



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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September 9, 2010

Dr. Kay O'Donnell
Managing Director
Reading Scientific Services Limited
Reading Science Centre, Whiteknights Campus
Pepper Lane, Reading
United Kingdom - RG6 6LA

Dear Dr. O'Donnell:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your manufacturing facility in Reading, United Kingdom by Investigators Simone Pitts and Jose A. Lopez Rubet on June 7-8, 2010. An FDA-483, List of Inspectional Observations with 4 observations was issued to you at the conclusion of the inspection.

We have also reviewed your firm's response dated June 16, 2010. 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).

Also, we note that this establishment is not registered with FDA as required by 21 CFR 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm

Additionally, we 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. It 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 number.

Sincerely,

Brian L. Belz
Compliance Officer
International Compliance Team

Enclosure: EIR