

## **Food and Drug Administration FY 2021 Operating Plan Narrative**

**Overview:** The FY 2021 fiscal year bill provides a total program level of \$6.0 billion. This is an increase of \$110 million.

**Budget Authority:** The bill provides \$3.3 billion in budget authority. This is a net increase of \$19.3 million over FY 2020. Within the total program level, there is a \$43.3 million increase for medical product, food safety, and crosscutting activities (including \$1.0 million for B&F) and an one-time \$1.0 million<sup>1</sup> increase for Seafood Safety Studies (GP Sec. 765) as well as a decrease of \$5.0 million in no-year funding for the 21st Century Cures Innovation Account and a decrease of \$20.0 million from the one-time increase for B&F in FY 2020.

**User Fees:** The bill provides \$2.8 billion for user fees.

### **Key Increases:**

**Crosscutting** – increases of \$8.0 million for Crosscutting activities below compared to FY 2020

- +\$7.0 million for Artificial Intelligence and Other Emerging Technologies
- +\$1.0 million for the Office of Chief Counsel support

**Food Safety** – increases of \$11.3 million for Food Safety activities below compared to FY 2020

- +\$5.0 million for Cannabis and Cannabis Derivatives Activities
- +\$1.0 million for Strengthening Response Capabilities for Foodborne Outbreaks
- +\$6.0 million for Seafood Pilot
- -\$3.0 million for Imported Seafood Safety Pilot (Machine Learning)<sup>2</sup>
- +\$1.25 million for Allergens
- +\$1.0 million for Cosmetics

**Medical Product Safety** – increases of \$18.0 million for Medical Product Safety activities compared to FY 2020

- +\$9.0 million to Transform Medical Device Safety, Cybersecurity, Review, and Innovation
- +\$5.0 million for Modernizing Influenza Vaccines
- +\$2.0 million for Compounding
- +\$2.5 million for Oncology Center of Excellence - Rare Cancers
- +\$1.0 million for FDA's 5-year plan for Antimicrobial Stewardship
- +\$3.5 million for Foreign Inspection Pilot
- -\$5.0 million for 21<sup>st</sup> 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.

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

<sup>2</sup> The total reduction for the one-time FY 2020 appropriation for Imported Seafood Safety Pilot (Machine Learning) is \$5.0 million, per the Joint Explanatory Statement.