

Food and Drug Administration FY 2022 Operating Plan Narrative

Overview: The FY 2022 fiscal year bill provides a total program level of \$6.3 billion. This is an increase of \$200.7 million.

Budget Authority: The bill provides \$3.4 billion in budget authority. This is a net increase of \$81.2 million over FY 2021. Within the total program level, there is a \$102.2 million increase for medical product, food safety, and crosscutting activities as well as a decrease of \$20.0 million in no-year funding for the 21st Century Cures Innovation Account and a decrease of \$1.0 million¹ from the one-time increase for Seafood Safety Studies (GP Sec. 765) in FY 2021.

User Fees: The bill provides \$2.9 billion for user fees.

Key Increases:

Infrastructure – increase of \$2.4 million for FDA Infrastructure below compared to FY 2021:

- +\$0.8 million for FDA White Oak Complex
- +\$2.5 million for Other Rent and Rent Related
- -\$0.8 million decrease for GSA Rental Payments

Crosscutting – increases of \$41.3 million for Crosscutting activities below compared to FY 2021:

- +\$3.0 million for Data Modernization Enterprise-Wide Technology and Data
- +\$10.0 million for Inspections
- +\$17.9 million for Pay Costs
- +\$4.7 million for the Office of Minority Health and Health Equity
- +\$1.5 million for Laboratory Safety
- +\$2.2 million for Office of the Chief Counsel
- +\$2.0 million for Essential Services

Food Safety – increases of \$29.5 million for Food Safety activities below compared to FY 2021

- +\$9.0 million for New Era of Smarter Food Safety
- +\$11.0 million for Maternal and Infant Health and Nutrition
- +\$7.0 million for Emerging Chemical and Toxicological Issues
- +\$1.5 million for Standards of Identity
- +\$1.0 million for Animal Feed Ingredient Reviews

Medical Product Safety – increases of \$29.0 million for Medical Product Safety activities compared to FY 2021

- +\$5.0 million for Shortages & Supply Chain
- +\$1.5 million for Animal Medical Product Supply Chain
- +\$8.0 million for Advancing the Goal of Ending the Opioid Crisis
- +\$3.0 million for Predictive Toxicology Roadmap
- +\$1.0 million for Data Modernization Medical Product Safety
- +\$2.5 million for Orphan Product Grants
- +\$1.0 million for Rare Cancer
- +\$5.0 million for Foreign Inspection Pilot

¹ Included in General Provisions Section 765; the total not included in Title VI of Division A of the PL 113-260.

- +\$1.5 million for Rare Diseases
- +\$0.5 million for BioFilm Regulatory Research

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.