1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Act (ADUFA), authorizes the Food and Drug Administration (FDA or the Agency) to collect fees from the animal pharmaceutical industry to supplement non-user fee appropriations spent on FDA's animal drug review process. FDA spends fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of animal drug applications to help ensure that safe and effective animal drug products reach the American public.

The Animal Drug User Fee Amendments of 2008 (Public Law 110-316) extended the program's authorization for an additional 5 years through FY 2013 (ADUFA II). On June 13, 2013, the program was reauthorized for an additional 5 years from FY 2014 through FY 2018 (ADUFA III).

Under ADUFA III, four types of user fees are established: (1) fees for certain types of animal drug applications and supplemental animal drug applications (for which safety or effectiveness data are required) (20 percent of estimated revenue); (2) annual fees for certain animal drug products (27 percent of estimated revenue); (3) annual fees for certain establishments where such products are made (26 percent of estimated revenue); and (4) annual fees for certain animal drug sponsors of animal drug applications and/or investigational animal drug submissions (27 percent of estimated revenue).

The total annual fee revenue amounts are set in the statute for ADUFA, with provisions for adjustment over time. ADUFA III authorizes FDA to set fees each fiscal year so that the total revenue FDA plans to receive in each category is estimated to equal the statutory amount, after adjustments are made for workload, if applicable, and inflation after FY 2014. The workload adjustment cannot result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year as specified in the statute.

In August 2015, FDA set fees for FY 2016 in accordance with the amounts specified in ADUFA III (see 80 FR 45993, August 3, 2015). Fee revenues are adjusted each year after FY 2014 to reflect changes in inflation and review workload, if applicable. In FY 2016, the fee revenues were adjusted by 2.1121 percent to account for inflation. A workload adjustment of 1.4066 was applied in FY 2016.

ADUFA III requires FDA to submit a financial report to Congress within 120 days after the end of each fiscal year. This financial report addresses the implementation and use of animal drug user fees by FDA during the period October 1, 2015, through September 30, 2016. The report discusses how the Agency met the legal conditions that must be satisfied for FDA to collect and spend animal drug user fees each year and shows how FDA determined that it met those requirements. This report also presents statements related to FY 2016 fee collections, cash carryover balances, obligations of user fees, and the total costs of the process for the review of animal drug applications paid from user fees and non-user fee appropriations.