DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2025

Food and Drug Administration

Justification of
Estimates for
Appropriations Committees

On behalf of the U.S. Food and Drug Administration (FDA or Agency), I am transmitting FDA's congressional justification for the fiscal year (FY) 2025 budget. The FY 2025 budget request of $7.2 billion is critical to supporting FDA's broad public health mission. As the oldest comprehensive consumer protection agency in the country, for more than a century, FDA has been responsible for ensuring the safety of products consumed by hundreds of millions of Americans each day.

Every year FDA reviews hundreds of product applications, ultimately determining which drugs, devices, or biological products (e.g., vaccines, or cell and gene therapies) will be marketed in the United States. The process is rigorous, thoughtful, and always adheres to standards for safety and effectiveness. Through this process, FDA helps ensure that the human and animal food supplies are safe, sanitary, and accurately labeled, and that cosmetic products are safe and properly labeled. The Agency also protects Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public about tobacco products and the dangers their use poses. The FDA also works to ensure the public has the accurate, science-based information needed to make health decisions.

The FDA is always in the public eye because the decisions that we make impact so many people every day. Despite the enormous workload and societal forces – like the ease of spreading misinformation and erosion of public trust in science – that make the mission more challenging, the FDA's public health employees continue to deliver on a wide range of priorities that protect the health and well-being of millions of people. The Agency continues to build on its accomplishments and lessons learned and to request new funding to modernize the FDA and its operations for the future.

The FY 2025 budget for FDA requests a total of $7.2 billion in annual funding. This represents an increase of $157 million in direct discretionary budget authority that focuses on preserving the FDA's public health mission and supporting the Agency's public health workforce. These critical investments will help the FDA address its most urgent public health priorities, strengthen its public health capacity and business operations, advance its Agency-wide IT modernization capabilities, and improve its Agency-wide infrastructure. The budget proposes $338 million in additional user fees and requests $670 million in mandatory funding to help the FDA combat the next pandemic.

The budget also provides support to strengthen FDA's food safety and nutrition capacity, demonstrating the Administration's ongoing commitment to these responsibilities. Last year, the FDA announced a new, transformative vision for the FDA Human Foods Program as a result of

findings and recommendations identified through an external evaluation[1] conducted by the Reagan-Udall Foundation and a separate internal review[2] of the Agency's infant formula supply chain response. Although structural and process changes are underway, there is still a significant need for additional resources to strengthen the Agency's foundational food safety and nutrition capacity. The budget complements this vision and provides targeted investments in activities that will protect and promote a safe and nutritious U.S. food supply.

The Agency takes its public health mandate seriously, and its focus is always on the well-being of patients and consumers. On behalf of FDA, I extend my thanks for your support of the FDA's mission and FY 2025 budget priorities.

Sincerely,

Robert M. Califf, M.D. Commissioner of Food and Drugs

[1] A Report of the Human Foods Independent Expert Panel. Henney, et al.; 2022. https://reaganudall.org/operational-evaluation-fdas-human-foods-programs.

[2] https://www.fda.gov/media/161689/download.

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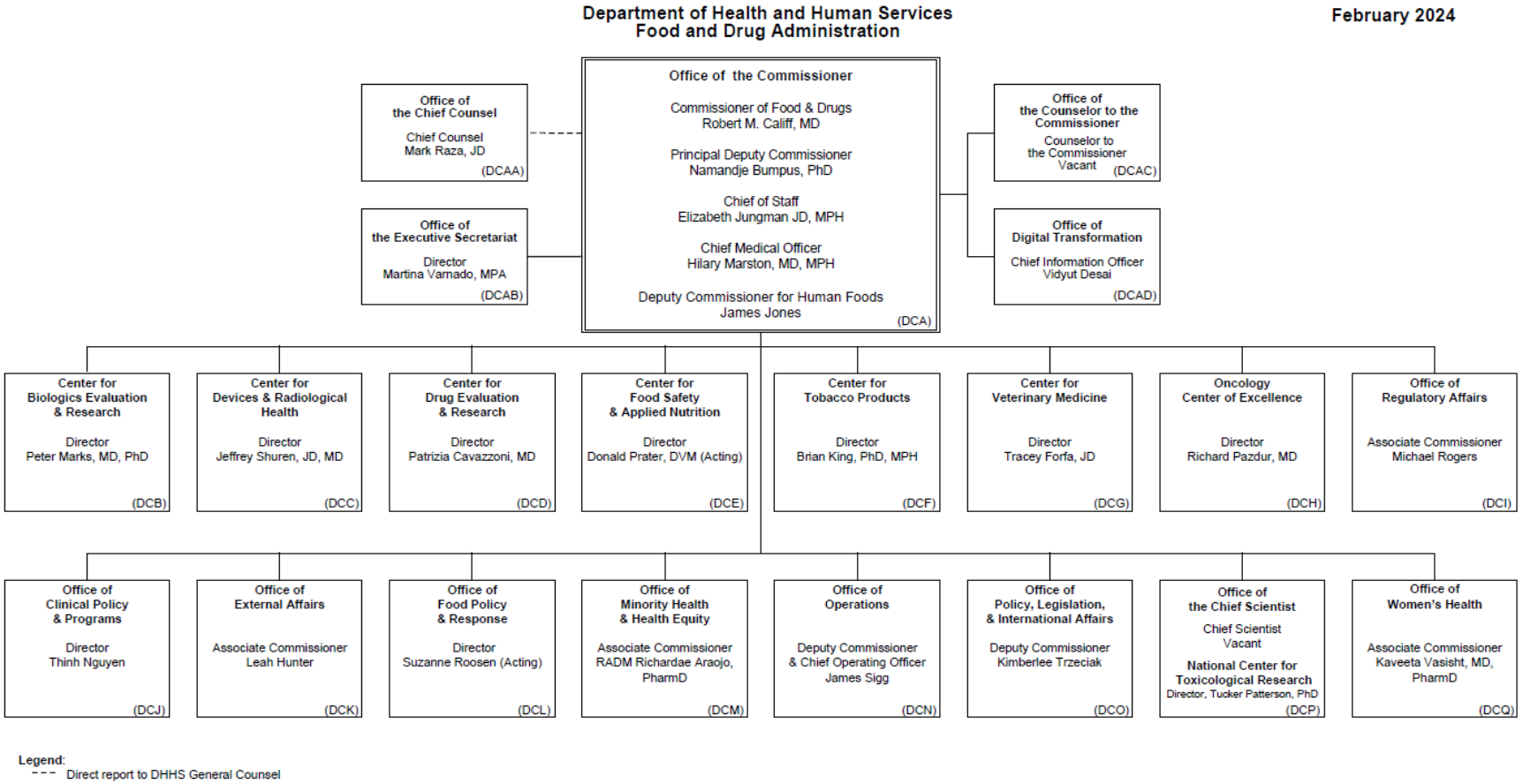

INTRODUCTION AND MISSION

The U.S. Food and Drug Administration (FDA) is the agency within the U.S. Department of Health and Human Services (HHS) responsible for protecting and promoting human and animal health by ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of human and animal foods, cosmetics, and radiation-emitting products; and regulating tobacco products. FDA's customers and key stakeholders include American patients and consumers; healthcare professionals; regulated industry; academia; and state, local, federal, and international governmental agencies.

ALIGNMENT TO HHS STRATEGIC PLAN

FDA collaborates closely with other HHS Agencies and federal departments on crosscutting topics, especially on initiatives and activities where coordination and collaboration to protect patients and consumers is critical. FDA is committed to advancing the national priorities set by the Administration and implementing strategies to advance all five strategic goals of the HHS Strategic Plan (2022 – 2026), including:

- Enabling diverse, agile supply chains for human and animal food and medical products to reduce and prevent shortages and to ensure continued access and continuous supply;
- Strengthening regulatory and compliance capacity, including by leveraging technology to anticipate and respond to rapid increase in research technology and data science;
- Taking actions to reduce the use of tobacco products, to protect American families and improve public health;
- Modernizing legacy information technology infrastructure, processes, and systems to deploy emerging technologies, avoid risks of exceeding end-of-life/end-of-service, begin standardizing data and approaches, automate processes, and move siloed systems to enterprise systems; and
- Advancing strong strategic management to foster prudent use of resources, strengthen human capital management, and enhance public trust.

HEALTH EQUITY

FDA is dedicated to advancing the health of our nation's most vulnerable and underrepresented populations to achieve health equity for all. In support of the Administration's Executive Orders, including Executive Order 13950, "On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," FDA facilitates the development and availability of therapeutics, vaccines, diagnostics, and other medical products, as well as efforts to ensure food safety and promote healthy eating – which have the potential to have a demonstrable impact on underserved communities and diverse populations. FDA is working to address gaps, such as efforts to advance clinical trial diversity efforts and to increase availability, understanding, and use of data on racial and ethnic minority groups to better inform its program activities. FDA also is amplifying its communications to ensure stakeholders, including consumers, are informed about FDA's intended outcomes to better understand diverse patient perspectives, preferences, and unmet needs.

OVERVIEW OF FY 2025 BUDGET REQUEST

As the oldest comprehensive consumer protection agency in the country, for more than a century, FDA has been responsible for ensuring the well-being of millions of patients and consumers in

the United States each day. The Fiscal Year (FY) 2025 request for FDA includes total program level funding of $7.2 billion, with several targeted requests to better advance the Agency's capabilities to meet the needs of the American public.

FDA's proposed FY 2025 Budget reflects an overall increase of 7.4 percent or $495 million. This includes $3.7 billion in budget authority, an increase of 4.4 percent or $157 million, and $3.5 billion in user fees, an increase of 10.8 percent or $338 million.

(Dollars in Millions)	FY 2023 Final	FY 2025 President's Budget	President's Budget +/- FY 2023 Final
Total Budget Authority Post Transfer	3,591.4	3,748.5	157.0
Total User Fees	3,128.6	3,466.7	338.1
Total Program Level	6,720.1	7,215.2	495.1

The funding and programmatic approaches described in the request are compared to the FY 2023 Final Level. The Budget includes five areas in support of protecting and promoting the public health:

- **Enhancing Food Safety and Nutrition** – ensures the human and animal food supply is safe, sanitary, wholesome, and accurately labeled.
- **Advancing Safe and Effective Medical Products** – ensures that safe, effective, and high-quality human and animal drugs, biological products, and devices are available to improve the health and quality of life for people in the United States, including medical countermeasures.
- **Investing in Core Operations** – provides crosscutting enterprise-wide policy, legal, information technology, financial, and supportive business services to enable FDA to carry out its programmatic responsibilities.
- **Infrastructure: Facilities Investments and Rent** – ensures FDA staff have the modern infrastructure and labs across the country to execute the agency's public health mission.
- **Tobacco Regulation** – protects Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products, and by educating the public about tobacco products and the dangers their use poses.

DISCRETIONARY BUDGET AUTHORITY OVERVIEW

The Budget proposes an increase of $157 million in direct discretionary budget authority, which reflects a 4.4 percent increase compared to the FY 2023 Final Level. These critical discretionary investments will help FDA address our most urgent public health priorities, strengthen our public health capacity and business operations, advance agency-wide IT modernization capabilities, and improve our facility and laboratory infrastructure. FDA's FY 2025 Budget includes the following changes:

(Dollars in Millions)	FY 2023	FY 2025	
	Final	President's Budget	FY 2025 President's Budget +/- FY 2023 Final
Budget Authority /1	**3,591.4**	**3,748.5**	**157.0**
Program Level /2	**6,720.1**	**7,215.2**	**495.1**
Enhancing Food Safety and Nutrition	**-**	**15.0**	**15.0**
Human Foods Program	-	15.0	15.0
Advancing Safe & Effective Medical Products	**50.0**	**55.0**	**5.0**
21st Century Cures	50.0	55.0	5.0
Strengthening FDA's Public Health & Mission Support Capacity	**-**	**146.3**	**146.3**
Public Health Employee Pay Costs	-	114.8	114.8
Modernization of Cosmetics	-	8.0	8.0
Enterprise Transformation	-	2.0	2.0
IT Stabilization & Modernization	-	8.3	8.3
Shortages and Supply Chain-Agency-wide	-	12.3	12.3
Foreign Office Expansion	-	1.0	1.0
Infrastructure: Facilities Investments and Rent	**333.6**	**324.3**	**-9.3**
White Oak	48.4	48.4	-
Other Rent and Rent Related	106.1	107.7	1.6
GSA Rental Payments	166.3	155.4	(10.9)
Buildings and Facilities	12.8	12.8	-

1/ Reflects total agency budget authority including required and permissive transfers and reprogrammings. Excludes supplemental appropriations.
2/ Reflects total agency budget authority and other sources of funding including required and permissive transfers and reprogrammings. Excludes supplemental appropriations.
3/ Table does not reflect zero sum comparability adjustments for FY 2023 and FY 2025, Office of Global Policy and Strategy (OGPS) Transfer or FDA Reauthorization Act Section 905 BA/UF shift.

Figure 1 - Executive Summary Table

PROGRAMMATIC AND CROSSCUTTING BUDGET AUTHORITY REQUESTS

FDA's budget request includes $157 million of new funding above FY 2023 Final Level. The Budget reflects FDA's top priorities by protecting FDA's ability to maintain its current standard of service given increased authorities and an inflationary environment, advancing FDA's work in key areas of importance to the public, and making investments to make FDA more efficient.

FDA's request for new activities above the FY 2023 Final Level reflects the Agency's top priorities in key areas of importance to human and animal health. This includes investing in a whole of agency approach to addressing disruptions and shortages of food and medical products, including infant formula. FDA's budget also supports the President's National Strategy for Hunger, Nutrition, and Health by funding innovative work on childhood nutrition and diet-related chronic diseases. Additionally, FDA's FY 2025 budget supports expanding FDA's presence in foreign offices to strengthen oversight and target resources to advance and protect public health as well as strengthen FDA's oversight of imported products.

Finally, FDA has proposed targeted investments that seek to improve the efficiency and effectiveness of its operations. The FDA enterprise transformation initiative supports modernization activities by centralizing planning, implementation, and governance of high-priority business process improvement efforts. This effort is already producing benefits for the agency such as designing a future state enterprise "backbone" process for inspections and

establishing enterprise governance of the new process and future technology. FDA's budget also supports the agency's efforts to address critical IT requirements to manage enterprise risk, stabilize the current IT environment, modernize through strategic IT spending, and invest in the future of IT through expanded capabilities that will enable the Agency to keep pace with the current technology landscape and drive necessary efficiencies for carrying out the FDA mission. These initiatives will help FDA create more value with the resources it receives as it enters the possibility of more difficult budget environments in years to come.

HIGHLIGHTS

- **Public Health Employee Pay Costs: (+$114.8 million)** to address approximately 72 percent of FDA's estimated inflationary pay costs for FY 2024 and FY 2025. This funding helps FDA minimize reductions to hiring capabilities and reduce the need to redirect resources away from critical initiatives and activities.
- **Modernization of Cosmetics Implementation: (+$8.0 million)** to support the implementation of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) including activities such as developing proposed and/or final regulations (e.g., for Good Manufacturing Practices, asbestos testing of talc-containing cosmetics products, and disclosing fragrance allergens on labeling); compliance policies; maintaining/updating submission platforms for registration and product listing, and adverse event reporting, as well as review of such information to ensure industry compliance with those requirements; and managing critical projects such as assessments of the use of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetic products. FDA is standing up this program to meet unfunded requirements in this act.
- **Enterprise Transformation: (+$2.0 million)** to enable FDA to coordinate and lead several high priority Agency-wide projects including the continuation of the critical inspection's platform implementation and expansion effort to analyze, optimize, and implement common business processes and data optimization. This new effort will revamp the approaches to conducting operations to limit siloed processes, data, and systems across the Agency. This creates an opportunity to apply an enterprise approach especially as it relates to FDA's inspection work.
- **Human Foods Program: (+$15.0 million)** to strengthen and modernize the Agency's capacity to protect and promote a safe, nutritious U.S. food supply. Funds will support microbiological methods and sampling improvements to support more rapid and effective mitigation of produce--borne outbreaks. This body of work will strengthen root-cause investigations essential to FDA's outbreak prevention strategy for produce. The FDA final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) establishes additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List. The proposed requirements would help FDA to effectively identify recipients of those foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death. The funds will be used for hiring consumer safety officers to support implementation with the rule as well as participate in outreach engagements, enhance IT systems, and training needed for this rule. Funding will also be used to grow FDA's nutrition program. With an emphasis on early childhood nutrition, this request assists FDA with its enormous public health burden

of diet-related chronic diseases and supports continued action to realize the gains of the President's National Strategy for Hunger, Nutrition, and Health. Within the $15 million, the Budget includes $1.3 million for the Office of Regulatory Affairs.

- **IT Stabilization and Modernization: (+$8.3 million)** to further build FDA's centralized enterprise data modernization capabilities and to strengthen FDA's common data infrastructure, data exchange, and IT analytic services, talent, and tools. With these resources, FDA will continue to improve data exchange and underlying technology platforms in support of FDA's programs and mission-critical responsibilities – to better meet the challenges of emerging threats, support needs for real-time evaluation, and more continuously access, analyze, and aggregate multiple sources of information, such as for recalls, adverse events, outbreaks, and pandemics. FDA is also requesting two-year budget authority (FY 2025 – FY 2026) for this funding to provide more flexibility and ensure the most effective use of these resources.
- **Shortages and Supply Chain: (+$12.3 million)** to advance FDA's capabilities to help prepare for, build resilience to, and respond to shortages that are supply-driven, demand-driven, or both through improved analytics to identify shortage threats and vulnerabilities, as well as regulatory approaches to assess disruptions and shortages. Through this agency-wide crosscutting initiative, FDA will hire additional investigators to fulfill inspectional needs associated with increased supply chain disruptions and consequent human food and medical product shortages seen in recent years. It will also continue to engage in efforts to promote manufacturing quality across the pharmaceutical industry and develop and implement modernized systems to allow for faster response time to shortages.
- **Foreign Office Expansion: (+$1.0 million)** to strengthen FDA's oversight of imported products by expanding the agency's foreign office footprint and deployed personnel. This investment serves to advance and safeguard the American people by strengthening the agency's knowledge of imported products and expanding FDA's ability to quickly complete in-person inspections of foreign facilities in specific countries.
- **CURES: (+$5.0 million)** – this total reflects the authorized level for CURES in FY 2025, for a total of $55 million.

Additional information on this request may be found within the various Program chapters on pages 52 (Foods Program), 110 (Animal Drugs and Foods Program), 72 (Human Drugs Program), 127 (Devices Program), 91 (Biologics Program), 161 (Field), and 205 (Headquarters).

INFRASTRUCTURE AND BUILDINGS & FACILITIES (B&F)

The Budget provides $377.15 million in budget authority for Infrastructure, and Buildings and Facilities, an increase of $43.6 million above FY 2023 Final Level.

The Budget provides funding to help ensure that FDA's offices and labs across the country and its fully integrated headquarters campus allow FDA staff to carry out the Agency's 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. Investing in FDA's facility objectives will

provide the high-quality infrastructure and facilities needed for FDA employees to ensure FDA achieves its strategic priorities. The Budget includes:

- **General Services Administration (GSA) Rent:** A reduction of -$10.9 million, for a total of $155.4 million of budget authority, to meet FDA's rent obligations. It includes estimates for rent changes including those associated with continuing occupancies for which renewal rents will reset to market.
- **Security Screening (Other Rent and Rent Related (ORRR))**: +$1.6 million within Other Rent and Rent Related to support operational needs related to security screenings for a total of $156.5 million in total Other Rent and Rent Related for operating, maintaining, and securing FDA and GSA facilities located nationwide.

The FY 2025 Budget includes a net zero realignment of budget authority and PDUFA, GDUFA, MDUFA, and BsUFA. The change impacts medical product centers and field components and the ORRR and White Oak infrastructure accounts. This realignment will allow FDA to fully implement Section 905(b) of the FDA Reauthorization Act of 2017 (FDARA) and still be able to fund critically important infrastructure requirements in FY 2024.

Additional information on this request may be found within the Infrastructure and B&F Program chapters on pages 243.

TOBACCO REGULATION

The Budget provides $798.6 million for the Tobacco program. With these resources, FDA will continue to invest in product review and evaluation, research, compliance and enforcement, public education campaigns, and policy development. The Budget also requests an additional $121.4 million in user fees. This request includes a program increase of $114.2 million in authority to include manufacturers and importers of all products subject to Chapter IX of the FD&C Act for which FDA assesses tobacco user fees. To ensure that resources keep up with all tobacco products, the proposal would also index future collections to inflation. The additional funding will support hiring more staff and help FDA bolster its tobacco product regulatory activities as it works to reduce tobacco related disease and death. This proposal would ensure that FDA has the resources to address all regulated tobacco products, including e-cigarettes, which currently have high rates of youth use, as well as future novel products.

FDA continues its critical work of reviewing new tobacco product applications before those products can be legally marketed. FDA has made considerable progress in reviewing the unprecedented volume of applications for more than 26 million tobacco products that have been submitted over the last three years while also ensuring that decisions are scientifically accurate, legally defensible, and aligned with the authorities granted by Congress. The Agency remains vigilant in overseeing the market and continues to prioritize the use of compliance and enforcement resources to curb the unlawful marketing of all tobacco products, especially those used prominently by youth.

Additional information on this request may be found within Tobacco Program chapter on page 186.

LEGISLATIVE PROPOSAL

The FY 2025 Budget includes several legislative proposals that better support Agency efforts to protect American consumers and patients. The proposals include enhanced 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 FDA--regulated 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.

Additional information on the legislative proposals may be found on page 36.

STRENGTHENING BIODEFENSE TO PROTECT AGAINST 21ST CENTURY BIOTHREATS

The COVID-19 pandemic highlighted the need to proactively plan for the next public health emergency and ensure FDA has the resources and capacity in place to fully respond. FDA has a unique and central role to the whole-of-government response to protect and promote public health. FDA requests funding to ensure there is an appropriate level of regulatory capacity to respond effectively to any future pandemic or high consequence biological threat.

The FY 2025 Budget provides mandatory funding for CDC, FDA, NIH, and ASPR strengthen the Nation's biodefense capabilities as outlined in the National Biodefense Strategy. The FY 2025 Budget Strengthening Biodefense to Protect Against 21st Century Biothreats request for FDA includes $670 million in new mandatory resources for spending over five years to advance activities to better prepare FDA for the next pandemic. These funds would support the Agency's biodefense efforts by bolstering FDA's cadre of reviewers and investing in data exchange and underlying technology platforms to help ensure that FDA can respond quickly and effectively in times of a public health crisis. It would also increase research and development; expand laboratory capacity; and support the development of diagnostics, next-generation personal protective equipment, and early warning technology. With these resources, we will have the opportunity to build on lessons learned and provide transformational investments to equip our Agency to respond to future challenges.

For more information on the Department-wide mandatory biodefense proposal, please find the detailed narrative in the Public Health Social Services and Emergency Fund budget justification.

TECHNICAL NOTES

The FY 2025 Budget includes four net zero alignments of funding:

FY 2024 Comparability Adjustment

The FY 2025 Budget includes a net zero comparability adjustment to realign funding from Headquarters to centers and field components so FDA can incorporate new offices into the Working Capital Fund beginning in FY 2024.

FY 2025 Comparability Adjustment

The FY 2025 Budget includes a net zero comparability adjustment to realign funding from Headquarters to centers and field components so FDA can incorporate additional office into the Working Capital Fund beginning in FY 2025.

FDA Infrastructure Cost Realignment

The FY 2025 Budget includes a net zero realignment of budget authority and PDUFA, GDUFA, MDUFA, and BsUFA. The change impacts medical product centers and field components and the ORRR and White Oak infrastructure accounts. This realignment will allow FDA to fully implement Section 905(b) of the FDA Reauthorization Act of 2017 (FDARA) and still be able to fund critically important infrastructure requirements in FY 2024.

Office of Global Policy and Strategy Funding Realignment

The FY 2024 Budget proposes to permanently realign $24.2 million of base budget authority from the Office of Regulatory Affairs (ORA) to FDA Headquarters to support the Office of Global Policy and Strategy (OGPS), formally Office of International Programs (OIP), for the foreign post field activities. This change would result in a net-neutral adjustment in the FY 2024 Budget.

The realignment of this funding will assist with administrative efficiency and enable FDA to continue to follow congressional intent for use of the funding by the foreign offices. The realignment of the funding, which is already administered by OGPS and intended by Congress for use by the foreign offices would: streamline FDA's administration of the foreign offices; streamline accounting practices and provide additional flexibility to administer the foreign office funding to better enable FDA to project and meet future funding needs for the foreign offices; and reduce the time spent on budget planning and execution by deployed personnel at post.

The FDA foreign offices in China, Europe, India, and Latin America work across all FDA commodity programs and having a single source of budget authority, rather than multiple program specific funding designations, will better enable FDA to coordinate across product centers. There are various costs that apply to an agency operating an overseas office, such as annual fixed International Cooperative Administrative Support Services and Capital Security Cost-Sharing payments made to the Department of State, as well as employee costs including housing at post and tuition for eligible family members. The posts are currently funded through a combination of the field funds transferred from ORA, budget authority directly appropriated to OGPS, and user-fee funds made available to OGPS for the oversight of foreign drug manufacturing facilities in India and China.

ALL-PURPOSE TABLE

(Dollars in Thousands)	FY 2023 Final		FY 2024 Annualized CR		FY 2025 President's Budget		FY 2025 President's Budget +/- FY 2023 Final	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	**3,969**	**1,207,864**	**3,944**	**1,197,992**	**3,977**	**1,258,987**	**8**	**51,123**
Budget Authority	***3,925***	***1,196,097***	***3,900***	***1,185,989***	***3,933***	***1,246,745***	***8***	***50,648***
User Fees	***44***	***11,767***	***44***	***12,003***	***44***	***12,242***	***---***	***475***
Center	1,227	402,768	1,227	405,725	1,256	435,497	29	32,729
Budget Authority	1,224	401,867	1,224	404,806	1,253	434,560	29	32,693
User Fees	3	901	3	919	3	937	---	36
Food and Feed Recall	1	263	1	268	1	273	---	10
Voluntary Qualified Importer Program	1	263	1	268	1	273	---	10
Third Party Auditor Program	1	375	1	383	1	391	---	16
Field	2,742	805,096	2,717	792,267	2,721	823,490	-21	18,394
Budget Authority	2,701	794,230	2,676	781,183	2,680	812,185	-21	17,955
User Fees	41	10,866	41	11,084	41	11,305	---	439
Food and Feed Recall	4	1,082	4	1,104	4	1,126	---	44
Food Reinspection	19	4,952	19	5,051	19	5,152	---	200
Voluntary Qualified Importer Program	18	4,676	18	4,770	18	4,865	---	189
Third Party Auditor Program	---	156	---	159	---	162	---	6

Figure 2 - All-Purpose Table 1/10

Human Drugs	**6,953**	**2,283,747**	**7,580**	**2,335,869**	**7,589**	**2,403,402**	**636**	**119,655**
Budget Authority	***2,290***	***761,494***	***2,283***	***719,540***	***2,288***	***754,049***	***-2***	***-7,445***
User Fees	***4,663***	***1,522,253***	***5,297***	***1,616,329***	***5,301***	***1,649,353***	***638***	***127,100***
Center	5,741	1,999,525	6,375	2,053,725	6,393	2,110,936	652	111,411
Budget Authority	1,356	550,993	1,356	513,638	1,361	539,372	5	-11,621
User Fees	4,385	1,448,532	5,019	1,540,087	5,032	1,571,564	647	123,032
Prescription Drug (PDUFA)	2,863	958,619	3,193	1,020,753	3,206	1,041,731	343	83,112
Generic Drug (GDUFA)	1,410	452,136	1,637	490,380	1,637	500,295	227	48,159
Biosimilars (BsUFA)	110	37,097	187	28,231	187	28,801	77	-8,296
Outsourcing Facility	2	680	2	723	2	737	---	57
Field	1,212	284,222	1,205	282,144	1,196	292,466	-16	8,244
Budget Authority	934	210,501	927	205,902	927	214,677	-7	4,176
User Fees	278	73,721	278	76,242	269	77,789	-9	4,068
Prescription Drug (PDUFA)	43	10,167	43	9,000	34	9,186	-9	-981
Generic Drug (GDUFA)	226	61,598	226	65,830	226	67,163	---	5,565
Biosimilars (BsUFA)	7	1,545	7	970	7	989	---	-556
Outsourcing Facility	2	411	2	442	2	451	---	40

