

CONDITIONS FOR ASSESSMENT AND USE OF FEES

The FD&C Act, amended by ADUFA and ADUFA II, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend animal drug user fees. A summary of the legal conditions was introduced on page 3 of this report. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2012.

In order to compare and determine whether the legal conditions are satisfied, FDA must calculate and incorporate adjustment factors [defined in section 739(10) of the FD&C Act, as amended by ADUFA II] in the assessments of the first and the third conditions. The FD&C Act states:

The term “adjustment factor” applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator month being October 2002.

Paragraph 735(8) of the FD&C Act, which is the adjustment factor for the Prescription Drug User Fee Act (PDUFA), provides the following definition:

The term “adjustment factor” applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 1996.

For ADUFA II, the base month is October 2002 rather than October 1996, as reflected in the first statutory citation above. The consumer price index (CPI) for October 2010, the October of the fiscal year preceding FY 2012 was 218.711. The CPI for October 2002 was 181.3. Dividing the CPI of October 2010 by the CPI of October 2002 yields an adjustment factor of 1.206349 (rounded to six decimal places) for FY 2012.

The **first legal condition** is found in section 740(f)(1) of the FD&C Act. It states:

Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2003 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

The first condition requires that FDA's Salaries and Expenses appropriation (excluding user fees) for FY 2012 must be greater than or equal to FDA's Salaries and Expenses appropriation (excluding user fees) for FY 2003 multiplied by the adjustment factor for inflation. FDA's Salaries and Expenses appropriation (excluding user fees) for FY 2003 was \$1,373,714,000 after the rescission. Multiplying this amount by the adjustment factor of 1.206349 (rounded to sixth decimal place) equals \$1,657,178,510.

In FY 2012 Congress appropriated \$2,497,021,000 to FDA for salaries and expenses, excluding user fees. Because the FY 2012 Salaries and Expenses appropriation is greater than the adjusted FY 2003 Salaries and Expenses appropriation (\$1,657,178,510), the first legal condition was met.

The **second legal condition** is described in section 740(g)(2)(A)(i) of the FD&C Act. It states that fees:

...shall be retained in each fiscal year in an amount not to exceed the amount specified in Appropriation Acts, or otherwise made available for obligation for such fiscal year.

On November 18, 2011 the President signed the Consolidated and Further Continuing Appropriations Act, 2012, Public Law 112-55 which appropriated \$21,768,000 from animal drug user fees for FDA in FY 2012. Therefore, the second legal condition was met.

The **third legal condition** is defined in section 740(g)(2)(A)(ii) of the FD&C Act. It states that fees:

Shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

The third condition requires a minimum spending from appropriations, excluding user fees, on the process of animal drug review. The minimum spending from appropriations is the amount that FDA spent on the process for the review of animal drug applications in FY 2003, adjusted for inflation. FDA must spend more than the amount that is three percent below the minimum spending level from appropriations.

In FY 2003, the amount spent from appropriations for the process for the review of animal drug applications was \$32,748,000 (rounded to the nearest thousand). After applying the adjustment factor of 1.206349 (rounded to the sixth decimal place), the minimum appropriation spending level for the process for the review of animal drug applications for FY 2012, excluding user fees, is \$39,505,517.

In FY 2012, FDA obligated \$49,019,929 from appropriations, exclusive of user fees, for the process for the review of animal drug applications, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.

Table 7 shows the amounts FDA spent on the process for the review of animal drug applications from appropriations and user fees for FY 2011 and FY 2012.

**TABLE 7
SUMMARY STATEMENT OF OBLIGATIONS FOR THE PROCESS FOR THE REVIEW OF
ANIMAL DRUG APPLICATIONS
AS OF SEPTEMBER 30, 2012**

	FY 2011	FY 2012
From Appropriations	\$45,880,781	\$49,019,929
From Fee Revenues	\$16,632,800	\$16,137,101
TOTAL OBLIGATIONS	\$62,513,581	\$65,157,030