1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments (MDUFA) (Title II of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144), authorizes the Food and Drug Administration (FDA or the Agency) to collect fees from the medical device industry to augment non-user fee appropriations spent on FDA's medical device review process. As amended, MDUFA authorization was extended for an additional 5 years, through fiscal year (FY) 2017. This reauthorization is referred to as "MDUFA III." FDA spends fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of medical device applications to ensure that safe and effective devices reach the American public more quickly.

Under MDUFA III, companies must pay application fees when submitting certain device applications to FDA. Fee-paying applications include premarket approval (PMA) applications; product development protocols (PDPs); premarket reports (PMRs); modular PMAs; biologics license applications (BLAs); certain supplements to all of these applications; premarket notification submissions (510(k)s); 30-day notices of changes to manufacturing procedures or methods of manufacture affecting device safety and effectiveness; and requests for classification information under section 513(g) of the FD&C Act. In addition, under MDUFA III, firms must pay an annual fee for each "establishment subject to a registration fee" and a fee for periodic reports regarding class III devices. The base fees for a PMA or BLA and for device establishment registration are specified in the statute for each year through FY 2017. Fees for other application types and for periodic reports are fixed by statute as a percentage of the PMA fee for each year.

MDUFA requires FDA to submit a financial report to Congress within 120 days of the end of each fiscal year. This financial report addresses the implementation and use of medical device 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 annually for FDA to collect and spend medical device user fees. It also presents information on the spending level for medical device inspections that must be satisfied for FDA to continue the third-party accreditation program. In addition, this report presents statements of FY 2016 user fee collections, carryover balances, obligations, and total costs of the process for the review of device applications from both fees and non-user fee appropriations.