Figure 3 - All-Purpose Table 2/10

Biologics	**1,467**	**490,465**	**1,643**	**570,632**	**1,651**	**589,682**	**184**	**99,217**
Budget Authority	***833***	***272,215***	***831***	***267,130***	***835***	***279,986***	***2***	***7,771***
User Fees	***634***	***218,250***	***812***	***303,502***	***816***	***309,696***	***182***	***91,446***
Center	1,227	440,329	1,406	520,972	1,407	536,798	180	96,469
Budget Authority	600	224,165	600	219,828	601	229,508	1	5,343
User Fees	627	216,164	806	301,144	806	307,290	179	91,126
Prescription Drug (PDUFA)	566	194,934	739	281,283	739	287,024	173	92,090
Medical Device (MDUFA)	56	19,857	60	18,495	60	18,873	4	-984
Generic Drug (GDUFA)	4	1,094	4	1,069	4	1,090	---	-4
Biosimilars (BsUFA)	1	279	3	297	3	303	2	24
Field	240	50,136	237	49,660	244	52,884	4	2,748
Budget Authority	233	48,050	231	47,302	234	50,478	1	2,428
User Fees	7	2,086	6	2,358	10	2,406	3	320
Prescription Drug (PDUFA)	6	1,768	6	2,358	10	2,406	4	638
Medical Device (MDUFA)	1	318	---	---	---	---	-1	-318

Figure 4 - All-Purpose Table 3/10

Animal Drugs and Foods	**1,066**	**288,353**	**1,057**	**285,299**	**1,087**	**297,312**	**21**	**8,959**
Budget Authority	***874***	***230,093***	***845***	***229,362***	***875***	***240,253***	***1***	***10,160***
User Fees	***192***	***58,260***	***212***	***55,937***	***212***	***57,059***	***20***	***-1,201***
Center	739	204,730	733	203,111	763	212,160	24	7,430
Budget Authority	553	148,141	527	148,484	557	156,438	4	8,297
User Fees	186	56,589	206	54,627	206	55,722	20	-867
Animal Drug (ADUFA)	115	29,100	115	30,852	115	31,472	---	2,372
Animal Generic Drug (AGDUFA)	71	27,368	91	23,652	91	24,125	20	-3,243
Third Party Auditor Program	---	121	---	123	---	125	---	4
Field	327	83,623	324	82,188	324	85,152	-3	1,529
Budget Authority	321	81,952	318	80,878	318	83,815	-3	1,863
User Fees	6	1,671	6	1,310	6	1,337	---	-334
Animal Drug (ADUFA)	2	400	2	291	2	297	---	-103
Animal Generic Drug (AGDUFA)	1	397	1	128	1	131	---	-266
Food Reinspection	3	874	3	891	3	909	---	35
Third Party Auditor Program	---	---	---	---	---	---	---	---

Figure 5 - All-Purpose Table 4/10

Devices and Radiological Health	**2,517**	**746,249**	**2,555**	**790,375**	**2,586**	**818,659**	**69**	**72,410**
Budget Authority	***1,539***	***449,597***	***1,535***	***444,534***	***1,544***	***465,778***	***5***	***16,181***
User Fees	***978***	***296,652***	***1,020***	***345,841***	***1,042***	***352,881***	***64***	***56,229***
Center	2,002	637,759	2,044	683,710	2,068	704,452	66	66,693
Budget Authority	1,044	356,362	1,044	352,697	1,046	366,695	2	10,333
User Fees	958	281,397	1,000	331,013	1,022	337,757	64	56,360
Prescription Drug (PDUFA)	15	5,652	15	2,135	15	2,181	---	-3,471
Medical Device (MDUFA)	915	268,425	957	321,411	979	327,960	64	59,535
Mammography Quality Standards Act (MQSA)	28	7,320	28	7,467	28	7,616	---	296
Field	515	108,490	511	106,665	518	114,207	3	5,717
Budget Authority	495	93,235	491	91,837	498	99,083	3	5,848
User Fees	20	15,255	20	14,828	20	15,124	---	-131
Medical Device (MDUFA)	11	3,283	11	2,617	11	2,670	---	-613
Mammography Quality Standards Act (MQSA)	9	11,972	9	12,211	9	12,454	---	482
National Center for Toxicological Research (BA Only)	**286**	**76,919**	**286**	**77,505**	**286**	**80,590**	**---**	**3,671**
Tobacco	**1,303**	**677,165**	**1,303**	**684,324**	**1,363**	**798,588**	**60**	**121,423**
Center	**1,218**	**654,671**	**1,213**	**661,627**	**1,273**	**775,891**	**55**	**121,220**
User Fees	1,218	654,671	1,213	661,627	1,273	775,891	55	121,220
Family Smoking Prevention and Tobacco Control Act	1,218	654,671	1,213	661,627	1,273	661,651	55	6,980
Expand tobacco products (Proposed)	---	---	---	---	---	114,240	---	114,240
Field	**85**	**22,494**	**90**	**22,697**	**90**	**22,697**	**5**	**203**
Family Smoking Prevention and Tobacco Control Act	85	22,494	90	22,697	90	22,697	5	203

Figure 6 - All-Purpose Table 5/10

FDA Headquarters	**963**	**362,323**	**988**	**377,042**	**1,018**	**396,735**	**55**	**34,412**
Budget Authority	550	222,940	591	232,427	621	250,403	71	27,463
User Fees	***413***	***139,383***	***397***	***144,615***	***397***	***146,332***	***-16***	***6,949***
Prescription Drug (PDUFA)	215	65,747	224	73,545	224	74,326	9	8,579
Medical Device (MDUFA)	36	14,271	34	11,741	34	11,845	-2	-2,426
Generic Drug (GDUFA)	100	38,986	80	44,479	80	45,248	-20	6,262
Biosimilars (BsUFA)	8	1,051	8	1,464	8	1,488	---	437
Animal Drug (ADUFA)	4	954	4	1,017	4	1,034	---	80
Animal Generic Drug (AGDUFA)	3	949	3	720	3	734	---	-215
Family Smoking Prevention and Tobacco Control Act	43	15,949	40	10,129	40	10,105	-3	-5,844
Mammography Quality Standards Act (MQSA)	---	79	---	80	---	82	---	3
Food and Feed Recall	---	81	---	83	---	85	---	4
Food Reinspection	2	519	2	529	2	540	---	21
Voluntary Qualified Importer Program	1	300	1	306	1	312	---	12
Third Party Auditor Program	---	42	---	43	---	44	---	2
Outsourcing Facility	1	455	1	479	1	489	---	34
Innovative Food Products (Proposed)	---	---	---	---	---	---	---	---
FDA White Oak Campus	**---**	**56,293**	**---**	**55,061**	**---**	**55,061**	**---**	**-1,232**
Budget Authority	---	48,414	---	52,498	---	52,498	---	4,084
User Fees	***---***	***7,879***	***---***	***2,563***	***---***	***2,563***	***---***	***-5,316***
Prescription Drug (PDUFA)	---	4,286	---	---	---	---	---	-4,286
Medical Device (MDUFA)	---	---	---	---	---	---	---	---
Generic Drug (GDUFA)	---	---	---	---	---	---	---	---
Biosimilars (BsUFA)	---	---	---	---	---	---	---	---
Animal Drug (ADUFA)	---	---	---	---	---	---	---	---
Animal Generic Drug (AGDUFA)	---	---	---	---	---	---	---	---
Family Smoking Prevention and Tobacco Control Act	---	3,593	---	2,563	---	2,563	---	-1,030

