ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

April 25, 2007

Marcia G. Crosse, Ph.D.
Director, Public Health and Military Health Care Issues
Government Accountability Office
441 G Street, NW, Room 5K21
Washington, DC 20548

Dear Dr. Crosse:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, March 22, 2007, at the hearing entitled, "The Adequacy of FDA to Assure the Safety of the Drug Supply - Part II." We appreciate the time and effort you gave as a witness before the Subcommittee.

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the questions and include the text of the Member's questions along with your response. In the event you have been asked questions from more than one Member of the Committee, please begin the responses to each Member on a new page.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business on **Wednesday, May 9, 2007.** Your written responses should be delivered to **2125 Rayburn House Office Building** and faxed to **202-225-5288** to the attention of Kyle Chapman. An electronic version of your response should also be sent by e-mail to Mr. Kyle Chapman at **kyle.chapman@mail.house.gov** in a single Word or WordPerfect formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Kyle Chapman with the committee staff at (202) 225-2927.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

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

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Bart Stupak

1. What is the most important reform that Food and Drug Administration (FDA) should undertake to address drug safety?

2. How has FDA addressed the major problems with drug safety the Government Accountability Office (GAO) identified a year ago?

3. Has the dispute resolution process instituted by FDA been used yet?

4. What are your concerns about the independence of the dispute resolution process?

5. What additional authority should Congress grant FDA to improve its drug safety programs?

6. Did your GAO team learn of any cases where Office of Drug Safety (ODS) personnel were excluded from Advisory Committee meetings by Office of New Drugs (OND) personnel?

7. Did FDA ever define the role of ODS in advisory committee meetings involving post market safety issues?

8. In your case study reviews, was there any pattern of OND resistance to instituting labeling changes or other safety measures?