

BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Act (AGDUFA), authorizes FDA to collect fees from the animal pharmaceutical industry to augment appropriations spent on FDA's generic new animal drug review process. FDA spends fee revenues and appropriations to hire, support, and maintain personnel for the review of generic new animal drug applications to ensure safe and effective generic new animal drug products reach the American public more quickly.

The Animal Generic Drug User Fee Act of 2008 (Public Law 110-316) was authorized for five years, through FY 2013; AGDUFA was patterned in part after the Animal Drug User Fee Act (ADUFA).

Under AGDUFA, three types of user fees are established: (1) a fee for each abbreviated application for a generic new animal drug at the time the application is submitted (30 percent of estimated revenue); (2) an annual fee for each marketed generic new animal drug product (35 percent of estimated revenue); and (3) an annual fees for each sponsor of a generic new animal drug application and/or investigational submission for a generic new animal drug (35 percent of estimated revenue).

The aggregate fee revenue amount, and amounts for each type of fee, are set forth in statute, with provisions for adjustment. AGDUFA 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 the workload. 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 2011, FDA set fees for FY 2012 in accordance with the amounts specified in AGDUFA (see 76 FR 45814). FDA used the statutory revenue amounts for each category of fees in determining its fee revenue target for FY 2012 because applying the workload adjustment factor for FY 2012 as calculated by FDA would have resulted in fee revenues lower than the statutory amount. Additional adjustments to the statutory fee revenue amounts for inflation were not necessary because inflation adjustments were built into the statutory fee revenue totals for each of the five years of AGDUFA.

AGDUFA requires FDA to submit two reports to Congress each fiscal year: (1) a performance report to be submitted within 60 days after the end of the fiscal year; and (2) a financial report to be submitted within 120 days after the end of the fiscal year.

The FY 2012 AGDUFA Performance Report, which describes FDA's progress in meeting the goals referred to in AGDUFA, is being transmitted separately to Congress. This report is the FY 2012 AGDUFA Financial Report and addresses the implementation and use of generic new animal drug user fees by FDA during the period of October 1, 2011 through September 30, 2012.

As required by AGDUFA, this report discusses the legal conditions that must be satisfied for FDA to collect and spend generic new animal drug user fees each year. In addition, this report presents statements of FY 2012 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 appropriations.