

1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Drug User Fee Amendments (GDUFA), authorizes the Food and Drug Administration (FDA or the Agency) to collect user fees from the human generic drug industry to supplement non-user fee appropriations spent on FDA's human generic drug activities. FDA spends user fee revenues and non-user fee appropriations to hire, support, and maintain resources allocated for the GDUFA program to ensure that safe and effective human generic drug products reach the American public more quickly.

GDUFA (Public Law 112-144, Title III) was authorized for 5 years, through FY 2017. It established fees for: (1) abbreviated new drug applications (ANDAs) in the backlog as of October 1, 2012 (assessed in FY 2013 only); (2) certain types of ANDAs and prior approval supplements (PASs) for human generic drug products; (3) generic drug finished dosage form (FDF) and active pharmaceutical ingredient (API) facilities; and (4) drug master files (DMFs) for APIs associated with human generic drug products (section 744B(a) of the FD&C Act).

GDUFA 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 human generic drug user fees by FDA for October 1, 2015, through September 30, 2016. This report discusses the legal conditions that must be satisfied for FDA to collect and spend human generic drug user fees each year. In addition, this report presents statements of FY 2016 fee collections, carryover balances, obligations, and the total costs of the GDUFA program paid from both user fees and non-user fee appropriations.