

Food and Drug Administration FY 2018 Operating Plan Narrative

Overview: The FY 2018 fiscal year bill provides a total program level of \$5.4 billion. The FY 2018 total funding includes \$3.0 billion in budget authority and \$2.4 billion in user fees.

Budget Authority: The bill provides \$3.0 billion in budget authority. This is an increase of \$164.7 million over FY 2017, which includes increases of \$12.3 million for Food Safety, and \$152.4 million for Medical Product Safety, including an increase of \$40.0 million in no-year funding for the 21st Century Cures Innovation Account, and \$94.0 million in one-time funding to process opioids and other imports through International Mail Facilities (IMFs).

User Fees: The bill provides \$2.4 billion in user fees, including medical product user fee funding levels consistent with the FDA Reauthorization Act (FDARA).

Key Initiatives:

Food Safety – an increase of \$12.3 million for Food Safety compared to FY 2017

- +\$0.5 million for botanical dietary supplements research
- +\$2.8 million for fish decomposition study
- -\$1.5 million for consumer education and outreach regarding biotechnology (was \$3.0 million in FY 2017)
- +\$10.5 million for FSMA Cooperative Agreements supporting produce safety

Medical Product Safety – an increase of \$152.4 million for Medical Product Safety compared to FY 2017

- +\$0.5 million for botanical drug and interaction research
- +\$0.4 million to support the Critical Path Initiative
- +\$2.5 million to help facilitate 503B Bulks compounding work (one-time, annual funding)
- +\$0.3 million to help expedite the clearance at ports and distribution hubs of medical products
- +\$9.7 million for animal drugs and feeds program to manage increased workloads
- +\$15.0 million for the Oncology Center of Excellence
- +\$94.0 million in one-time funding for processing opioids and other articles imported or offered for import through IMFs to remain available until expended.
- +\$40.0 million increase for 21st Century Cures in no-year funding for a total of \$60.0 million.
- -\$10.0 million for Emerging Health Threats

Required Transfer: The bill directs FDA to transfer \$1.5 million from FDA Headquarters (HQ) to HHS' Office of Inspector General to support oversight of FDA's expanded authorities.

Reprogrammings: The Operating Plan also reflects the Office of Food Veterinary Medicine reorganization that is reflected in CFSAN's funding level and within the FDA HQ. The

operating plan reflect the realloaction of \$3.9 million from FDA HQ Office of Foods and Veterinary Medicine (OFVM) to FDA HQ Office of the Commissioner (OC) , consistent with the reorganization package submitted to the Hill in December. As a technical change, the operating plan also reprograms \$500,000 from Foods field activities to the Center for Food Safety and Applied Nutrition. This will allow FDA to maintain the FY 2017 level for Center and Food Field base activities while also supporting the specific increases included in the FY 2018 Omnibus.

NOTE: The Operating Plan does not include \$7.6 million in one-time, no year funding for Hurricane related facilities and related costs included in the Further Additional Supplemental Appropriations for Disaster Relief and Requirement Act, 2018.