1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Act (AGDUFA), 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 generic new animal drug review process. FDA spends fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of generic new animal drug applications to help ensure that safe and effective generic new animal drug products reach the American public.

AGDUFA (Title II, Public Law 110-316) was enacted on August 14, 2008, and authorized the animal generic drug user fee program for 5 years from FY 2009 through FY 2013 (AGDUFA I). On June 13, 2013, the program was reauthorized for an additional 5 years from FY 2014 through FY 2018 by the Animal Generic Drug User Fee Amendments of 2013 (AGDUFA II, Title II, Public Law 113-14).

Under AGDUFA II, three types of user fees are established: (1) fees for certain types of abbreviated applications for generic new animal drugs (25 percent of estimated revenue); (2) annual fees for certain generic new animal drug products (37.5 percent of estimated revenue); and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (37.5 percent of estimated revenue). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication.

The total annual fee revenue amount and amounts for each type of fee are set forth in the statute for AGDUFA, with provisions for workload adjustment. AGDUFA II authorizes FDA to set fees for 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 to reflect changes in review workload, if applicable. However, 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 AGDUFA II (see 80 FR 46012). FDA used the statutory revenue amounts for each category of fees in determining its fee revenue target for FY 2016. Fee revenues are adjusted each year after FY 2014 to reflect changes in review workload, if applicable. In FY 2016, the fee revenues were adjusted by 30.6305 percent to account for increased workload. Additional adjustments to the statutory fee revenue amounts for FY 2016 for inflation were not necessary because inflation adjustments were built into the statutory fee revenue totals for each of the 5 years of AGDUFA II.

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