EXECUTIVE SUMMARY

The Animal Generic Drug User Fee Act of 2008 (AGDUFA), as amended, requires the Food and Drug Administration (FDA or the Agency) to report annually to Congress on the financial aspects of its implementation of AGDUFA. This report covers activities for fiscal year (FY) 2016.

AGDUFA, as amended, specifies that the following three legal conditions must be satisfied each fiscal year in order for FDA to collect and spend AGDUFA 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 appropriation acts.

3. FDA must spend at least as much from appropriations for the review of generic new animal drug applications as it spent in FY 2008, 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 generic new animal drug user fee collections, expenditures, and carryover balances, as well as comparative data from earlier periods.

In FY 2016, FDA had net collections of $8.85 million in generic new animal drug user fees, spent $8.91 million in user fees for the generic new animal drug review process, and carried a cash balance of $11.84 million forward for future fiscal years.

In FY 2016, AGDUFA user fees and non-user fee appropriations supported 71 full-time equivalents, including salaries and operational expenses to support the process for the review of generic new animal drug applications. Detailed program accomplishments can be found in the FY 2016 AGDUFA Performance Report.

In FY 2017, FDA will spend user fees to continue enhancing the generic new animal drug review process, focusing on improving the efficiency, quality, and predictability of the program. Some challenges FDA faces in 2017 include implementing a two-phased Chemistry, Manufacturing and Controls technical and review process; creating a question-based review process for bioequivalence studies; increasing communication and transparency with industry through timely meetings; and responding to an increase in submissions while continuing to meet the performance goals.