



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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August 5, 2005

Mr. Andrew McCallum
QA Manager
Tepnel Scientific Services
34 York Place
Edinburgh,
United Kingdom

Dear Mr. McCallum:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your testing facility Edinburgh, United Kingdom, on June 27-28, 2005, by FDA Investigator Dale Nyberg. Based on this 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.

We note that this establishment is not registered with FDA as required by 21 CFR 207.40. Information on how to register the facility is available on-line at the following internet website: http://www.fda.gov/cder/drls/registration_listing.htm.

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. However, you may request additional information under the Freedom of Information Act.

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

Sincerely,

Carole L. Jones
Compliance Officer
Foreign Inspection Team, HFD-325

Enclosure: