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

FEB 25 2008

Dear Mr. Chairman:

Thank you for your letter of February 21, 2008, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, requesting written clarification of the Food and Drug Administration's (FDA or the Agency) policy relating to pre-approval inspections for drugs. Also, your letter requests that the Agency make certain staff available for a briefing with Committee staff.

Under section 505 of the Federal Food, Drug, and Cosmetic Act, prior to approval of a new drug application (NDA), abbreviated new drug application (ANDA), or certain manufacturing supplements, FDA determines that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the applicant's drug are adequate to preserve the drug's identity, strength, quality, and purity. Our policy has been, and continues to be, that we approve drugs after verifying that this standard is met based upon a recent inspection of the manufacturing facility or facilities named in the application. If we have a recent, satisfactory inspection on record for a given facility named in the application, we generally will not conduct a new pre-approval inspection of that facility prior to approving the application. However, even if there is a recent inspection, we will inspect again if we determine that the circumstances warrant it. For example, FDA will inspect again if it believes that the manufacturing facility may not be in compliance with current good manufacturing practices (cGMPs), if the application raises questions that need to be resolved by inspection, or if the facility is using a new or unique technology for the product that we would want to evaluate by inspection.

In the case of the manufacturing supplement filed by Baxter in 2004 that named a new Chinese supplier of Heparin active pharmaceutical ingredient (API), FDA mistakenly believed that there had been a recent inspection of the facility named in the supplement. Therefore, it did not conduct an inspection at that time before approving the supplement. In light of the discovery of that mistake, we have moved rapidly to inspect the Chinese facility, as part of our wide-ranging efforts to identify the cause of the recent spike in adverse events associated with the product.

It is important to note that the issues related to Heparin have just recently been identified, and the investigation is still underway. The Agency has determined neither the cause of the adverse events nor whether the adverse events are associated with the Chinese Heparin API supplier.

We are working with Committee staff to accommodate your request for a briefing. We expect to brief Committee staff this week and will continue to work with them to respond to your questions. Thank you for your interest in this matter. A similar letter has been sent to Chairman Stupak.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

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

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