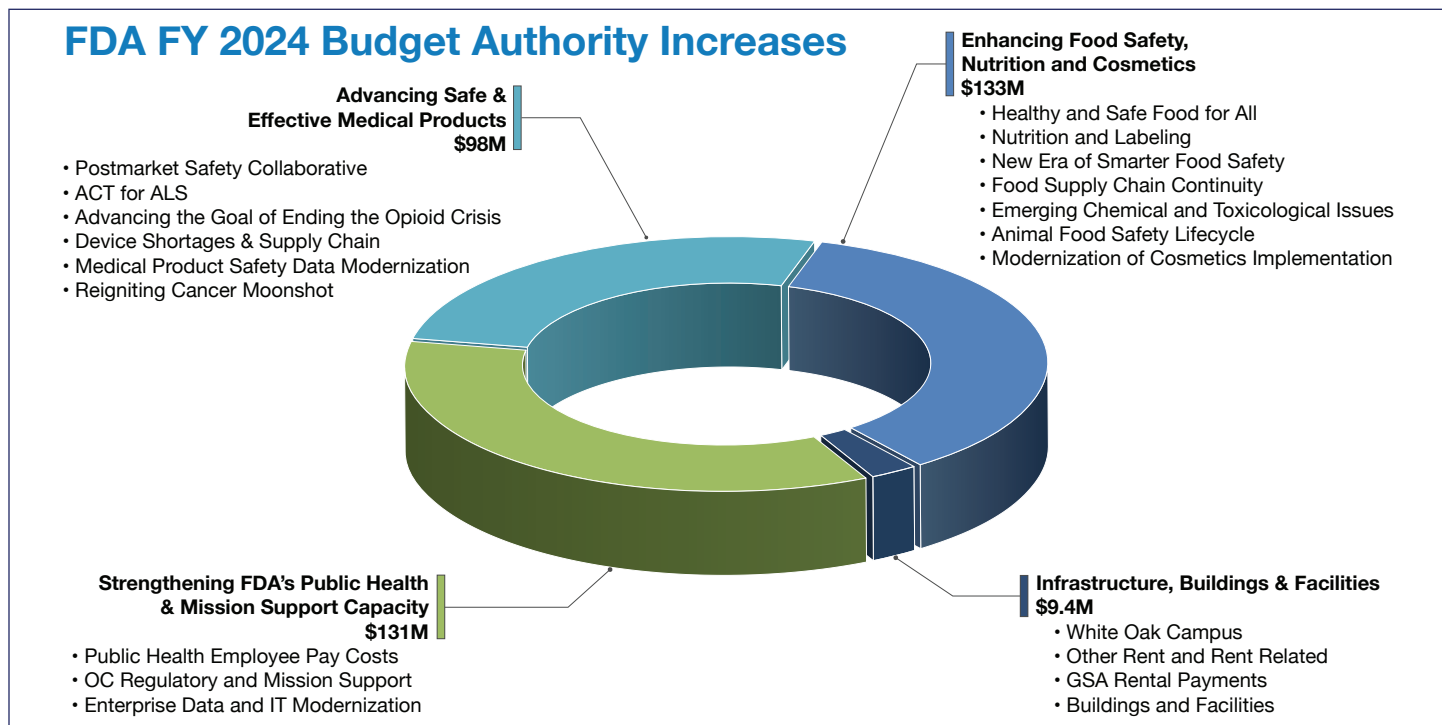




FY 2024 FDA Budget Summary

FDA’s responsibilities are ever growing and more complex due to advances in food and medical product technology, global supply chains, and artificial intelligence. The FY 2024 budget provides a \$7.2 billion total program level for FDA. This includes an increase of \$372 million in budget authority—or 10 percent above the FY 2023 funding level—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 \$3.3 billion in user fees.



Enhancing Food Safety, Nutrition, and Cosmetics

The budget provides a historic investment—an increase of \$133 million—to strengthen FDA’s food safety and nutrition capacity, demonstrating the Administration’s ongoing commitment to these responsibilities. FDA recently announced a new, transformative vision for the FDA Human Foods Program as a result of findings and recommendations identified through the external evaluation conducted by an expert panel of the Reagan-Udall Foundation and the separate internal review of the agency’s infant formula supply chain response. The budget complements this vision and provides targeted investments in activities that will protect and promote a safe, nutritious U.S. food supply. FDA is requesting funding to modernize oversight of infant formula, empower consumers to make healthier food choices, and reduce exposure to toxic chemicals in the food supply. The budget also will allow FDA begin to modernize FDA’s oversight of the vast and growing \$80+ billion cosmetics industry.

Advancing Medical Product Safety

The budget provides a \$98 million increase in funding to advance efforts to strengthen medical product safety and availability across FDA’s medical product Centers. The budget includes funding to evaluate the performance, safety, and effectiveness of medical products, support resilience in the medical supply chain for devices, and funding to support public health programs to combat the opioid epidemic. The budget also provides funding to implement the ACT for ALS Act.

Further, FDA's budget provides \$50 million for FDA to advance the President's Cancer Moonshot goals. These funds will enhance FDA's ability to improve evidence generation for underrepresented subgroups in oncology clinical trials, as well as to support pragmatic, decentralized trials and sources of evidence through patient-generated data and real-world evidence. Additionally, these resources will assist in the expansion of FDA's efforts to facilitate the approvals of innovative and new cancer treatments by international regulatory authorities at the time of FDA approval and will foster collaboration on cancer treatments within other countries with standards comparable to the U.S. standard of care.

Strengthening Public Health and Mission Support Capacity

The budget provides an increase of \$131 million in funding to strengthen FDA's public health mission and support capacity. The budget provides full funding, for the first time, for the anticipated increase in FDA's public health employee pay costs. The budget also expands on FDA's data and IT infrastructure modernization efforts and strengthens central enterprise-wide business and policy services within the Office of the Commissioner.

Infrastructure, Buildings & Facilities

The budget provides an increase of \$9.4 million in funding to help 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, evaluate food safety and medical products, and respond to emergencies. This will 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. Investing in FDA's facility objectives will provide the high-quality infrastructure and facilities needed for FDA employees to work to ensure FDA can achieve its strategic priorities.

Legislative Proposals

The FY 2024 budget includes several legislative proposals that better support agency efforts to protect American consumers and patients, particularly during public health emergencies like the COVID-19 pandemic. The proposals include enhanced authorities related to shortages of drugs, medical devices, and foods, particularly requirements for manufacturers to notify FDA when they will be unable to supply an increase in demand; additional tools to allow FDA to continue certain oversight activities when inspections are not feasible; expanded authorities for information sharing with the states; and additional authorities 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, better support our Closer to Zero initiative and protect infants and young children from exposure to toxic elements, 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 2024 budget includes a total of \$3.3 billion from existing user fees and proposes an increase to the export certification fee program and the tobacco user fee program. The FY 2024 budget proposes to reauthorize the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act. These two user fee programs enhance the FDA's ability to maintain a predictable and timely animal drug review process, foster innovation in drug development, and expedite access to new therapies concerning animal drug reviews. FDA's Medical product user fee programs were reauthorized from FYs 2023 to 2027 by the FDA User Fee Reauthorization Act of 2022. The user fees reauthorized include: the Prescription Drug User Fee Act, the Generic Drug User Fee Act, the Biosimilars User Fee Act, and the Medical Device User Fee Act.