4: APPENDICES

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

Introduction

The FD&C Act, as amended by GDUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend human generic 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 744A(3) of the FD&C Act, as amended by GDUFA) in the assessments of the first and third conditions. The FD&C Act states:

> The term 'adjustment factor' means a factor applicable to a fiscal year that 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 2011.

The Consumer Price Index (CPI) for October 2014, the October of the fiscal year preceding FY 2016, was 237.433. The CPI for October 2011 was 226.421. Dividing the CPI of October 2014 by the CPI of October 2011 yields an adjustment factor of 1.048635 (rounded to the sixth decimal place) for FY 2016.

Legal Condition 1

The first legal condition, defined in section 744B(h)(1) of the FD&C Act states that fees:

> Shall be refunded for a fiscal year beginning after fiscal year 2012, 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 fiscal year 2009 (excluding the amount of fees appropriated for such a fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

The first condition requires that FDA's FY 2016 salaries and expenses appropriation (excluding user fees) be equal to or greater than FDA's FY 2009 salaries and expenses appropriation (excluding user fees), multiplied by the adjustment factor. FDA's FY 2009 salaries and expenses appropriation (excluding user fees) was $2,038,964,000. Multiplying this amount by the adjustment factor of 1.048635 equals $2,138,129,014.

In FY 2016, Congress appropriated $2,719,308,000 to FDA for salaries and expenses, (excluding user fees). Since the FY 2016 salaries and expenses non-user fee appropriation is greater than the adjusted FY 2009 salaries and expenses appropriation of $2,138,129,014, the first legal condition was satisfied.

Legal Condition 2

The second legal condition, defined in section 744B(i)(2)(A)(i) of the FD&C Act, states that fees:

> Shall 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 Consolidated Appropriations Act, 2016 (Public Law 114-113), which the President signed on December 18, 2015, made appropriations for FDA salaries and expenses, through September 30, 2016. It specified that $318,363,000 shall be derived from human generic drug user fees, and that human generic drug user fees collected in excess of this amount are also appropriated for FDA. Thus, the second legal condition was satisfied.

Legal Condition 3

The third legal condition, defined in section 744B(i)(2)(A)(ii) of the FD&C Act states that fees:

> Shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved.

The third condition requires a minimum spending from appropriations (excluding user fees) on the GDUFA program. For FY 2016, FDA's minimum spending from appropriations (excluding user fees) is set at $97,000,000 multiplied by the adjustment factor of 1.048635, which yields a minimum non-user fee appropriation spending of $101,717,595. Further, FDA is considered to have met this spending requirement even if it underspends this amount by up to 10 percent without any financial penalty (see section 744B(i)(2)(B)).

In FY 2016, FDA obligated $120,714,671 from appropriations (excluding user fees) for the GDUFA program, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.