



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality  
Foreign Inspection Team, HFD-325  
11919 Rockville Pike  
Rockville, Maryland 20852

TELEPHONE: (301) 827-9004  
FAX: (301) 827-8909

December 14, 2004

Mr. Rafi Barkan  
Co-Director  
Aminolab, Ltd  
Weizmann Science Park  
P.O. Box 4074  
Ness Ziona, Israel 70400

Dear Mr. Barkan:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your control testing laboratory, Aminolab in Ness Ziona, Israel on October 13-15, 2004 by FDA Investigator Patricia A. Cochran and Analyst Barbara L. Rogolsky. Based on the profile coverage of this inspection, we are classifying your facility as acceptable. However, it remains your responsibility to assure continued compliance with CGMPs.

Additionally, we enclosed a copy of the EIR for the inspection. This report is being provided to you for information purposes. Since the Agency is working to make its regulatory process and activities more transparent to the regulated industry, enclosed is a copy of the Establishment Inspection Report (EIR) for the above inspection. 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 FOIA and C.F.R. Part 20. This, however, you may request additional information under the Freedom of Information Act (FOIA).

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

Sincerely,

Marybet Lopez  
Compliance Officer  
Foreign Inspection Team, HFD-325

Enclosure: