1: BACKGROUND

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

PDUFA was reauthorized in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), and 2012 (PDUFA V) with the support of the pharmaceutical industry, public stakeholders, and the Administration.

Over time, PDUFA has been a tremendous success, creating a predictable, streamlined review process and dramatically reducing the average time to new drug approval. Today, almost 60 percent of new active substances approved in the world market are launched first in the United States. That is more than triple the rate approved first in the United States in the first year of PDUFA (1993). Success has been achieved, in large part, through earlier and enhanced communications between FDA and industry made possible by increased FDA resources funded through PDUFA user fees.

Since its creation, PDUFA has relied on the same user fee structure. Under PDUFA, application fees, establishment fees, and product fees are set to each contribute one-third of the total revenue amount in a fiscal year, though actual collections may vary from this formula. An application fee is collected when certain new drug applications (NDAs) or biologics license applications (BLAs) and supplements are submitted. Product fees are assessed for marketed products with certain exceptions. An establishment fee is assessed for each establishment listed in an approved human drug application as an establishment that manufacturers the prescription drug named in the application in final dosage form, and, if an establishment is listed in a human drug application by more than one applicant, the establishment fee is apportioned among all applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees. Product and establishment fees are due annually. The base fee revenue amount is set in the statute for PDUFA V, and it is then adjusted for annual changes in inflation and human drug review workload.

PDUFA requires FDA to submit a financial report to Congress no later than 120 days after the end of each fiscal year. This financial report addresses the implementation and use of prescription drug user fees by FDA during the period of October 1, 2015, through September 30, 2016. This report presents the legal conditions that FDA must satisfy to collect and spend prescription drug user fees each year and shows how FDA determined that it met those requirements. In addition, this report presents summary statements of FY 2016 fee collections, carryover balances, obligations of user fees, and total costs of the process for the review of human drug applications from both PDUFA fees and non-user fee appropriations.