4: APPENDICES

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

Introduction

The FD&C Act, as amended by BsUFA, specifies two legal conditions that must be met each fiscal year for FDA to collect and spend biosimilar biological product 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

The "adjustment factor applicable to a fiscal year" referred to in section 744H(e)(2)(B) is defined in section 744G(1) of the FD&C Act. It provides that the adjustment factor applicable to a fiscal year is the Consumer Price Index (CPI) for all urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by the CPI for September 2011.

For FY 2016, the applicable adjustment factor, rounded to six decimal places, is 1.058378. It is calculated via the following: the numerator is the CPI for September 2015, 156.278; the denominator is the CPI for September 2011, 147.658. After applying the adjustment factor of 1.058378, the minimum appropriation spending level for the BsUFA program for FY 2016 is $21,167,560.

Legal Condition 1

The first legal condition, provided in section 744H(e)(2)(A) of the FD&C Act, states:

> Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation acts.

The Consolidated Appropriations Act, 2016 (Public Law 114-113), which the President signed on December 18, 2015, made appropriations through September 30, 2016, for the salaries and expenses account of FDA. It specified that $21,540,000 shall be derived from BsUFA fees, and that BsUFA fees collected in excess of this amount are also appropriated for FDA. Therefore, the first legal condition was satisfied for FY 2016.

Legal Condition 2

The second legal condition, provided in section 744H(e)(2)(B) of the FD&C Act, states:

> The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (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 process), 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 $20,000,000 multiplied by the adjustment factor applicable to the fiscal year involved.

In other words, the second legal condition requires FDA to allocate a minimum of $20,000,000 in non-user fee appropriations, multiplied by the adjustment factor applicable to that fiscal year, 1.058378, for the costs of the BsUFA program.

In FY 2016, FDA obligations from appropriations (excluding user fees) for the BsUFA program were $32,353,416, which exceeded the required minimum of $21,167,560 by $11,185,856. Therefore, the second legal condition was satisfied, and the full amount of fees collected for FY 2016 will be retained for FDA to spend in subsequent fiscal years on the BsUFA program.