

Congress of the United States
House of Representatives
Washington, DC 20515-0530

HENRY A. WAXMAN
30TH DISTRICT, CALIFORNIA

March 28, 2006

The Honorable Andrew von Eschenbach
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

This year, my colleagues in the Congress and I will consider the reauthorization of the Prescription Drug User Fee Act (PDUFA). Given the critical importance of PDUFA to the FDA-regulated biopharmaceuticals industry, I have closely followed the FDA's progress under this important statute, and specifically the progress as set forth in the Agency's FY 2007 Congressional Budget Request.

At the same time, I have a long-standing interest in FDA's administration of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman"). As you know, I have been watching with concern as FDA has repeatedly delayed both the issuance of a guidance on approval of generic versions of insulin and human growth hormone¹ and a final decision on a so-called "505(b)(2) application" for human growth hormone filed under Hatch-Waxman by Sandoz in 2003.

I am now writing because it has come to my attention that the FDA is making apparently inconsistent statements about its performance under PDUFA and its review of the Sandoz application for human growth hormone.

As you know, Sandoz has filed a lawsuit against the FDA for the Agency's failure to issue a final decision on its application for human growth hormone. In the context of that lawsuit, FDA has claimed that the review process for the Sandoz NDA has not yet been completed.²

¹ Letter from Rep. Henry A. Waxman and Senator Orrin G. Hatch to FDA Acting Commissioner Andrew von Eschenbach, M.D. (February 10, 2006) (online at: http://www.waxman.house.gov/pdfs/letter_fda_2.10.06.pdf).

² See, e.g., Memorandum of Points and Authorities in Support of Defendants' Cross Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment, (February 13, 2006), *Sandoz Inc. v. U.S. Dept. of Health and Human Services and U.S. Food and Drug Admin.*, D.D.C. (No. 1:05 CV 01810 (RMU)).

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In apparent conflict with this assertion to a federal court, the FDA's Performance Analysis included in the FY 2007 Congressional Budget Request states that the FDA had reviewed and acted on "100% of 82" FY 2003 NDA submissions—which would include the Sandoz NDA—by September 30, 2004. If the FDA's statement to Congress is correct, all of the reviews of the FY 2003 NDA submissions (including the Sandoz NDA) had been completed for well over a year when the FDA told the court that the Sandoz NDA review was not completed.

It is extremely difficult to reconcile the FDA's statements to the court with its statement to Congress. I am therefore writing to request an explanation for what appears to be a conflict in FDA's statements to the Congress and to the Judiciary. Please provide a response stating whether the review of the Sandoz NDA is ongoing or whether it is instead completed. If your response is that the NDA review is ongoing, please provide an explanation of how the report to Congress in support of the FDA's budget request came to misstate the percentage of 2003 NDAs that had been acted upon. As part of that explanation, please provide all sources of the information that the FDA relied upon in reporting to Congress that 100% of FY 2003 NDAs had been acted upon.

Your attention to this important issue is greatly appreciated. The integrity of the drug review process and management of PDUFA funding are critical issues as we begin considering the PDUFA IV legislative process for FY 2007.

Please provide a response to this request no later than April 11, 2006. If you have any questions, please contact Ann Witt or Rachel Sher of my staff at (202) 225-3976.

Sincerely,


HENRY A. WAXMAN
Member of Congress