



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality
International Compliance Team
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April 7, 2011

Mr. Guido Strijbos
Managing Director
Regilabs Bv
Morsestraat P.O. Box 600
6710 BP Ede
The Netherlands

Reference: FEI 3008566420

Dear Mr. Strijbos:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your control testing laboratory in Utrecht, The Netherlands by Investigator Simone E. Pitts and Microbiologist Susan M. Jackson on November 3-4, 2010. An FDA-483, Notice of Inspectional Observations was issued at the conclusion of the inspection.

We have also reviewed your company's initial response dated November 17, 2010, as well as the updated response dated January 7, 2011 with supportive documentation. 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).

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,

Allison A. Aldridge, Ph.D.
Compliance Officer
International Compliance Branch

Enclosure: EIR