mr. Ami Bechar  
CEO  
Aminolab Ltd.  
Weizmann Science Park  
P.O. Box 4074  
Ness Ziona, 70400 Israel

Reference: FEI 3003011665

Dear Mr. Bechar:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your contract testing laboratory in Ness Ziona, Israel by Investigator Leonard Lavi and Investigator and Analyst Heriberto Negron-Rivera during the period of June 1, 2014 to June 2, 2014.

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 practices (CGMPs).

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,

Alicia Mozzachio  
Branch Chief  
Division of International Drug Quality

Enclosure: EIR