Congress of the United States

House of Representatives

Washington, D.C. 20515

January 29, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857-0001

Dear Dr. von Eschenbach:

Pursuant to Rules X and XI of the Rules of the United States House of Representatives, the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce is conducting an inquiry regarding the adequacy of the generic drug approval process at the Food and Drug Administration (FDA). Among the issues of particular interest in this inquiry is the failure of FDA to use its existing authority to approve generic biopharmaceutical drugs under Sections 505 (b)(2) or 505 (j) of the Food Drug and Cosmetic Act (FDCA); Section 351of the Public Health Service Act (PHSA); or elsewhere. Another issue of importance to the Subcommittee is the adequacy of resources devoted to the Office of Generic Drugs (OGD).

The Subcommittee intends to monitor the progress of FDA in ensuring that American consumers enjoy the benefits of affordable drugs. To that end we request that you provide the Subcommittee with a list of FDA-approved drugs scheduled to go off patent or otherwise lose exclusivity during calendar year 2007. We further ask that you provide, for each year from 2002 through 2006, an accounting of the backlog of applications within the generic drug approval process, the funds expended in the review process, and number of full-time equivalent employees (FTEs) within the OGD.

In addition, please provide the Subcommittee with a list of biopharmaceutical drugs (also referred to as follow-on biologic drugs) for which the FDA has received abbreviated applications under Section 505 the FDCA or Section 351 of the PHSA. The list should include the name of the drug and the date that the initial application for abbreviated approval was received by FDA.

Lastly, please state whether you believe your existing authority is sufficient to accept and approve abbreviated applications for biopharmaceutical drugs. If not, please provide us with a copy of any draft legislation that you believe is required to facilitate the timely approval of these drugs that are critical to achieving affordable, quality health care in this country.

We ask that the information requested in this letter be sent to the Committee by no later than Thursday, February 15, 2007. Should you have any questions regarding this request, please contact David Nelson with the Committee staff at (202) 225-2927.

Sincerely,

John D. Dingell
Chairman
Committee on Energy and Commerce

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce