



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 Branch
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May 13, 2009

Mr. Detlef Lurig,
CEO
HameIn RDS S.A.
Harna 36
900 01 Modra Slovakia

Dear Mr. Lurig:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your control testing laboratory in Modra, Slovakia, on February 9 – 11, 2009 by Investigator Laurie Bem Frazier. Based on this 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.

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

Sincerely,

Edwin Melendez
Consumer Safety Officer

Enclosure: