

Food and Drug Administration FY 2017 Operating Plan Narrative

Overview: The FY 2017 fiscal year bill provides a total program level of \$4.8 billion. This amount includes a total user fee level of \$2.0 billion, a decrease of \$63 million attributable to offsets to PDUFA and MDUFA user fee collections in the last year for these programs.

Budget Authority: The bill provides \$2.8 billion in budget authority. This is an increase of \$51.6 million over FY 2016, of which \$48.6 million is for Salaries and Expenses, including \$10.0 million for emerging health threats, and \$3.0 million is for Buildings & Facilities. The FY 2017 Enacted includes resources to increase Food Safety and Medical Product Safety by \$49.6 million. The FY 2017 budget level also includes \$13.5 million in reductions:

- -\$5.0 million from WO Consolidation
- -\$1.5 million from OR&RR
- -\$0.5 million FDA Headquarters
- -\$6.5 million from GSA Rent. ¹

The Operating Plan also reflects resources previously appropriated in the FY 2017 Continuing Resolution to support 21st Century Cures Activities, bringing the total increase in FY 2017 above FY 2016 to \$71.6 million.

User Fees: Congress did not authorize new user fees, such as the Food Import fee or Food Facility Registration and Inspection fee. The bill allows FDA to collect fees for the Medical Countermeasure Priority Review Voucher program. FDA continues to develop estimates for fee collection.

Key Initiatives:

Food Safety – an increase of \$38.7 million for Food Safety compared to FY 2016

- \$18.8 million for National Integrated Food Safety System
- \$16.9 million for Import Safety
- \$3.0 million for Crop Biotechnology and Biotech Ingredients

For Crop Biotechnology and Biotech Ingredients, FDA will carry out the required activities using the \$3.0 million increase provided to CFSAN as part of the FY 2017 appropriation.

Medical Product Safety – an increase of \$10.9 million for Medical Product Safety compared to FY 2016

- \$4.4 million for Animal Drug and Medical Device Review
- \$2.5 million for Precision Medicine
- \$3.0 million for Pediatric Device Consortia Grant
- \$1.0 million for Medical Device Postmarket Safety

¹ The Omnibus provides \$170 million in budget authority for GSA Rent. This reflects a reduction of \$6.5 million relative to FY 2016 Enacted level of \$177 million

Foreign High Risk Inspections – an increase \$2.5 million for Foreign High Risk Inspections for a total of \$7.5 million in FY 2017.

Buildings and Facilities

The bill also includes an increase of \$3.0 million for Buildings and Facilities, bringing the total for that account to \$11.8 million.

Emerging Health Threats

The bill provides \$10.0 million for FDA to prevent, prepare for, and respond to emerging health threats, including the Ebola and Zika viruses, domestically and internationally and to develop necessary medical countermeasures and vaccines.

Transfers: The bill directs FDA to transfer \$1.5 million from FDA Headquarters to HHS' Office of Inspector General to support oversight of FDA's expanded authorities. The Operating Plan also reflects the reorganization of the Oncology Center of Excellence, including \$3.6 million transferred from CDER to FDA HQ.