EXECUTIVE SUMMARY

The Prescription Drug User Fee Act of 1992 (PDUFA), as amended, requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of its implementation. This report covers fiscal year (FY) 2016.

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

1. FDA's overall Salaries and Expenses Appropriation, excluding fees, must equal or exceed FDA's overall FY 1997 Salaries and Expenses Appropriation, excluding fees and adjusted for inflation.

2. The fee amounts FDA may collect must be provided in appropriation acts.

3. FDA must spend at least as much from appropriated funds for the review of human drug applications as it spent in FY 1997, adjusted for inflation.

FDA met the three legal conditions in FY 2016, and this report explains how these legal conditions were satisfied. The statements and tables in the report provide data on prescription drug user fee collections, expenditures, and carryover balances, as well as comparative data from prior years.

In FY 2016, FDA had net collections of $883.7 million in prescription drug user fees, spent $836.9 million in user fees for the human drug review process, and carried a cumulative balance of $409.8 million forward for future fiscal years.

PDUFA user fees and non-user fee appropriations in FY 2016 supported 4,125 full-time equivalents, including salaries and operational expenses, to support the review of human drug applications. Detailed program accomplishments can be found in the FY 2016 PDUFA Performance Report.