



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
* Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

MAR 5 2008

Dear Mr. Chairman:

Thank you for your letter of February 14, 2008, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, requesting information and documents regarding the drug Heparin and the Food and Drug Administration's (FDA or the Agency) foreign inspection program. This is a partial response.

Information contained in the enclosures includes information that is trade secret, commercial confidential or other information protected from disclosure to the public under the Freedom of Information Act (Title 5, *United States Code* [U.S.C.] 552), the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), and Food and Drug Administration (FDA or the Agency) regulations. The Committee should not publish or otherwise make public any such information. We would be glad to discuss with the Committee staff the protected status of any specific information.

We have repeated your request below followed by our response.

7. All inspection reports of manufacturers of Heparin for the past five years.

We are sending two boxes of Establishment Inspection Reports.

Thank you again for your interest in this matter. If you have any further questions, please let us know. A similar letter without the enclosures has been sent to Chairman Stupak.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

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cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigation