Alliance for a Stronger FDA

FY 25 "Ask" For FDA Funding

April 18, 2024

The Alliance for a Stronger FDA requests that FDA receive a budget authority appropriation of $3.896 billion for FY 25 salaries and expenses (S&E) plus an additional $19 million for buildings and facilities (B&F).[1]

This is the same amount that the Administration proposed for FY 24 in March 2023 and substantially greater than the amount the President recently proposed for FY 25.

FDA's needs have not diminished in the intervening year and additional funds were not provided in the final FY 24 Ag/FDA appropriations bill. Accordingly, the Alliance "ask" for FY 25 is based on the FY 24 request, which provides a clearer picture of the FDA's funding needs during the coming fiscal year.

FDA's work affects every American multiple times each day. The agency is responsible for 80% of the food supply and 100% of drugs, medical devices, biologics, vaccines, veterinary food/medicine, dietary supplements, and cosmetics. Altogether, the agency oversees products and services that represent 20% of all consumer spending (more than $3.6 trillion).[2]

The FDA's mission expands and its responsibilities grow every year. Its vital activities must keep up with more sophisticated and complex markets that are driven by globalization, competition, and innovation. Its commitment to science-based decision-making in both food and medical products requires more scientific and technical staff, and better analytical tools. The growing complexity of science, interwoven with new advances in technology, is a challenge across the agency.

The Alliance's FY 25 "ask" has three components:

- Food Safety, Nutrition, and Animal Health
- Advancing Access to Safe and Effective Medical Products
- Strengthening Public Health and Mission Support Capacity (agency-wide impact) and Cosmetics

At the end of this document, you will find a final section including charts summarizing the Alliance's FY 25 "ask" and a comparison of the President's FY 24 and FY 25 Requests.

Food Safety, Nutrition, and Animal Health

The Alliance is asking for FY 25 funding of:

- ***at least $1.35 billion for human food safety programs (HFP)***
- ***at least $255 million for animal drugs and feed (CVM)***

[1] Our request for FY 25 funding focuses exclusively on appropriations that come from monies paid by taxpayers (BA) and intentionally does not include medical product and tobacco user fees and mandated funding (e.g., Cures monies transferred from the National Institutes of Health). However, we urge Congress to fully fund those programs, as well.

[2] https://www.fda.gov/about-fda/economics-staff/fda-glance (accessed 4/13/24)

Resources are needed to strengthen and modernize the Agency's capacity to protect and promote a safe, nutritious U.S. food supply and assure safe veterinary food and drugs. Among other things, FDA is expected to mitigate and prevent foodborne illness outbreaks, address the public health burden of diet-related chronic diseases, and counter supply chain disruption and shortages.

Accordingly, we urge additional funding over and above the FY 25 request and comparable to the amounts proposed in the President's request for FY 24.

Areas of particular need include:

Food Chemical Safety. A robust food chemical safety/post-market review program is a pressing need that is supported by a broad range of consumer and industry stakeholders, many of whom view it as their highest food safety funding priority. Additional funding--well beyond the President's budget request—is needed to ensure rigorous and timely review of chemical and toxicological issues now pending before the agency, including twenty-one chemicals currently prioritized for reassessment. Such reviews can take many months to complete, so there is an urgency to get started and a need for substantial funding in FY 25.

Rule Implementation and Prevention Activities. FDA, state partners, and industry are currently working to implement the traceability rule and are anticipating upcoming changes to agricultural water standards. This, combined with advancements in the scientific understanding of the root causes of food contamination make it important for FDA to maintain and grow efforts to work with state regulators and industry stakeholders to implement standards and practices that can improve food safety.

Cooperation with State and Local Governments. FDA's cooperative relationships with state and local regulatory programs (including state human and animal food testing laboratories) have been extremely valuable and should be sustained and made more predictable. In many instances, the agency achieves better coverage at lesser expense by having a state and local presence.

Establishing Nutrition Center of Excellence. The planned reorganization of the Human Foods Program includes the establishment of a Nutrition Center of Excellence. Given the relatively small size of the current nutrition program at FDA, additional funds will be needed to realize the vision for nutrition in the new organization. Priorities include children's health, chronic disease, and consumer-facing food labeling.

Enhancements in Risk-Based Targeting of Foods and Animal Health Program Oversight Activities. As the agency restructures to establish a new Human Foods Programs, additional resources (advanced data systems, external data sets, and data scientists) are needed to create a data-driven foundation to improve risk-based oversight and surveillance activities in both human foods and animal food and drugs. More substantial investments in FY 25 could also help to accelerate work planning and data sharing with state regulatory partners.

