4: APPENDICES

4.1 – APPENDIX A: CONDITIONS FOR ASSESSMENT AND USE OF FEES

Introduction

The FD&C Act, as amended by ADUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend animal drug user fees. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2016. A summary of the legal conditions is provided in section 2 – Legal Conditions.

Adjustment Factor

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 III) 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.

Section 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 III, 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 2014, the October of the fiscal year preceding FY 2016, was 237.433. The CPI for October 2002 was 181.3. Dividing the CPI of October 2014 by the CPI of October 2002 yields an adjustment factor of 1.309614 (rounded to six decimal places) for FY 2016.

Legal Condition 1

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 2016 must be greater than or equal to FDA's Salaries and Expenses appropriation (excluding user fees) for FY 2003 multiplied by the adjustment factor. FDA's Salaries and Expenses appropriation (excluding user fees) for FY 2003 was $1,373,714,000. Multiplying this

amount by the adjustment factor of 1.309614 (rounded to the sixth decimal place) equals $1,799,035,086.

In FY 2016, Congress appropriated $2,719,308,000 to FDA for salaries and expenses, excluding user fees. Because the FY 2016 Salaries and Expenses appropriation is greater than the adjusted FY 2003 Salaries and Expenses appropriation, $1,799,035,086, the first legal condition was met.

Legal Condition 2

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

> [s]hall be collected and available 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 Appropriations Act, 2016 (Public Law 114-113) on December 18, 2015. It specified that $22,818,000 shall be derived from animal drug user fees for FDA in FY 2016, and that animal drug user fees collected in excess of this amount are also appropriated for FDA. Therefore, the second legal condition was met.

Legal Condition 3

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

> [s]hall be 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 ADUFA program. The minimum spending from appropriations is the amount that FDA spent on the process for the review of animal drug applications in FY 2003, multiplied by the adjustment factor. Further, FDA is considered to have met this requirement if it underspends this amount by up to 3 percent (see section 740(g)(2)(B)).

In FY 2003, the amount spent from appropriations for the ADUFA program was $32,748,000 (rounded to the nearest thousand). After applying the adjustment factor of 1.309614 (rounded to the sixth decimal place), the minimum appropriation spending level for the ADUFA program for FY 2016, excluding user fees, is $42,887,239.

In FY 2016, FDA obligated $45,569,857 from appropriations, exclusive of user fees, for the ADUFA program, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.