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Health, Education and Human Services Division

B-277557

July 21, 1997

The Honorable James Jeffords
Chairman
Committee on Labor and Human Resources
United States Senate

Dear Chairman Jeffords:

Subject: PDUFA: Information About Reauthorization

The Prescription Drug User Fee Act of 1992 (PDUFA) authorizes the Food and Drug Administration (FDA) to collect fees from the prescription drug industry to augment FDA's base resources. Such fees are credited to the appropriation account for FDA's salaries and expenses. FDA is to use these additional funds to expedite its review of human drug applications so that prescription drug products can reach the marketplace more quickly. Unless reauthorized by the Congress, the act and the user fee program under PDUFA, including FDA's authority to collect fees, expire at the end of this fiscal year. Your Committee is currently considering reauthorizing the act.

You understand that, if PDUFA were not reauthorized, FDA staff would be subject to a reduction in force (RIF), and that, according to regulations promulgated by the Office of Personnel Management (OPM), FDA must give notice to employees 60 days before a RIF.[1] Thus, even though the authorization for collecting fees does not expire until October 1, 1997, RIF notices are currently slated to be issued on August 1, 1997. User fees currently fund 700 full-time equivalents (FTE) dispersed over 1,977 employees. In addition, you understand that FDA has a carry-over account that would provide for an orderly transition should PDUFA not be reauthorized. In your letter of July 17, 1997, you asked us to answer several questions about the account and its implications regarding RIF notices. We have responded to your questions in the following paragraphs.

[1]The Director of OPM, at the request of an agency head, is authorized to approve a notice period of less than 60 days but at least 30 days, when a RIF is caused by circumstances not reasonably foreseeable.

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We obtained most of the information to answer your questions from FDA's Office of Financial Management. We also examined FDA's legal authority, applicable regulations, and other relevant documents. Due to the short turnaround time for this request, we did not verify the estimates FDA gave us. With this exception, we conducted our work in accordance with generally accepted government auditing standards.

1. **What is the current balance in the carry-over account?**

   No "carry-over account" exists. If, at the end of the fiscal year, the funds available under the user fee program have exceeded program obligations, the balance is "carried over" to the next fiscal year. The enclosure, reprinted from the fiscal year 1996 PDUFA Financial Report to Congress, shows the revenues, obligations, and balances by fiscal year for the first 4 years of the program. FDA began fiscal year 1997 with a carry-over of $27,517,075 (total balance minus total accounts receivable). The precise amount that will be carried over from fiscal year 1997 cannot be determined until the fiscal year ends. FDA officials estimate, however, that funds carried over will total about $24 million.

   FDA expects additional user fee revenues in fiscal year 1998, even if the user fee program is not reauthorized. Because the drug companies pay only half of the application fee upon submission of the drug application and the remainder after FDA issues an action letter related to the application, FDA officials believe that fees for submissions received in previous years (estimated at approximately $10 million) will come due and be collectable in fiscal year 1998, even without PDUFA reauthorization. FDA does not have an estimate of the rate of those collections throughout the fiscal year.

2. **What is the purpose of the carry-over account? Is it in any part to provide adequate funds to close down the program if it is not reauthorized?**

   PDUFA funds carried over from the previous fiscal year may be used to fund the obligations of the subsequent fiscal year. FDA believes and we agree that if the user fee program were not reauthorized, funds carried over from the final year of the program (fiscal year 1997) could be used to cover costs associated with the expiration of PDUFA authority, including the cost of terminating staff.

3. **Does the carry over account contain funds that would permit the agency to delay issuing RIF notices (currently slated for August 1, to meet the 60-day requirement)? If so, what is the latest date that the FDA could issue such notices and still fulfill its obligations under OPM regulations?**

   If the user fee program is not reauthorized, FDA could use some portion of the funds carried over from fiscal year 1997 to effect an orderly shutdown of the program. Any funds not needed for closing down the program would presumably be available to continue daily operations, delaying the need to issue RIF notices for the time period during which operations would continue.

   Because FDA has developed only very preliminary estimates for the cost of closing down the user fee program, however, it is not possible to estimate how long FDA could continue operations into fiscal year 1998 using funds carried over from fiscal year 1997. Moreover, to the extent that FDA chooses to make them available, FDA could use funds from its agencywide salaries and expenses account. We therefore cannot determine the latest date that FDA could issue RIF notices and still fulfill its obligations under OPM regulations.

   If FDA were to assume that the user fee program would be reauthorized and therefore no shutdown or RIF would be necessary, it could use the funds carried over from fiscal year 1997 to continue operations for some time. FDA estimates that its daily average user fee program obligations for fiscal year 1998 would be about $206,000. Without shutdown costs, the program could operate for more than 3 months with estimated funds carried over of $24 million. The risk of proceeding on this assumption, however, is that if the program were not reauthorized, FDA could have insufficient user fee funds for closing the program down. Funds to effect an orderly shutdown of the program would then have to come from elsewhere. If funds were not available, however, an even larger RIF might be necessary than would be necessary if planned for in advance.

We discussed the information contained in this correspondence with FDA officials, who agreed with most of the information. They pointed out, however, that although several factors affect the cost of shutting down the user fee program, their very preliminary estimates indicated that it will require a significant portion of the $24 million funds carried over. We have incorporated FDA's technical suggestions where appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 14 days from the date of this letter. At that time, we will send copies to interested parties and make copies available to others on request.

If you have any questions about this correspondence, please call me at (202) 512-6543 or Michele Orza at (202) 512-9228. Other major contributors to this study included Bertha Dong, Barry Bedrick, and Julian Klazkin.

Sincerely yours,

Bernice Steinhardt

Bernice Steinhardt
Director, Health Services Quality and Public Health Issues

FDA'S STATEMENT OF USER
FEE REVENUES AND RELATED OBLIGATIONS

	FY 1993	FY 1994	FY 1995	FY 1996	Total
Revenues					
Fees collected, FY 1993	$28,531,996				$28,531,996
Fees collected, FY 1994	5,707,994	$48,022,250			53,730,244
Fees collected, FY 1995	1,153,500	6,466,800	$63,333,200		70,953,500
Fees collected, FY 1996	416,000	1,774,200	12,253,800	$67,874,400	82,318,400
Total fees collected	35,809,490	56,263,250	75,587,000	67,874,400	235,534,140
Accounts receivable	116,000	206,400	676,000	1,004,700	2,003,100
Total revenues	**$35,925,490**	**$56,469,650**	**$76,263,000**	**$68,879,100**	**$237,537,240**
Obligations					
Fees obligated, FY 1993	(8,949,000)				(8,949,000)
Fees obligated, FY 1994	(25,290,990)	(14,660,030)			(39,951,020)
Fees obligated, FY 1995	(1,153,500)	(39,829,020)	(33,081,495)		(74,064,015)
Fees obligated, FY 1996	(416,000)	(1,774,200)	(42,505,505)	(40,357,325)	(85,053,030)
Total obligations	(35,809,490)	(56,263,250)	(75,587,000)	(40,357,325)	(208,017,065)
Balance as of 9/30/96	**$116,000**	**$206,400**	**$676,000**	**$28,521,775**	**$29,520,175**

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