

### CONDITIONS FOR ASSESSMENT AND USE OF FEES

The FD&C Act, as amended by AGDUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend generic new animal drug user fees. A summary of the legal conditions was introduced on page three 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 741(k)(2) of the FD&C Act, as amended by AGDUFA] in the assessments of the first and third conditions.

Paragraph 741(k)(2) of the FD&C Act states 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 –

- (A) for the purpose of subsection (f)(1), such Index for October 2002;  
and
- (B) for purposes of subsection (g)(2)(A)(ii), such Index for October 2007.

We refer to item (A) above as the first legal condition adjustment factor, and to item (B) above as the third legal condition adjustment factor. (The second legal condition does not have an adjustment factor associated with it.)

For the first legal condition [subsection (f)(1)], 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.

For the third legal condition [subsection (g)(2)(A)(ii)] adjustment factor above, the base month is October 2007. The CPI for October 2010, the October of the fiscal year preceding FY 2012, was 218.711. The CPI for October 2007 was 208.936. Dividing the CPI of October 2010 by the CPI of October 2007 yields an adjustment factor of 1.046785 (rounded to six decimal places) for FY 2012.

The **first legal condition** is found in section 741(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 2008 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 741(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."

The President signed the Consolidated and Further Continuing Appropriations Act, 2012 (Public Law 112-55) on November 18, 2011. It specified that \$5,706,000 shall be derived from generic new animal drug user fees for FDA in FY 2012. Therefore, the second legal condition was met.

The **third legal condition** is defined in section 741(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 abbreviated applications for generic new animal drugs (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 2008 multiplied by the adjustment factor.

The third condition requires a minimum spending from appropriations (excluding user fees) on the process of generic new animal drug review. The minimum spending from appropriations is the amount that FDA spent on the process for the review of abbreviated applications for generic new animal drugs in FY 2008, adjusted for inflation. FDA must spend more than the amount that is three percent below the minimum spending level from appropriations.

In FY 2008, the amount spent from appropriations for the process for the review of abbreviated applications for generic new animal drugs was \$5,510,000 (rounded to a thousand). After applying the adjustment factor of 1.046785 (rounded to the sixth decimal place), the minimum appropriation spending level for the process for the review of abbreviated applications for generic new animal drugs for FY 2012, excluding user fees, is \$5,767,785.

In FY 2012, FDA obligated \$7,649,902 from appropriations, exclusive of user fees, for the process for the review of abbreviated applications for generic new animal drugs, 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 abbreviated applications for generic new animal drugs from appropriations and user fees for FY 2011 and FY 2012.

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

	FY 2011	FY 2012
From Appropriations	\$6,819,284	\$7,649,902
From Fee Revenues	\$4,685,800	\$4,366,351
<b>TOTAL OBLIGATIONS</b>	<b>\$11,505,084</b>	<b>\$12,016,253</b>