EXECUTIVE SUMMARY

The Animal Drug User Fee Act of 2003 (ADUFA), as amended, requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of its implementation of ADUFA. This report covers activities for fiscal year (FY) 2016.

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

1. FDA's overall Salaries and Expenses Appropriation, excluding fees, must meet or exceed FDA's overall FY 2003 Salaries and Expenses Appropriation, excluding fees and multiplied by the adjustment factor.

2. The fee amounts FDA can collect must be provided in appropriations acts.

3. FDA must spend at least as much from appropriations for the review of animal drug applications as it spent in FY 2003, multiplied by the adjustment factor.

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 FY 2016 animal drug user fee collections, expenditures, and carryover balance, as well as comparative data from earlier periods. In FY 2016, FDA had net collections of $25.1 million in animal drug user fees, spent $23.0 million in user fees for the animal drug review process, and carried a cash balance of $23.1 million forward for future fiscal years.

In FY 2016, ADUFA user fees and non-user fee appropriations supported 319 full-time equivalents, including salaries and operational expenses to support the process for the review of animal drug applications. Detailed program accomplishments can be found in the FY 2016 ADUFA Performance Report.

In FY 2017, FDA will spend user fees to continue enhancing the new animal drug review process, focusing on improving the efficiency, quality, and predictability of the program. Some challenges FDA faces in FY 2017 include implementing the two-phased Chemistry, Manufacturing, and Controls technical and review process; enhancing the exchange of scientific information earlier in the development process; and increasing the flexibility for sponsors to submit scientific data or information concurrent with study protocol review.