Figure 7 - All-Purpose Table 6/10

Other Rent and Rent Related	**---**	**164,550**	**---**	**161,127**	**---**	**162,749**	**---**	**-1,801**
Budget Authority	---	106,095	---	154,879	---	156,479	---	50,384
User Fees	**---**	***58,455***	**---**	***6,248***	**---**	***6,270***	**---**	***-52,185***
Prescription Drug (PDUFA)	---	29,391	---	---	---	---	---	-29,391
Medical Device (MDUFA)	---	7,200	---	---	---	---	---	-7,200
Generic Drug (GDUFA)	---	14,541	---	---	---	---	---	-14,541
Biosimilars (BsUFA)	---	1,145	---	---	---	---	---	-1,145
Animal Drug (ADUFA)	---	820	---	335	---	342	---	-478
Animal Generic Drug (AGDUFA)	---	272	---	250	---	255	---	-17
Family Smoking Prevention and Tobacco Control Act	---	4,572	---	5,176	---	5,176	---	604
Food and Feed Recall	---	47	---	48	---	49	---	2
Food Reinspection	---	220	---	224	---	228	---	8
Voluntary Qualified Importer Program	---	184	---	188	---	192	---	8
Third Party Auditor Program	---	26	---	27	---	28	---	2
Outsourcing Facility	---	37	---	---	---	---	---	-37
GSA Rental Payments	**---**	**244,884**	**---**	**231,328**	**---**	**221,533**	**---**	**-23,351**
Budget Authority	---	166,286	---	166,286	---	155,386	---	-10,900
User Fees	**---**	***78,598***	**---**	***65,042***	**---**	***66,147***	**---**	***-12,451***
Prescription Drug (PDUFA)	---	39,755	---	33,030	---	33,691	---	-6,064
Medical Device (MDUFA)	---	11,423	---	8,117	---	8,279	---	-3,144
Generic Drug (GDUFA)	---	14,145	---	11,780	---	12,016	---	-2,129
Biosimilars (BsUFA)	---	483	---	147	---	150	---	-333
Animal Drug (ADUFA)	---	870	---	1,005	---	1,025	---	155
Animal Generic Drug (AGDUFA)	---	317	---	250	---	255	---	-62
Family Smoking Prevention and Tobacco Control Act	---	10,721	---	9,808	---	9,808	---	-913
Food and Feed Recall	---	79	---	81	---	83	---	4
Food Reinspection	---	377	---	384	---	392	---	15
Voluntary Qualified Importer Program	---	314	---	320	---	326	---	12
Third Party Auditor Program	---	51	---	52	---	53	---	2
Outsourcing Facility	---	63	---	68	---	69	---	6

Figure 8 - All-Purpose Table 7/10

Color Certification	37	10,891	37	11,109	37	11,331	---	440
Export Certification	26	5,083	26	5,185	26	5,289	---	206
Export Certification (Proposed)	---	---	---	---	---	4,633	---	4,633
Priority Review Vouchers (PRV) Tropical Disease	---	2,660	---	2,713	---	2,767	---	107
Priority Review Vouchers (PRV) Pediatric Disease	11	8,320	11	8,486	11	8,656	---	336
Priority Review Vouchers (PRV) Medical Countermeasures	---	2,660	---	---	---	---	---	-2,660
Over the Counter Monograph	---	30,356	93	32,253	93	32,898	93	2,542
21st Century Cures (BA Only)	187	50,000	187	50,000	187	55,000	---	5,000
Subtotal, Salaries and Expenses	**18,785**	**6,708,782**	**19,710**	**6,876,300**	**19,911**	**7,203,872**	**1,126**	**495,090**
Buildings and Facilities (Budget Authority)	---	**12,788**	**---**	**12,788**	**---**	**12,788**	---	---
Total Program Level	**18,785**	**6,721,570**	**19,710**	**6,889,088**	**19,911**	**7,216,660**	**1,126**	**495,090**
Non-Field Activities	*13,477*	*4,838,994*	*14,439*	*5,043,163*	*14,631*	*5,318,633*	*1,154*	*479,639*
Field Activities	*5,121*	*1,354,061*	*5,084*	*1,335,621*	*5,093*	*1,390,896*	*-28*	*36,835*
White Oak, Rent Activities, and B&F	---	*478,515*	---	*460,304*	---	*452,131*	---	*-26,384*
Food and Drug Safety -- No Year	---	---	---	---	---	---	---	---
MCMi - No Year	---	---	---	---	---	---	---	---
Opioids - No Year	---	---	---	---	---	---	---	---
21st Century Cures	*187*	*50,000*	*187*	*50,000*	*187*	*55,000*	---	*5,000*
User Fees:								
Current Law								
Prescription Drug (PDUFA)	*3,708*	*1,310,319*	*4,220*	*1,422,104*	*4,228*	*1,450,545*	*520*	*140,226*
Medical Device (MDUFA)	*1,019*	*324,777*	*1,062*	*362,381*	*1,084*	*369,627*	*65*	*44,850*
Generic Drug (GDUFA)	*1,740*	*582,500*	*1,947*	*613,538*	*1,947*	*625,812*	*207*	*43,312*
Biosimilars (BsUFA)	*126*	*41,600*	*205*	*31,109*	*205*	*31,731*	*79*	*-9,869*
Animal Drug (ADUFA)	*121*	*32,144*	*121*	*33,500*	*121*	*34,170*	---	*2,026*
Animal Generic Drug (AGDUFA)	*75*	*29,303*	*95*	*25,000*	*95*	*25,500*	*20*	*-3,803*
Family Smoking Prevention and Tobacco Control Act	*1,346*	*712,000*	*1,343*	*712,000*	*1,403*	*712,000*	*57*	---
Subtotal, Current Law	**8,135**	**3,032,643**	**8,993**	**3,199,632**	**9,083**	**3,249,385**	**948**	**216,742**

Figure 9 - All-Purpose Table 8/10

Indefinite								
Mammography Quality Standards Act (MQSA)	*37*	*19,371*	*37*	*19,758*	*37*	*20,152*	*---*	*781*
Color Certification	*37*	*10,891*	*37*	*11,109*	*37*	*11,331*	*---*	*440*
Export Certification	*26*	*5,083*	*26*	*5,185*	*26*	*5,289*	*---*	*206*
Priority Review Vouchers (PRV) Tropical Disease	*---*	*2,660*	*---*	*2,713*	*---*	*2,767*	*---*	*107*
Priority Review Vouchers (PRV) Pediatric Disease	*11*	*8,320*	*11*	*8,486*	*11*	*8,656*	*---*	*336*
Priority Review Vouchers (PRV) Medical Countermeasures	*---*	*2,660*	*---*	*---*	*---*	*---*	*---*	*-2,660*
Food and Feed Recall	*5*	*1,552*	*5*	*1,584*	*5*	*1,616*	*---*	*64*
Food Reinspection	*24*	*6,942*	*24*	*7,079*	*24*	*7,221*	*---*	*279*
Voluntary Qualified Importer Program	*20*	*5,737*	*20*	*5,852*	*20*	*5,968*	*---*	*231*
Third Party Auditor Program	*1*	*771*	*1*	*787*	*1*	*803*	*---*	*32*
Outsourcing Facility	*5*	*1,646*	*5*	*1,712*	*5*	*1,746*	*---*	*100*
Over the Counter Monograph	*---*	*30,356*	*93*	*32,253*	*93*	*32,898*	*93*	*2,542*
Subtotal, Indefinite	**166**	**95,989**	**259**	**96,518**	**259**	**98,447**	**93**	**2,458**
Proposed								
Export Certification (Proposed)	*---*	*---*	*---*	*---*	*---*	*4,633*	*---*	*4,633*
Expand tobacco products (Proposed)	*---*	*---*	*---*	*---*	*---*	*114,240*	*---*	*114,240*
Subtotal, Proposed	***---***	***---***	***---***	***---***	***---***	***118,873***	***---***	***118,873***
Total User Fees	**8,301**	**3,128,632**	**9,252**	**3,296,150**	**9,342**	**3,466,705**	**1,041**	**338,073**
Total Budget Authority, Pre-Transfer	**10,484**	**3,592,938**	**10,458**	**3,592,938**	**10,569**	**3,749,955**	**85**	**157,017**
BA, S&E	*10,297*	*3,530,150*	*10,271*	*3,530,150*	*10,382*	*3,682,167*	*85*	*152,017*
BA, B&F	*---*	*12,788*	*---*	*12,788*	*---*	*12,788*	*---*	*---*
21st Century Cures	*187*	*50,000*	*187*	*50,000*	*187*	*55,000*	*---*	*5,000*
Total Program Level, Pre-Transfer	**18,785**	**6,721,570**	**19,710**	**6,889,088**	**19,911**	**7,216,660**	**1,126**	**495,090**

