

EXECUTIVE SUMMARY

The Medical Device User Fee Amendments of 2012 (MDUFA) requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation. As required under the statute, this report covers activities for fiscal year (FY) 2016.

MDUFA specifies that the following three legal conditions must be satisfied each fiscal year in order for FDA to collect and spend MDUFA user fees:

1. Within FDA's Salaries and Expenses Appropriation, the amount appropriated for devices and radiological health, excluding fees, each fiscal year must be more than 1 percent less than \$280,587,000, multiplied by an adjustment factor specified in the statute.
2. The fee amounts FDA can collect must be specified in appropriation acts.
3. FDA must spend at least as much from appropriated funds (excluding user fees) for the review of medical device applications as it spent in FY 2009, multiplied by the adjustment factor.

MDUFA also contains a provision that FDA must spend at least as much on medical device inspections as it spent in FY 2002, increased by 5 percent 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.

FDA met the three legal conditions in FY 2016, and this report explains how these legal conditions were satisfied. FDA also fulfilled the provision regarding spending on medical device inspections, which enables FDA to continue with the third-party accreditation program. The statements and tables in the report provide data on FY 2016 medical device user fee collections, obligations, and carryover balances, as well as comparative data from prior years.

In FY 2016, FDA had net collections of \$150.1 million in medical device user fees, spent \$139.6 million in user fees for the review process, and carried a user fee balance of \$103.2 million forward for future fiscal years. Of the total carryover balance there are existing claims on roughly \$72.2 million, leaving \$30.9 million available for allocation.

In FY 2016, MDUFA user fees and non-user fee appropriations supported 1,616 full-time equivalents, including salary and operational expenses to support the staff responsible for the process for the review of device applications. Detailed program accomplishments can be found in the FY 2016 MDUFA Performance Report.

In FY 2017, FDA will spend user fees to continue enhancing the medical device review process, focusing on improving the efficiency, quality, and predictability of the MDUFA program. The promotion of a culture of quality and organizational excellence is among FDA's FY 2017 priorities for the program.