THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

SEP 27 2007

John D Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Chairman Dingell:

I want to congratulate you for completing action on the FDA Amendments Act, H.R. 3580. As you know, this bill contains the reauthorization of user fees for drugs and devices as well as other key provisions vital to the Food and Drug Administration. We appreciate your support and hard work on this legislation, the commitment of Members of the Committee in working out these measures, and the support shown by the full House.

I am including as enclosures to this letter the two commitment documents for the drug and device user fee programs which outline the agreements between the Agency and the industries with regard to application approval timeframes, issuance of guidances, post market program enhancements, and milestones for other activities to be supported by user fees. These documents cover fiscal years 2008 through 2012 and they represent the commitment of the Department and the FDA to carry out the goals under the mutual agreement with the industries.

Thank you again for successful enactment of the FDA Amendments Act. I look forward to working with you as we proceed with the implementation of this legislation.

Sincerely,

Michael O. Leavitt

Enclosures

cc: Representative Barton