Figure 10 - All-Purpose Table 9/10

HHS OIG transfer (BA Only)	---	-1,500	---	-1,500	---	-1,500	---	---
Total Budget Authority, Post-Transfer	10,484	3,591,438	10,458	3,591,438	10,569	3,748,455	85	157,017
Total User Fees	8,301	3,128,632	9,252	3,296,150	9,342	3,466,705	1,041	338,073
Total Program Level, Post-Transfer	18,785	6,720,070	19,710	6,887,588	19,911	7,215,160	1,126	495,090
Strengthening Biodefense (non-add)	---	---	---	---	---	670,000	---	670,000
NEF	---	109,070	---	62,600		113,900	---	4,830

*FY 2023 Actuals do not include $152.34M COVID-19 Supplemental, $66.3M collections and refunds.

**FY 2023 Actual FTE figures do not include 49 Reimbursable, 169 COVID-19 Supplemental, 4 FOIA, 31 PEPFAR, 25 HCFAC, 5 COVID-19 IDDA.

***FY 2023 Final level reflects Transfer/Reprogramming notification reallocating $1.5M provided in FY 2023 to support Foreign Unannounced Human Drug Inspection Pilots from Human Drugs Center to Human Drugs Field. This level also includes transfer notification #2 for the Neurology Drug Program which moved $2 million from FDA Headquarters to Human Drugs ($1 million), Devices and Radiological Health ($0.3 million) and Biologics ($0.7 million).

****FY 2023 Final level corrects Opioids FTEs enacted to FY 2018 Omnibus.

*****FDA Headquarters Budget Authority shown is not inclusive of the $1.5M OIG transfer amount.

******FY 2024 CR level includes Sec 905 BA/UF swap, ORA/OGPS transfer, and an updated FY 2024 comparability adjustment.

*******FY 2024 Annualized CR user fee estimates reflect the FRN target revenue based on a proportional allocation of the FY 2024 five-year plans.

********The FY 2025 budget also provides $20 billion in mandatory funding across HHS for strengthening biodefense, which is reflected in the Public Health and Social Services Emergency Fund chapter. Of this total, FDA will receive $670 million.

*********FY 2025 PB reflects a comparability adjustment for WCF new entrants.

**********FY 2025 PB user fee estimates reflect a 2% increase in dollars from FY 2024 Annualized CR levels.

**********Reflects amounts appropriated and any reprogrammings or reallocations notified to Congress.

**********Amounts are different from what is reflected in MAX due to reallocations. FDA will formally transmit these corrections as part of the Administration's corrections package after transmission. □

**********The APT will not include future estimates for PRV MCM as the authority to issue new PRVs expired after 10.01.2023. However, FDA did retain authority to assess and collect when an existing PRV is used which may result in funding amounts under actuals.

Figure 11 - All-Purpose Table 10/10

BUDGET AUTHORITY CROSSWALK

(Dollars in Thousands)	FY 2023 Final		FY 2024 Adjustments and Shifts							
			ORA Transfer to HQ/OGPS		FDARA Sec. 905 BA Shift		FY 2024 Comparability Adjustment		Total Changes	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:										
Foods	**3,925**	**1,196,097**	**-25**	**-16,214**	**---**	**---**	**---**	**6,106**	**-25**	**-10,108**
Center	1,224	401,867	---	---	---	---	---	2,939	---	2,939
Field	2,701	794,230	-25	-16,214	---	---	---	3,167	-25	-13,047
Human Drugs	**2,290**	**761,494**	**-7**	**-3,630**	**---**	**-41,669**	**---**	**3,345**	**-7**	**-41,954**
Center	1,356	550,993	---	---	---	-39,667	---	2,312	---	-37,355
Field	934	210,501	-7	-3,630	---	-2,002	---	1,033	-7	-4,599
Biologics	**833**	**272,215**	**-2**	**-968**	**---**	**-5,816**	**---**	**1,699**	**-2**	**-5,085**
Center	600	224,165	---	---	---	-5,761	---	1,424	---	-4,337
Field	233	48,050	-2	-968	---	-55	---	275	-2	-748
Animal Drugs and Foods	**874**	**230,093**	**-3**	**-1,452**	**---**	**---**	**---**	**721**	**-3**	**-731**
Center	553	148,141	---	---	---	---	---	343	---	343
Field	321	81,952	-3	-1,452	---	---	---	378	-3	-1,074
Devices and Radiological Health	**1,539**	**449,597**	**-4**	**-1,936**	**---**	**-5,383**	**---**	**2,256**	**-4**	**-5,063**
Center	1,044	356,362	---	---	---	-5,320	---	1,655	---	-3,665
Field	495	93,235	-4	-1,936	---	-63	---	601	-4	-1,398
National Center for Toxicological Research	**286**	**76,919**	**---**	**---**	**---**	**---**	**---**	**586**	**---**	**586**
FDA Headquarters	**550**	**222,940**	**41**	**24,200**	**---**	**---**	**---**	**-14,713**	**41**	**9,487**
FDA White Oak Complex	**---**	**48,414**	**---**	**---**	**---**	**4,084**	**---**	**---**	**---**	**4,084**
Other Rent and Rent Related	**---**	**106,095**	**---**	**---**	**---**	**48,784**	**---**	**---**	**---**	**48,784**
GSA Rental Payments	**---**	**166,286**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Subtotal, Salaries and Expenses Account	**10,297**	**3,530,150**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Buildings and Facilities Account	**---**	**12,788**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Total Budget Authority, Pre-Transfer	**10,297**	**3,542,938**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Non-Field Activities	**5,613**	**1,981,387**	**41**	**24,200**	**---**	**-50,748**	**---**	**-5,454**	**41**	**-32,002**
Field Activities	**4,684**	**1,227,968**	**-41**	**-24,200**	**---**	**-2,120**	**---**	**5,454**	**-41**	**-20,866**
Rent Activities, B&F, and White Oak	**---**	**333,583**	**---**	**---**	**---**	**52,868**	**---**	**---**	**---**	**52,868**
21st Century Cures	**187**	**50,000**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Total Budget Authority with 21st Century Cures	**10,484**	**3,592,938**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
HHS OIG transfer	**---**	**-1,500**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Total Budget Authority, Post-Transfer	**10,484**	**3,591,438**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**