Advancing Access to Safe and Effective Medical Products

The Alliance is asking for FY 25 funding of:

- ***at least $775 million for human drug programs (CDER)***
- ***at least $280 million for biologics and cell and gene therapy (CBER)***
- ***at least $478 million for devices and radiological health (CDRH)***

FDA is the leader in global efforts to ensure the safety and efficacy of medical products and assure that Americans have access to timely, safe, and effective drugs and medical devices. Through investments in medical product

safety programs, FDA evaluates the safety of products before they are marketed so the public can have confidence in the safety and effectiveness of their products.

Accordingly, we urge additional funding over and above the FY 25 request and comparable to the amounts proposed in the President's request for FY 24.

Areas of particular need include:

Expand regulatory sciences investments. Science, by its nature, involves a constantly changing body of information, data, and evidence. FDA must keep pace with scientific advancement by embracing, developing, and applying innovative regulatory science and technology that can be used to improve processes and help to regulate innovative approaches developed and employed by regulated industry. The regulatory science enhancements can make clinical and post-market evaluation more efficient; expand the use of medical product drug and device development tools and manufacturing innovations; leverage electronic health records; address substance use, misuse, and addiction and more effectively empower patients and consumers.

Further develop integrated knowledge management systems that improve the accuracy and efficiency of FDA's medical product decisions. FDA continues to develop its cross-center knowledge management capabilities, which provide a systematic approach to acquiring, analyzing, storing, and disseminating information related to medical products. The new system would store and manage medical review staff's experiences; identify how decisions are made across different functions; make note of how scientific precedents are established; and capture the knowledge that is developed through the process. When fully operational, the knowledge management system will more effectively provide comprehensive product lifecycle oversight, reduce uncertainty in the regulatory process, and enable greater risk-based decision-making. Additional governmental support and funding will further expedite the implementation of the system and enhance the predictability of medical product development, product review, and patient understanding.

Address unmet medical needs and rare diseases through cell and gene therapies (including gene editing). The advancement of cell and gene therapies provides the opportunity to prevent, treat, and cure diseases which have previously had limited or no treatment options. There has been a rapid increase in cell and gene therapy development over the past several years, and FDA must be equipped with resources to meet this demand and not slow down the availability of these important products. While expansion of these efforts was part of the PDUFA VII agreement (FY2023-2027), additional government investment is needed to realize even greater benefits for patients and for public health outcomes. Greater funding can help implement and expand important new initiatives, such as the "Support for clinical Trials Advancing Rare disease Therapeutics (START)" pilot.

Expand medical product inspection capabilities. FDA is improving risk prioritization and modernizing medical product inspections through the restructuring of the Office of Regulatory Affairs (ORA). This effort will streamline the work across product centers and help to achieve FDA's public health and prevention-oriented goals. The Agency needs additional resources to effectively update their processes and accelerate the transformation of the program. When fully operational, a restructured ORA will help to ensure more timely access to new and innovative medical products by improving the capabilities to meet review goals and facilitating more first-cycle approvals.

Strengthening Public Health and Mission Support Capacity (agency-wide impact)

- ***at least $81 million for the National Center for Toxicological Research (NCTR)***
- ***at least $301 million for programs in the Office of the Commissioner and crosscut activities (OC)***

- ***at least $8 million for cosmetics regulation[3]***
- ***at least $377 million for rent and facilities cost (including White Oak Consolidation)***
- ***at least $19 million for buildings and facilities repairs***

Areas of particular need include:

Modernizing Cosmetics Regulation. The Modernization of Cosmetics Regulation Act of 2022 (MoCRA), is a major overhaul of the regulation of cosmetics, amending a law that has been unchanged since 1938. Monies are needed for the development of regulations, compliance policies, product registration and listing platforms, adverse event reporting and other activities. Congress funded the program at $7 million in FY 24 and the President's FY 25 request is for $8 million. This is a good start, but developing an effective program in a reasonable timeframe will require more money and sooner. For reference, the legislation authorizes more than $41 million for FY 25.

Shortages and Supply Chain. This agency-wide crosscutting initiative supports FDA's efforts to prepare for, build resilience to, and respond to shortages through improved analytics and regulatory approaches. Among other uses, FDA should be using monies to hire additional investigators, domestically and abroad, to fulfill inspectional needs associated with increased supply chain disruptions and consequent human food and medical product shortages in recent years. For much of the stakeholder community, it is a priority to upgrade the FDA's efforts to a level that will require additional funding--well beyond the President's budget request.

