EXECUTIVE SUMMARY

The Biosimilar User Fee Act of 2012 (BsUFA) requires the Food and Drug Administration (FDA or the Agency) to report annually to Congress on the financial aspects of its implementation. This report covers fiscal year (FY) 2016 and is the fourth annual financial report submitted to Congress since the inception of BsUFA.

BsUFA specifies that the following two legal conditions must be satisfied each year for FDA to collect and spend biosimilar biological product user fees:

1. The fee amounts FDA may collect for each fiscal year must be specified in that year's appropriation acts.

2. FDA must allocate a minimum of $20,000,000 in non-user fee appropriations, multiplied by the adjustment factor applicable to that fiscal year, for the process for the review of biosimilar biological product applications.

FDA met the two legal conditions in FY 2016, and this report explains how they were satisfied. The statements and tables in the report also provide data on biosimilar biological product user fee collections, expenditures, and carryover balances.

In FY 2016, FDA had net collections of $26.9 million in BsUFA fees, spent $13.2 million in user fees for the BsUFA program, and carried a balance of $52.6 million forward to support the BsUFA program in future fiscal years. In FY 2016, FDA supported the BsUFA program with both BsUFA fees (29 percent) and non-user fee appropriations (71 percent).

BsUFA fees and non-user fee appropriations in FY 2016 supported 174 full-time equivalents, including salaries and operational expenses to support the staff responsible for the BsUFA program. Detailed program accomplishments can be found in the FY 2016 BsUFA Performance Report.