

Food and Drug Administration FY 2020 Operating Plan Narrative

Overview: The FY 2020 fiscal year bill provides a total program level of \$5.9 billion. This is an increase of \$216 million.

Budget Authority: The bill provides \$3.3 billion in budget authority. This is an increase of \$116.0 million over FY 2019, of which \$83,900,000 is for medical product and food safety activities, including an increase of \$5.0 million in no-year funding for the 21st Century Cures Innovation Account. The increase also provides \$32,100,000 for critical infrastructure improvements, including \$20.0 million for Building and Facilities for necessary expenses of plans, construction, repair, improvement, extension, alteration, demolition and purchase of fixed equipment or facilities of or used by FDA for seafood safety.

User Fees: The bill provides \$2.7 billion for user fees.

Key Increases:

Food Safety – increases of \$31.5 million for Food Safety activities below compared to FY 2019

- +\$0.5 million for National Antimicrobial Resistance Monitoring System-Seafood
- +\$7.0 million for Advancing FSMA
- +\$8.0 million for Strengthening Response Capabilities for Foodborne Outbreaks
- +\$5.0 million for Promoting Innovation and Emerging Technology While Maintaining Product Safety, of which \$500,000 is to address pentobarbital in pet food
- +\$2.0 million for Cannabidiol Activities
- +\$3.0 million for Dietary Supplements
- +\$5.0 million for Imported Seafood Safety Pilot (Machine Learning)
- +\$1.0 million for Standards of Identity

Medical Product Safety – increases of \$53.9 million for Medical Product Safety activities compared to FY 2019

- +\$2.0 million for MedTech Manufacturing
- +\$4.0 million to Transform Medical Device Safety, Cybersecurity, Review, and Innovation
- +\$1.0 million for Pediatric Device Consortia
- +\$1.9 million for Modernizing Generic Drug Development and Review
- +\$5.0 million for Oncology Center of Excellence - Rare Cancers
- +\$8.0 million for Opioids-International Mail Facilities
- +\$7.0 million for Medical Countermeasures Initiatives
- +\$10.0 million for Integrated Pathogen Reduction of the Blood Supply
- +\$1.0 million for Office of Laboratory Science and Safety
- +\$9.0 million for Compounding
- +\$5.0 million for 21st Century Cures

Required Transfer: 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.