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

APR 2 8 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. We have sent partial responses on February 27 and March 5, and April 24, 2008. This is a further partial response.

Information contained in the enclosures may include 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 FDA 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 question below in bold followed by our response.

1. **All inspection reports related the Chinese company that Baxter International Inc. was apparently using to produce Heparin (e.g., all FDA form 483s).**

   Documents responsive to this request are enclosed as TAB A.

8. **All documents in the Data Master Files or elsewhere relating to FDA approval of raw material suppliers of the active ingredient in Heparin.**

   Documents responsive to this request are enclosed as TAB B.

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

Enclosure

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

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

CDRH Efforts Regarding Contaminated Heparin used in Medical Devices
CDRH Office of Compliance
April 24, 2008

- Retrieve data from 510(k) and PMA database and cross referenced it with the Registration and Listing database.
- Identified and verified the current manufacturers of heparin containing and coated products and the initial distributors of those products.
- Issued letter to industry dated April 8, 2008, identifying the problem and issues known regarding heparin. Manufacturers were requested to test all API and crude heparin using the NMR and CE tests. Recommendations were included that manufacturers should recall if the tests were positive for the contaminant.
- Initial suppliers of the contaminated heparin were advised to recall and notify their subaccounts to also recall if warranted.
- 1-800 Heparin Hotline was established for calls relating to heparin.
- Notification letters regarding the heparin issue are provided to manufacturers during premarket review if it is found that their devices contain heparin. The letter encourages them to test their API.
- A letter to Healthcare facilities/Healthcare Professionals asking them to identify and report adverse events will issue this week. Requested MDRs to be submitted within 5 days to allow for prompt review and response as appropriate.
- A list of known heparin containing devices will be posted this week on CDER's heparin website to serve as guidance for healthcare practitioners.
- All written information is updated to CDRH's web and linked to CDER's webpage.
- Several manufacturers have recalled their contaminated heparin products as requested by the API supplier (Baxter, B. Braun, Medefil, Covidien & Physicians Industries).
- Called several device manufacturers to verify receipt of the recall notification from SPL Wisconsin.
- Classified 5 recalls relating to contaminated heparin to date. All recalls were Class II.
- For any manufacturer who has received a known contaminated lot, discussions are ongoing to ensure appropriate actions are taken.
- A follow up letter to the industry letter, dated April 8, 2008, is being prepared.
- Participated in the International Heparin meeting on April 17 & 18, 2008, with CDER and other international experts.
- Collaborated with CDER on all known heparin issues and continues to participate in the Heparin Task Force conference calls.
- Participated in discussions with District Offices who are inspecting suppliers of heparin.
- Collaborated with DIOP in collecting test data for contaminated products that were detained as a result of the import bulletin.
- Reviewed analytical data from several firms that received crude and API heparin.
- Collaborated with Office of Science and Engineering Laboratories (OSEL), District Offices, and Forensic Chemistry Center on analytical test methods pertaining to identifying the contaminant and impurities found in medical devices.
- Office of In Vitro Diagnostics (OIVD) is in discussion with IVD manufacturers that have heparin containing devices.