

LETTER FROM THE COMMISSIONER



I am pleased to present the FY 2018 Food and Drug Administration (FDA) Budget. FDA has broad responsibilities to protect and promote public health by ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of our nation's food supply, cosmetics, radiation-emitting products; and regulating tobacco products.

These responsibilities continue to expand as we work to fulfill the mandates of groundbreaking legislation passed in recent years, including the 21st Century Cures Act of 2016 (Cures Act). The Cures Act is designed to help advance medical product development and to bring today's remarkable innovations and advances to patients who need them faster and more efficiently.

FDA accomplishments span areas of food safety, medical product innovation, safety and oversight, nutrition, and tobacco regulation. In 2016, FDA:

- approved 22 novel drugs, more than 800 generics, 91 medical devices, and 11 original applications for biological products
- mobilized more than 500 staff members to rapidly respond to the Zika virus outbreak
- awarded nearly \$22 million to states to improve produce safety
- modernized the Nutrition Facts label to help consumers make informed choices
- improved the alignment of field activities to FDA-regulated products
- conducted more than 165,000 tobacco retailer inspections.

Mindful of the current budget environment, the FY 2018 Budget will allow FDA to continue to obtain the most public health protection and promotion for the federal dollar. FDA is requesting a total of \$5.1 billion; an increase of almost 10 percent above the FY 2017 annualized Continuing Resolution. The FY 2018 request includes:

- a total of \$60 million to implement the Cures Act
- recalibration of FDA medical product user fees to more than \$2.5 billion, an increase of \$1.2 billion over FY 2017, consistent with the America First Budget Blueprint.

The FY 2018 request also includes reductions in budget authority targeted to certain areas where better tools and policies will allow us to do more with less, while preserving core mission activities. These reductions will be coupled with policy efforts to improve the efficiency of the programs that see reductions, to make sure that we are improving our effectiveness and taking a risk-based approach to our consumer protection mission.

FDA is fully committed to protecting and advancing the public health, based on the latest science, by helping to make the process for developing safe and effective medical products more efficient and less costly; strengthening food safety for domestic and imported products; reducing the harms of tobacco; and improving agency efficiency by taking a risk-based approach to our core mission to protect consumers, so that we can get the most public health protection for the resources that are entrusted to us.

A handwritten signature in blue ink, appearing to read "Scott Gottlieb, M.D.". The signature is fluid and cursive, written over a white background.

Scott Gottlieb, M.D., Commissioner of Food and Drugs