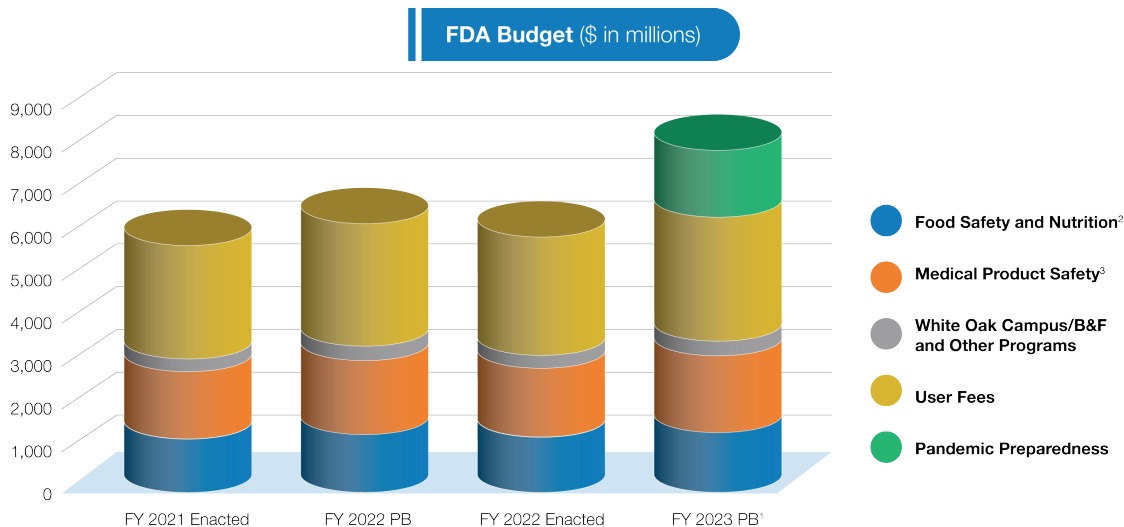


FY 2023 FDA Budget Summary

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 2023 budget provides an \$8.4 billion total program level for FDA. This includes \$356 million in budget authority above the FY 2022 funding level to enhance food safety and nutrition, advance medical product safety, improve core operations, and modernize FDA’s infrastructure, buildings, and facilities. The budget proposes \$3 billion in user fees and \$1.63 billion in funding over the next 5 years for Pandemic Preparedness.



¹ Core Operations are included in Food Safety and Nutrition (\$52.3 million) and Medical Product Safety (\$105.7 million)
² Funding for Infrastructure programs "Other Rent and Rent Related" and "GSA Rental Payments" are included in FS totals: FY 2021 Enacted (\$121.1 M); FY 2022 PB (\$129.2 M); FY 2022 Omnibus (\$121.4 M); and FY 2023 PB (\$131.7 M)
³ Funding for Infrastructure programs "Other Rent and Rent Related" and "GSA Rental Payments" are included in MPS totals: FY 2021 Enacted (\$130.3 M); FY 2022 PB (\$139.2 M); FY 2022 Omnibus (\$131.6 M); and FY 2023 PB (\$141.7 M)

Investing in Core Operations

The budget provides a \$158 million increase above the FY 2022 funding level to support cross-cutting agency-wide efforts that provide resources, technology, capacity, and infrastructure to address public health needs and tackle complex challenges due to advances in the global food and medical product technology and supply chains.

Recruiting, training and retaining skilled personnel requires that FDA prioritize employee safety, provide incentives for hiring and retention, keep pace with inflation and the rising cost of living, and implement efficient and well-functioning administrative systems.

The budget modernizes data retention, analysis, and communication technology systems that secure agency and private industry information essential for FDA’s consultation, review, approval, and continued oversight of foods and medical products, while allowing FDA reviewers and investigators to efficiently conduct their work.

The budget request also supports FDA’s offices that oversee compliance with legal requirements and quickly and accurately report out publicly requested information, ensuring that the agency’s work serves all and not only some of the diverse and changing U.S. population. The funds will also support updates to scientific practices to

reflect public priorities. The continued success of FDA’s existing programs and FDA’s ability to adapt to changing markets and novel challenges relies on these efforts.

Enhancing Food Safety and Nutrition

FDA’s budget includes \$76 million in new funding towards ensuring healthy and safe food for every American. The agency will continue working to use the latest technologies to identify foodborne illnesses, prevent them from reoccurring, and remove implicated products from the market. FDA will focus resources on food and nutrition issues that affect the most vulnerable people: infants, toddlers, and pregnant and lactating women. The agency will update its approach to chemicals that are in foods—both those directly added as food ingredients and those that come into contact with food. And for our pets and livestock, these funds will allow FDA to partner more closely with States to ensure that animal food manufacturers are following required safety practices.

Advancing Medical Product Safety

The budget provides a \$95 million increase for FDA’s medical product safety work. This includes continuing the development of supply chain monitoring and resilience planning and improved oversight of drugs safety for products that are already on the market. The budget makes a substantial investment in combatting two issues that have touched almost every family in America: the opioid crisis and cancer. This funding will also help to speed FDA’s review of animal drugs and further the agency’s efforts to help the medical industry reduce animal testing. The budget also addresses medical device cybersecurity, which is increasingly important as more medical devices become digitally connected.

Modernizing Infrastructure, Buildings and Facilities

FDA’s facilities budget includes an increase of \$40 million for the upkeep and rental of FDA’s laboratories and buildings, to improve the functionality and reliability of FDA’s owned buildings and site infrastructure, and to make progress on facilities projects that support FDA’s ability to carrying out its mission, evaluate food safety and medical products, and respond to emergencies.

Pandemic Preparedness

The FY 2023 budget makes a transformative investment of \$81.7 billion in pandemic preparedness and biodefense across the Department of Health and Human Services (HHS) to enable an agile, coordinated, and comprehensive public health response to future threats and protect American lives, families, and the economy.

\$1.6 billion of this mandatory funding will support preparedness activities within FDA, allowing FDA to expand and modernize regulatory capacity, information technology, and laboratory infrastructure to respond rapidly and effectively to any future pandemic or high consequence biological threat. With these investments, FDA aims to strengthen the personal protective equipment supply chain by building analytics and creating predictive modeling capabilities. FDA would also use these new resources to speed development of diagnostics, as well as support efforts with international partners to strengthen foreign inspections, harmonize premarket review of therapeutics and diagnostics, and reduce zoonotic pathogen spillover.

Legislative Proposals

The 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 (including infant formula); 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 medical device manufacturers to address cybersecurity issues, ensure that confirmatory studies under the accelerated approval pathway progress in a timely manner, and encourage timely marketing of first generics that leads to cost savings. Finally, the budget would provide FDA with additional authorities to increase oversight of cosmetics and dietary supplements, 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

The budget proposes \$3 billion in user fees, which will help the agency 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 budget proposes an additional \$100 million and authority to include manufacturers and importers of all deemed products among the tobacco product classes for which FDA assesses tobacco user fees. This additional funding will help FDA bolster compliance and enforcement efforts for all tobacco products and expand public education campaigns and science and research programs, as it works to address substance use and to protect consumers from the dangers of tobacco use.

