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 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) ²
- +$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 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.

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¹ Included in General Provisions Section 765; the total not included in Title VI of Division A of the PL 113-260.
² 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.