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ONE HUNDRED TENTH CONGRESS

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

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March 28, 2008

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The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

Despite our letter dated March 19, 2008, which clearly requested documents relating to the Committee on Energy and Commerce's inquiry into the Food and Drug Administration (FDA) mistaken failure to inspect the Chinese facilities that manufactured the active pharmaceutical ingredient and supplied the bulk heparin for Baxter Laboratories, we have been requested to send another letter that requests the specific personnel files of those FDA employees involved in the errors that led to this tragic failure.

Although we view the requirement for such a second request as obstructionist, to say the least, the Committee herein requests access to all personnel files of the following employees of the Center for Drug Evaluation and Research (CDER):

- Deborah Autor, Director, Office of Compliance;
- Moheb Nasr, Director, Office of New Drug Quality Assessment;
- Ali Al-Hakim, Medical Officer, Office of New Drug Quality Assessment; and
- John Dietrick, Team Leader, International Compliance Team, Division of Medical Product Quality, Office of Compliance

We expect that the files—maintained at CDER since 2004—be made available for Committee staff review at the Humphrey Building no later than Tuesday, April 1, 2008. At that

The Honorable Andrew C. von Eschenbach, M.D.
Page 2

time, the staff will inform you if any additional files should be made available and/or delivered to the Committee. We expect that these and other FDA employees who agree to voluntary interviews will be made available in the Committee offices by no later than Wednesday, April 2, 2008.

If further information is required, please have your staff contact David Nelson or Chris Knauer with the Committee staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

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

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