EXECUTIVE SUMMARY

In November 2013, the President 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), created a new category of compounders known as outsourcing facilities. A human drug compounder can elect to register with the Food and Drug Administration (FDA) as an outsourcing facility. Drug products compounded by or under the direct supervision of a licensed pharmacist in a registered outsourcing facility can qualify for exemptions from specific sections of the Federal Food, Drug, and Cosmetic Act if certain conditions are met. CQA authorizes FDA to assess and collect fees from human drug compounders that register with the Agency as outsourcing facilities. FDA spends fee revenues to hire, support, and maintain personnel for the oversight of these outsourcing facilities.

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) 2016.

In FY 2016, a total of 68 entities registered as outsourcing facilities. Four facilities that were initially registered as outsourcing facilities in FY 2016 withdrew their registration before the end of the fiscal year. On the last day of FY 2016, 64 facilities were registered.

In FY 2016, FDA spending to support oversight of outsourcing facilities totaled $12,986,407. This included budget authority, outsourcing facility fees, and one-time no-year drug safety funds. These funds supported 55 full-time equivalents (FTEs) across FDA. (In this report, the time worked by one full-time person for 1 year is referred to as an FTE). Outsourcing facility fees supported 7 FTEs in FY 2016 out of the total of 55 FTEs dedicated to oversight of outsourcing facilities. Oversight of outsourcing facilities includes activities conducted by the Center for Drug Evaluation and Research, the Office of Regulatory Affairs, and FDA Headquarters. This does not include the Center for Veterinary Medicine or the Center for Biologics Evaluation and Research as CQA does not cover the compounding of animal drugs or biologics.

FDA had net collections of $1,161,546 in outsourcing facility fees during FY 2016. In addition, FDA had a carryover balance of $663,958 from the prior fiscal year. Of the total amount of outsourcing facility fees available in FY 2016 ($1,825,504), FDA spent $1,482,911 to support oversight of outsourcing facilities in FY 2016 (11 percent of total spending for this purpose) and carried a balance of $342,593 forward to pay for the costs of oversight of outsourcing facilities in future fiscal years. Under CQA, fees collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA in future fiscal years. Going forward, FDA intends to 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 budget authority for oversight of outsourcing facilities.

In FY 2017, 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 and engage in outreach that will assist outsourcing

facilities in complying with the law. Further, FDA will continue to coordinate and collaborate with the states.