



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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23 February 2011

Mr. Ian Johnson
Operations Director/Manager
International Lab Service
Shardlow Business Park
London Road,
Shardlow, Derbyshire
DE72 2GD United Kingdom

RE: Inspection of firm FEI 3002807256

Dear Mr. Johnson,

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your pharmaceutical contract testing facility in Derbyshire, United Kingdom, on November 8-9, 2010 by FDA Investigator Barbara J. Rincon. Based on the inspection, we are classifying your facility as acceptable. It remains your responsibility to assure continued compliance with current good manufacturing practices. This letter is not intended as an endorsement or certification of the facility.

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

Sincerely,

Elizabeth L. Philpy
Compliance Officer
International Compliance Team

Enclosure: