2: LEGAL CONDITIONS

MDUFA imposes three legal conditions that must be satisfied in each fiscal year for FDA to collect and spend medical device user fees. A summary of how each of these legal conditions was satisfied in FY 2016 is described below.

Legal Condition 1 – The Device and Radiological Health line of FDA's Salaries and Expenses Appropriation (excluding user fees) each fiscal year may not be more than 1 percent less than $280,587,000 (rounded to the nearest thousand dollars), multiplied by an adjustment factor, or $291,291,000 (rounded to the nearest thousand dollars) for FY 2016. In FY 2016, the final appropriation for the Device and Radiological Health line of FDA's Salaries and Expenses Appropriation (excluding user fees) was $323,253,000. Therefore, the first legal condition was satisfied.

Legal Condition 2 – The amount of user fees collected for each fiscal year must be specified in that year's appropriation acts. 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 satisfied.

Legal Condition 3 – User fees may be collected and used only in the fiscal years when FDA spends a specified minimum amount of appropriated funds for the review of medical device applications. This specified minimum is the amount FDA spent on the review of medical device applications from appropriations (exclusive of user fees) in FY 2009, multiplied by an adjustment factor. That specified minimum level for FY 2016 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 review of medical device applications. Because FDA spent more than the specified minimum amount from appropriations in FY 2016, the third legal condition was satisfied.

MDUFA also provides that FDA obligations for medical device establishment inspections must be equal to or greater than the amount spent in FY 2002, increased by 5 percent each fiscal year. If this condition is not met for 2 consecutive years, FDA is not allowed to use accredited third parties to conduct certain medical device establishment inspections in future years. That specified minimum level for FY 2016 is $38,460,000 (rounded to the nearest thousand dollars). In FY 2016, FDA obligated $43,634,000 from appropriations (exclusive of user fees) for medical device inspections. Because spending on medical device establishment inspections exceeded the specified minimum level for each of the most recent two fiscal years, FDA may continue to permit accredited third parties to conduct certain medical device establishment inspections in future years.

References

Detailed explanations and calculations of how each of these legal conditions were satisfied in FY 2016 are described in section 4.1 - Appendix A.