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

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April 4, 2007

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The Honorable Andrew C. von Eschenbach, M.D. Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

The House and Senate recently received the recommendations of the Food and Drug Administration (FDA) and interested stakeholders with regard to the reauthorization of the Prescription Drug User Fee Act (PDUFA). Given the importance of this program, we will work to ensure reauthorization of this valuable program, which is set to expire on September 30, 2007.

As the Committee on Energy and Commerce conducts the PDUFA reauthorization process, we believe it is important that the Congress understand the specific time frame in which work must be completed in order to avoid any personnel disruptions in this program.

We request that you provide to us a date certain by which the FDA would need to issue a reduction- in- force (RIF) notice under part 351 of title 5, Code of Federal Regulations, to those affected employees should it appear that PDUFA reauthorization will not be completed by its expiration under current law.

Thank you for your attention to this matter. We look forward to working with you and other stakeholders as we move forward in the reauthorization of PDUFA. We ask that you please respond to this inquiry by no later than Tuesday, April 17, 2007.

The Honorable Andrew C. von Eschenbach Page 2

If you have any questions regarding this request, please have your staff contact John Ford with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,

John D. Dingell

Chairman

Frank J. Pallone, Jr.

Chairman

Subcommittee on Health

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

The Honorable Nathan Deal, Ranking Member Subcommittee on Health