EXECUTIVE SUMMARY

The Generic Drug User Fee Amendments of 2012 (GDUFA) require the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of its implementation. Required under GDUFA, this report covers activities for fiscal year (FY) 2016. This is the fourth GDUFA Financial Report.

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

1. FDA's total appropriations for salaries and expenses (excluding user fees) must be equal to, or greater than, FDA's FY 2009 appropriations for salaries and expenses (excluding user fees) multiplied by the adjustment factor.

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

3. FDA must allocate a minimum of $97,000,000 of appropriations (excluding user fees) multiplied by the adjustment factor, and these funds shall be available to defray the costs of human generic drug activities.

As it has in each year since the enactment of GDUFA, FDA met these three legal conditions in FY 2016, and this report explains how these legal conditions were satisfied. The statements and tables in the report also provide data on FY 2016 human generic drug user fee collections, expenditures, and carryover balances.

In FY 2016, FDA had net collections of $315.3 million in human generic drug user fees, spent $373.2 million of fee revenue on human generic drug activities, and carried a balance of $173.7 million forward for human generic drug activities in future fiscal years.

GDUFA fees and non-user fee appropriations in FY 2016 supported 1,765 full-time equivalents, including salaries and operational expenses to support human generic drug activities. Detailed program accomplishments can be found in the FY 2016 GDUFA Performance Report.

Pursuant to GDUFA's design, FDA has restructured the human generic drug program. The restructuring has prepared FDA to meet, starting in FY 2015, goal dates agreed upon in the GDUFA Commitment Letter.[1] The restructuring included the hiring and training of new staff, reorganizing the Office of Generic Drugs, establishing a new Office of Pharmaceutical Quality, replacing fragmented information technology systems with a new integrated system, and enhancing review and business processes.

Directly related to FDA's restructuring effort, in FY 2016 FDA met its backlog goal over a year ahead of the commitment and approved a human generic drug program record of 835 abbreviated new drug applications.[2] In FY 2017, FDA will spend user fees to continue modernizing the human generic drug program, as agreed to in the GDUFA Commitment Letter, by continuing to focus efforts on improving the efficiency, quality, and predictability of human generic drug activities. These efforts are more important than ever as FDA prepares to meet its primary challenge to review original applications within the shortest GDUFA goal dates, which will shrink from 15 months to 10 months in FY 2017.

[1] http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf
[2] This number represents tentative and final approvals.