EXECUTIVE SUMMARY

In November 2013, President Obama signed into law the Drug Quality and Security Act (DQSA), Public Law 113-54, which contains important provisions related to oversight of human drug compounding activities. Title I of the DQSA, the Compounding Quality Act (CQA), authorizes the Food and Drug Administration (FDA) to assess and collect fees from human drug compounders that register with FDA as outsourcing facilities.

The CQA requires FDA to submit an annual report to Congress that includes: A description of fees assessed and collected for such year, a summary description of entities paying the fees, a description of the hiring and placement of new staff, a description of the use of fee resources to support inspecting outsourcing facilities, and the number of inspections and reinspections of such facilities performed each year. This report covers fiscal year (FY) 2015.

In this report, the time worked by one full-time person for one year is referred to as a full-time equivalent (FTE). In FY 2015, FDA spending to support oversight of outsourcing facilities totaled $14.4 million including Budget Authority (BA), outsourcing facility fees, and one-time no-year drug safety funds. These funds supported 61 FTEs across the Agency. Oversight of outsourcing facilities includes activities conducted by the Center for Drug Evaluation and Research (CDER), the Office of Regulatory Affairs (ORA), and the Office of the Commissioner. This does not include the Center for Veterinary Medicine (CVM) or Center for Biologics Evaluation and Research (CBER) as the CQA does not cover the compounding of animal drugs or biologics.

FDA collected $1.1 million in outsourcing facility fees during FY 2015. Outsourcing facility fees supported two FTEs in FY 2015, out of a total of 61 FTEs dedicated to oversight of outsourcing facilities. Of the $1.1 million collected, FDA spent $396,268 to support oversight of outsourcing facilities in FY 2015 and carried a balance of $663,958 forward to pay for the costs of oversight of outsourcing facilities in future fiscal years. Going forward, FDA intends to fully utilize these carryover funds as well as new fees collected to support oversight of outsourcing facilities. FDA also will continue to ensure the fees supplement and do not supplant BA for oversight of outsourcing facilities.

In FY 2016, FDA will continue to enhance oversight of outsourcing facilities, which includes promptly investigating reports of serious adverse events and product quality issues such as drug contamination, inspecting outsourcing facilities according to a risk-based schedule, and taking regulatory action, as appropriate when compounding activities violate the law. FDA will also continue to develop policy documents that will assist outsourcing facilities with complying with the law.