

4: APPENDICES

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

Introduction

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

Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate adjustment factors (defined in section 735(8) of the FD&C Act as amended) in the assessments of the first and third conditions. The FD&C Act states:

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.

The Consumer Price Index (CPI) for October 2014, the October of the fiscal year preceding FY 2016, was 237.433. The CPI for October 1996 was 158.3. Dividing the CPI of October 2014 by the CPI of October 1996 yields an adjustment factor of 1.499893 (rounded to the sixth decimal place) for FY 2016.

Legal Condition 1

The first legal condition is found in section 736(f)(1) of the FD&C Act. It states that fees:

[S]hall be refunded for a fiscal year beginning after FY 1997 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 1997 (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 FY 2016 Salaries and Expenses Appropriation (excluding user fees and rent payments to GSA) be greater than or equal to FDA’s Salaries and Expenses Appropriation (excluding user fees and rent payments to GSA) for FY 1997 multiplied by the adjustment factor for inflation. FDA’s Salaries and Expenses Appropriation (excluding user fees and rent payments to GSA) for FY 1997 was \$819,971,000. Multiplying this amount by the adjustment factor of 1.499893 equals \$1,229,868,763.

In FY 2016, Congress appropriated \$2,542,625,000 to FDA for salaries and expenses, excluding user fees and rent payments to GSA. Because the FY 2016 Salaries and Expenses Appropriation is greater than the adjusted FY 1997 Salaries and Expenses Appropriation, \$1,229,868,763, the first legal condition was met.

Legal Condition 2

The second legal condition is described in section 736(g)(2)(A)(i) of the FD&C Act and 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

On December 18, 2015, the President signed the Consolidated Appropriations Act, 2016, Public Law 114-113, which specified that \$851,481,000 shall be derived from prescription drug user fees, and that prescription drug user fees collected in excess of this amount, if any, are also appropriated for FDA. Therefore, the second legal condition was met.

Legal Condition 3

The third legal condition is defined in section 736(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 human 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 1997 multiplied by the adjustment factor.

The third condition requires a minimum spending from appropriations, excluding user fees, on the PDUFA program. The minimum spending from appropriations is the amount that FDA spent on the PDUFA program in FY 1997, multiplied by the adjustment factor.

In FY 1997, the amount spent from appropriations on the PDUFA program was \$147,959,689. After applying the adjustment factor of 1.499893 (rounded to sixth decimal place), the minimum appropriation spending level for the PDUFA program for FY 2016, excluding user fees, is \$221,923,702.

In FY 2016, FDA obligated \$320,942,599 from appropriations, exclusive of user fees, for the PDUFA program, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.