



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Compliance
International Compliance Branch
10903 New Hampshire Avenue, WO Bldg 51
Silver Spring, MD 20993

July 28, 2009

Dr. Gilles Martin
CEO
Biolab S.P.A.
Via Bruno Buozzi 2
Vimodrone (Milano), Italy

Dear Dr. Martin:

FDA has completed the review of the Establishment Inspection Report (EIR) for the inspection conducted at your contract testing laboratory facility in Vimodrone (Milano), Italy on May 18-20, 2009 by FDA Investigator Paul C. Mouris.

Based on this inspection, FDA is classifying your laboratory facility as acceptable for contract testing. However, it remains your responsibility to assure continued compliance with Current Good Manufacturing Practices (CGMPs). This letter is not intended as an endorsement or certification of the facility.

Additionally, we have enclosed 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. The EIR is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the FOIA and 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 telephone numbers.

Sincerely,

Hidee L. Molina

Compliance Officer/Chemist

Enclosure: