4: APPENDICES

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

Introduction

The FD&C Act, as amended by MDUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend medical device 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 was 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 an adjustment factor (defined in section 737(10) of the FD&C Act) 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 2011.

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

Legal Condition 1

The first legal condition is found in section 738(h)(1)(A) of the FD&C Act. It states:

> With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $280,587,000 multiplied by the adjustment factor applicable to such fiscal year.

This provision specifies a minimum that must be appropriated each year for the Device and Radiological Health line of FDA's appropriation, exclusive of user fees. The minimum amount for FY 2016 is 1 percent less than $280,587,000 multiplied by the adjustment factor of 1.048635, or $291,291,000 (rounded to the nearest thousand dollars) for FY 2016. In FY 2016, the Device and Radiological Health line of FDA's appropriation, exclusive of user fees, was $323,253,000. Since this amount is greater than $291,291,000, the first legal condition was met.

Legal Condition 2

The second legal condition is described in section 738(i)(2)(A)(i) of the FD&C Act. It states that fees:

> Subject to subparagraph (C), 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 President signed the Consolidated Appropriations Act, 2016 (Public Law 114-113) on December 18, 2015. It specified that $137,677,000 shall be derived from medical device user fees, and that medical device 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 738(i)(2)(A)(ii) of the FD&C Act. It states that fees:

> [S]hall only be available to defray increases in the costs of the resources allocated for the process for the review of device 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 2009 multiplied by the adjustment factor.

The third condition requires a minimum spending from appropriations, excluding user fees, on the process of medical device review. The minimum spending from appropriations is the amount that FDA spent on the MDUFA program in FY 2009, multiplied by the adjustment factor. FDA must spend at or above this minimum spending level from appropriations.

In FY 2009, the amount spent from appropriations for the MDUFA program was $223,545,692. After applying the adjustment factor of 1.048635, the minimum appropriation spending level for the MDUFA program for FY 2016, excluding user fees, is $234,418,000 (rounded to the nearest thousand dollars).

In FY 2016, FDA obligated $242,831,997 from appropriations, exclusive of user fees, for the MDUFA program, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.

In addition, MDUFA includes a provision that FDA's fiscal year obligations for medical device establishment inspections must be equal to or greater than its obligations for this purpose in FY 2002, with a 5 percent increase for each fiscal year. If FDA does not satisfy this condition for 2 consecutive years, FDA is prohibited from allowing accredited third parties to conduct certain device establishment inspections. This condition is cited in section 704(g)(10) of the FD&C Act.

Table 9 shows the required statutory minimum to be obligated for device establishment inspections (FY 2002 base level increased by 5 percent in each subsequent fiscal year, rounded to the nearest thousand dollars) and FDA obligations for medical device establishment inspections from FY 2002 to FY 2016.

TABLE 9: OBLIGATIONS FOR THE INSPECTION OF MEDICAL DEVICE ESTABLISHMENTS (ROUNDED TO $1000) AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	Minimum 2002 – Obligations Increased by 5% Per Year	Actual Obligations	Excess or Shortfall	Notes
2002 Base	$19,425,000	$19,425,000	$0	
2003	$20,396,000	$22,576,000	$2,180,000	
2004	$21,416,000	$21,430,000	$14,000	
2005	$22,487,000	$21,515,000	($972,000)	
2006	$23,611,000	$29,230,000	$5,619,000	
2007	$24,792,000	$31,926,000	$7,134,000	
2008	$26,031,000	$32,989,000	$6,958,000	
2009	$27,333,000	$35,927,000	$8,594,000	
2010	$28,700,000	$41,596,000	$12,896,000	
2011	$30,135,000	$43,261,000	$13,126,000	
2012	$31,641,000	$43,620,000	$11,979,000	
2013	$33,223,000	$40,304,000	$7,081,000	
2014	$34,885,000	$43,990,000	$9,105,000	
2015	$36,629,000	$43,262,000	$6,633,000	
2016	$38,460,000	$43,634,000	$5,174,000	A

Notes

A. FDA has spent more than the statutory minimum for device inspections for each of the past 2 fiscal years, and therefore may continue to allow accredited third parties to conduct certain device establishment inspections in future years.