



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

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July 5, 2007

Mr. Martin Adamson, Quality Manager
International Laboratory Services
Shardlow Business Park
London Road Shardlow
Derbyshire
United Kingdom

Dear Mr. Adamson:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your laboratory facility in Derbyshire, United Kingdom by Investigator Simone Pitts and Chemist Burnell M. Henry. Based on this inspection, we are classifying your facility as acceptable for control testing laboratory operations. 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.

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 enclosed copy contains only the narrative portion of the report and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and C.F.R. Part 20. However, you may request additional information under the FOIA. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

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

Sincerely,

Douglas A. Campbell
Compliance Officer
International Compliance Team, HFD-325

Enclosure: