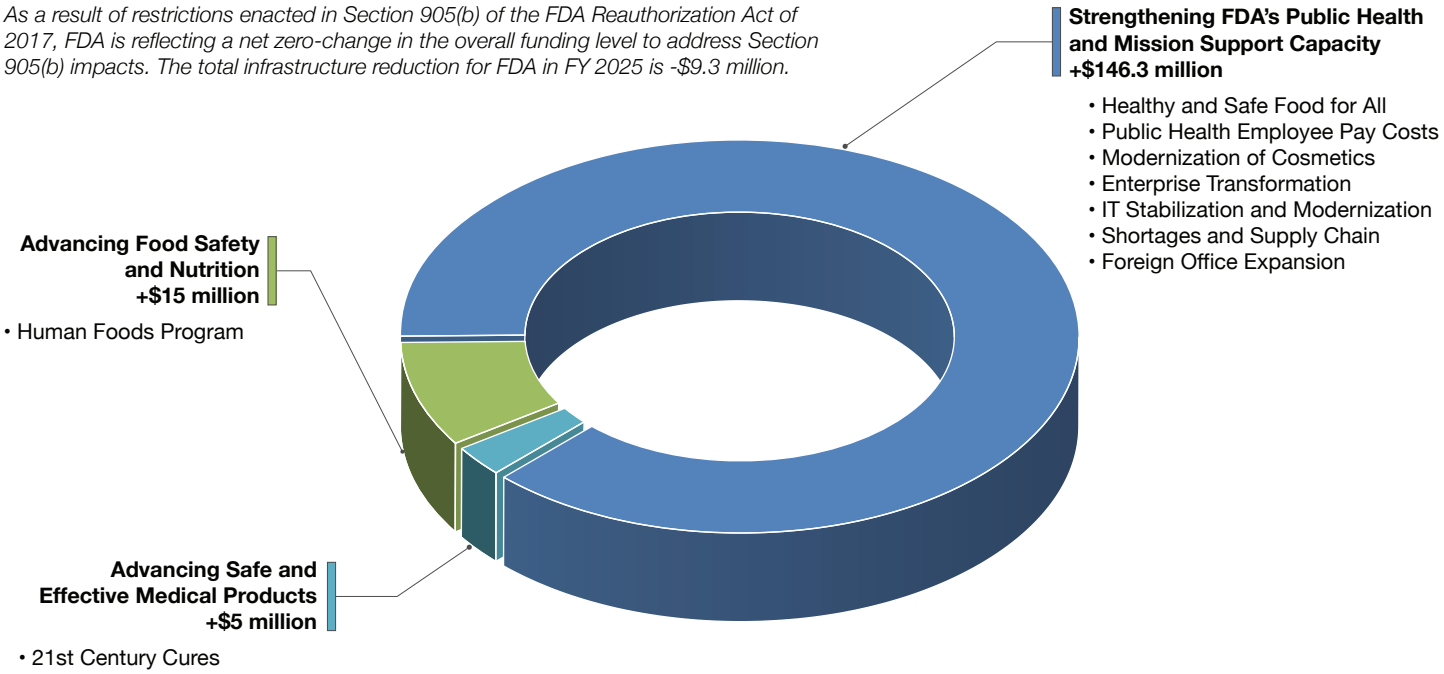
FY 2025 FDA Budget Summary

The FY 2025 Budget provides a $7.2 billion total program funding level for the U.S. Food and Drug Administration. This includes an overall increase of 7.4 percent or $495 million over the FY 2023 funding level. The increase includes $157 million in budget authority to enhance food safety and nutrition, advance medical product safety, strengthen the Agency's public health and mission support capacity, and modernize FDA's infrastructure, buildings, and facilities. The Budget includes $3.5 billion in user fees. FDA's request for new activities reflects the Agency's top priorities in key areas of importance for human and animal health.

FDA FY 2025 Budget Authority Increases

As a result of restrictions enacted in Section 905(b) of the FDA Reauthorization Act of 2017, FDA is reflecting a net zero-change in the overall funding level to address Section 905(b) impacts. The total infrastructure reduction for FDA in FY 2025 is -$9.3 million.



Public Health Employee Pay Costs

The Budget includes an increase of $114.8 million to address approximately 72 percent of FDA's estimated inflationary pay costs associated with the FY 2024 and FY 2025 Cost-of-Living Adjustments. This funding helps FDA minimize reductions to hiring capabilities and reduce the need to redirect resources away from critical public health initiatives and activities.

Modernization of Cosmetics Implementation

The Agency requires additional funding to support the implementation of the Modernization of Cosmetics Regulation Act (MoCRA). FDA will use the $8 million increase to continue developing a modernized cosmetics regulatory program to enhance the Agency's efforts to protect consumers from unsafe cosmetics. Funds will be used for activities such as developing regulations, managing submission platforms associated with MoCRA provision compliance, and hiring additional experts to manage critical products such as the assessments of the use of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetic products.

Enterprise Transformation

FDA proposes targeted investments to improve the efficiency of its operations. The $2 million increase will support modernization activities by centralizing planning, implementation, and governance of highpriority business process improvement efforts. These include the continuation of the critical inspection's platform implementation and expansion effort to implement common business processes and data optimization across the Agency. The Budget also proposes new two-year spending authority to support these critical investments.

Human Foods Program

The Budget provides a $15 million increase to strengthen and modernize FDA's capacity to protect and promote a safe, nutritious U.S. food supply. Funds will be used to prevent or mitigate foodborne illness outbreaks by investing to strengthen necessary tools and processes within root-cause investigations and by ensuring compliance with the requirements outlined in the Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule). The Budget also supports FDA with its enormous public health burden of diet-related chronic diseases and supports the continued action of the President's National Strategy for Hunger, Nutrition, and Health.

IT Stabilization and Modernization

The Budget provides an $8.3 million increase to continue building FDA's centralized enterprise data modernization capabilities and strengthen its common data infrastructure; data exchange; and IT analytic services, talent, and tools. The Budget also proposes new two-year spending authority to support these critical investments.

Shortages and Supply Chain

Through this Agency-wide crosscutting initiative, FDA will advance its capabilities to help prepare for, build resilience to, and respond to shortages through improved analytics and regulatory approaches. FDA will use the $12.3 million increase to, amongst other initiatives, hire additional investigators to fulfill inspectional needs associated with increased supply chain disruptions and consequent human food and medical product shortages in recent years. The Agency will also continue engaging in efforts to promote manufacturing quality across the pharmaceutical industry and develop and implement modernized systems to respond to shortages faster.

Foreign Office Expansion

This $1 million investment will strengthen FDA's oversight of imported products by expanding the Agency's foreign office footprint and deployed personnel.

Infrastructure: Facilities Investments and Rent

The Budget provides $43.6 million in funding to offset the user-fee reductions required to comply with FDARA Section 905 for an overall reduction of -$9.3 million. This funding helps ensure that FDA's offices and labs across the country and its fully integrated headquarters campus are optimally functioning and enable FDA to carry out its mission, including to evaluate food safety and medical products, and respond to emergencies. Optimally functioning facilities directly support FDA's priorities by providing secure, modern, reliable, and cost-effective office and laboratory space that empowers FDA's workforce to protect and promote the safety and health of American families.

21st Century Cures Act

This $5 million increase reflects the authorized level for CURES in FY 2025, for a total of $55 million.

Legislative Proposals

The FY 2025 Budget includes several legislative proposals that better support Agency efforts to protect American consumers and patients. The proposals include authorities related to enhancing supply chain resiliency for drugs, medical devices, and foods, such as requirements for manufacturers to notify FDA when they will be unable to supply an increase in demand and to provide manufacturing volume and supplier information; supporting innovation and competition, such as creating a new category for certain animal food substances to facilitate marketing of innovative products; amending certain exclusivity provisions for drugs to encourage meaningful innovation and timely competition; improving hiring authority for the FDA tobacco program to effectively meet its public health mandate; providing additional oversight tools, such as expanding authorities for information sharing with the states, for requesting records or other information in advance of or in lieu of inspections to all FDAregulated commodities, and for destruction of products which present a significant public health concern. The Budget also proposes new authorities which would require animal drug sponsors to make post-approval safety changes and expand FDA's mandatory recall authority to cover all human and animal drugs. Finally, the Budget would provide FDA with additional authorities to increase oversight of dietary supplements to better protect consumers and to modernize the tobacco user fee framework to allow for a fair distribution of tobacco user fee assessments to all regulated tobacco products.

User Fees

User fees are critical to enabling FDA to fulfill its mission of protecting public health and enabling the Agency to strengthen its efficiency and increase the speed at which products are available to the public. The FY 2025 Budget includes a total of $3.5 billion from existing user fees.