Public Health Employee Pay Costs. The President's request included $115 million to offset part of the cost of mandatory pay raises. The amounts have been allocated to Centers and offices and the monies are incorporated in each component of our ask.

Enterprise Transformation. FDA needs targeted investments to improve the efficiency of its operations and support modernization activities, such as centralizing planning, implementation, and governance of high priority business process improvement efforts. These include the continuation of the critical inspections' platform implementation and expansion effort to implement common business processes and data optimization across the FDA.

IT Stabilization and Modernization. FDA needs monies 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.

Conclusion, Chart Summarizing Alliance FY 25 Ask, and Comparison of the President's FY 24 and F 25 Requests

We urge Congress to recognize the multiple opportunities for FDA to be a more effective protector of public health, as well as continuing to be a fair and efficient regulator. Additional investment in FDA will result in substantial added value to the American public.

The Alliance thanks the Congress for its support of the agency and looks forward to working with Members of Congress and staff on FY 25 appropriations for FDA.

[3] Cosmetics regulation is now located in the Office of the Commissioner.

Summary chart of Alliance FY 25 Ask

Function Note: budget authority only, by center*	**FY 24 Consolidated Appropriations Act**	**FY 25 President's Budget Request (proposed pay costs included)**	**FY 25 Alliance Ask (proposed pay costs included)**	**FY 25 Alliance Ask vs FY 25 President's Request (in millions)**	**FY 25 Alliance Ask vs FY 24 Consolidated Appropriations Act (in millions)**
Food	$1.186 billion	$1.247 billion	$1.349 billion	$102	$163
Human Drugs	$720 million	$754 million	$ 775 million	$21	$55
Biologics	$267 million	$280 million	$ 280 million	$0	$13
Animal Drugs/Feed	$229 million	$240 million	$ 258 million	$18	$29
Devices & Radiological Health	$445 million	$466 million	$ 478 million	$12	$33
Natl. Ctr. For Toxicological Research	$78 million	$81 million	$ 81 million	$0	$3
HQ, Office of Commissioner and Other Activities	$224 million	$250 million	$ 301 million	$51	$77
Rent & Facilities Cost (Including White Oak Consolidation)	$373 million	$367 million	$ 377 million	$10	$4
SUBTOTAL, Salaries and Expenses	**$3.522 billion**	**$3.685 billion**	**$3.899 billion**	**$214**	**$377**
Building and Facilities Repair	$5 million	$13 million	$ 19 million	$6	$14
TOTAL, ALL Budget Authority Appropriations	**$3.527 billion**	**$3.698 billion**	**$3.918 billion**	**$220 million**	**$391 million**

*Note: This table does not include funding provided for the 21st Century Cures Act ($55 million), and Cooperative Research and Development ($2 million).

Comparison of the President's FY 24 and FY 25 Requests

Consistent with the overall discretionary spending targets set forth in last year's budget agreement, the President's FY 25 budget request for FDA is substantially less than his FY 24 request. As a result, all of FDA is at risk for another lean year.

Specifically, the President's FY 24 request for FDA was an increase of about $370 million over FY 23, including $105 million in mandatory pay raises. For FY 25, the President's request is for an increase of about $170 million over FY 24, including $115 million in mandatory pay raises.

Thus, the program (non-salary) portion of the Administration request for FDA has shrunk from an increase of about $265 million (FY 24) to an increase of about $55 million (FY 25).

In the face of FDA's expanding mission and growing responsibilities, this is not a budget that will meet the needs of FDA or the American people.

This table below compares the FY 25 and FY 24 budget requests and shows the dramatic pullback in proposed program support.

FY 25 explanation	FY 24 explanation
Total Food Safety–$15 million · Foods - $15 million	Total Food Safety - $133.2 million · Foods - $112.9 million · Animal Drugs and Food - $13.3 million · HQ - $6.9 million
Total Medical Product Safety	Total Medical Product Safety - $98.2 million · Human Drugs - $27.2 million · Biologics - $0.81 million · Animal Drugs and Foods - $4.74 million · Devices and Radiology Health - $17.06 million · HQ - $48.42 million
ADDITIONAL CROSS-CUT REQUESTS	**ADDITIONAL CROSS-CUT REQUESTS**
Modernization of Cosmetics · FDA HQ - $8 million	
Shortages and Supply Chain - $12.3 million	
Foreign Office Expansion · HQ - $1 million	
IT Stabilization and Modernization - $8.25 million	Enterprise Data and IT Modernization - $10 million
Public Health Employee Pay Costs - $114.77 million	Public Health Employee Pay Costs - $105.3 million
Enterprise Transformation - $2 million	OC Regulatory and Mission Support - $15.8 million