Figure 12 - Budget Authority Crosswalk 1/3

(Dollars in Thousands)	FY 2023 Final		FY 2025 CJ									
			FY 2025 Comparability Adjustment		Infrastructure and B&F		Enhancing Food Safety and Nutrition				Advancing Medical Product Safety	
							Human Foods Program		Total Food Safety		Total Medical Product Safety	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:												
Foods	**3,925**	**1,196,097**	---	**579**	---	---	**29**	**15,000**	**29**	**15,000**	---	---
Center	1,224	401,867	---	196	---	---	27	13,700	27	13,700	---	---
Field	2,701	794,230	---	383	---	---	2	1,300	2	1,300	---	---
Human Drugs	**2,290**	**761,494**	---	**468**	---	---	---	---	---	---	---	---
Center	1,356	550,993	---	327	---	---	---	---	---	---	---	---
Field	934	210,501	---	141	---	---	---	---	---	---	---	---
Biologics	**833**	**272,215**	---	**148**	---	---	---	---	---	---	---	---
Center	600	224,165	---	114	---	---	---	---	---	---	---	---
Field	233	48,050	---	34	---	---	---	---	---	---	---	---
Animal Drugs and Foods	**874**	**230,093**	---	**141**	---	---	---	---	---	---	---	---
Center	553	148,141	---	95	---	---	---	---	---	---	---	---
Field	321	81,952	---	46	---	---	---	---	---	---	---	---
Devices and Radiological Health	**1,539**	**449,597**	---	**325**	---	---	---	---	---	---	---	---
Center	1,044	356,362	---	252	---	---	---	---	---	---	---	---
Field	495	93,235	---	73	---	---	---	---	---	---	---	---
National Center for Toxicological Research	**286**	**76,919**	---	**-47**	---	---	---	---	---	---	---	---
FDA Headquarters	**550**	**222,940**	---	**-1,614**	---	---	---	---	---	---	---	---
FDA White Oak Complex	---	**48,414**	---	---	---	---	---	---	---	---	---	---
Other Rent and Rent Related	---	**106,095**	---	---	---	**1,600**	---		---	---	---	---
GSA Rental Payments	---	**166,286**	---	---	---	**-10,900**	---		---	---	---	---
Subtotal, Salaries and Expenses Account	**10,297**	**3,530,150**	---	---	---	**-9,300**	**29**	**15,000**	**29**	**15,000**	---	---
Buildings and Facilities Account	---	**12,788**	---	---	---	---	---	---	---	---	---	---
Total Budget Authority, Pre-Transfer	**10,297**	**3,542,938**	---	---	---	**-9,300**	**29**	**15,000**	**29**	**15,000**	---	---
Non-Field Activities	**5,613**	**1,981,387**	---	**-677**	---	---	**27**	**13,700**	**27**	**13,700**	---	---
Field Activities	**4,684**	**1,227,968**	---	**677**	---	---	**2**	**1,300**	**2**	**1,300**	---	---
Rent Activities, B&F, and White Oak	---	**333,583**	---	---	---	**-9,300**	---	---	---	---	---	---
21st Century Cures	**187**	**50,000**	---	---	---	---	---	---	---	---	---	**5,000**
Total Budget Authority with 21st Century Cures	**10,484**	**3,592,938**	---	---	---	**-9,300**	**29**	**15,000**	**29**	**15,000**	---	**5,000**
HHS OIG transfer	---	**-1,500**	---	---	---	---	---	---	---	---	---	---
Total Budget Authority, Post-Transfer	**10,484**	**3,591,438**	---	---	---	**-9,300**	**29**	**15,000**	**29**	**15,000**	---	**5,000**

Figure 13 - Budget Authority Crosswalk 2/3

(Dollars in Thousands)	FY 2023 Final		FY 2025 CJ														Total Changes		FY 2025 President's Budget	
			Investing in Core Operations - Crosscutting																	
			Modernization of Cosmetics		Shortages and Supply Chain		Foreign Office Expansion		IT Stabilization & Modernization		Public Health Employee Pay Costs		ETO		Total Crosscutting					
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:																				
Foods	**3,925**	**1,196,097**	—	—	**2**	**1,084**	—	—	—	**1,500**	—	**42,156**	**2**	**437**	**4**	**45,177**	**8**	**50,648**	**3,933**	**1,246,745**
Center	1,224	401,867	—	—	2	1,084	—	—	—	479	—	14,156	—	139	2	15,858	29	32,693	1,253	434,560
Field	2,701	794,230	—	—	—	—	—	—	—	1,021	—	28,000	2	298	2	29,319	-21	17,955	2,680	812,185
Human Drugs	**2,290**	**761,494**	—	—	**3**	**4,767**	—	—	—	**3,500**	—	**25,081**	**2**	**693**	**5**	**34,041**	**-2**	**-7,445**	**2,288**	**754,049**
Center	1,356	550,993	—	—	3	4,767	—	—	—	3,075	—	16,956	2	609	5	25,407	5	-11,621	1,361	539,372
Field	934	210,501	—	—	—	—	—	—	—	425	—	8,125	—	84	—	8,634	-7	4,176	927	214,677
Biologics	**833**	**272,215**	—	—	**4**	**2,032**	—	—	—	**700**	—	**9,788**	—	**188**	**4**	**12,708**	**2**	**7,771**	**835**	**279,986**
Center	600	224,165	—	—	1	1,218	—	—	—	608	—	7,577	—	163	1	9,566	1	5,343	601	229,508
Field	233	48,050	—	—	3	814	—	—	—	92	—	2,211	—	25	3	3,142	1	2,428	234	50,478
Animal Drugs and Foods	**874**	**230,093**	—	—	**4**	**1,349**	—	—	—	**400**	—	**8,900**	—	**101**	**4**	**10,750**	**1**	**10,160**	**875**	**240,253**
Center	553	148,141	—	—	4	1,349	—	—	—	264	—	6,179	—	67	4	7,859	4	8,297	557	156,438
Field	321	81,952	—	—	—	—	—	—	—	136	—	2,721	—	34	—	2,891	-3	1,863	318	83,815
Devices and Radiological Health	**1,539**	**449,597**	—	—	**7**	**2,148**	—	—	—	**1,000**	—	**17,522**	**2**	**249**	**9**	**20,919**	**5**	**16,181**	**1,544**	**465,778**
Center	1,044	356,362	—	—	—	256	—	—	—	782	—	12,514	2	194	2	13,746	2	10,333	1,046	366,695
Field	495	93,235	—	—	7	1,892	—	—	—	218	—	5,008	—	55	7	7,173	3	5,848	498	99,083
National Center for Toxicological Research	**286**	**76,919**	—	—	—	**52**	—	—	—	**150**	—	**2,891**	—	**39**	—	**3,132**	—	**3,671**	**286**	**80,590**
FDA Headquarters	**550**	**222,940**	**24**	**8,000**	**2**	**868**	**4**	**1,000**	—	**1,000**	—	**8,429**	—	**293**	**30**	**19,590**	**71**	**27,463**	**621**	**250,403**
FDA White Oak Complex	—	**48,414**	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	**4,084**	—	**52,498**
Other Rent and Rent Related	—	**106,095**	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	**50,384**	—	**156,479**
GSA Rental Payments	—	**166,286**	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	**-10,900**	—	**155,386**
Subtotal, Salaries and Expenses Account	**10,297**	**3,530,150**	**24**	**8,000**	**22**	**12,300**	**4**	**1,000**	—	**8,250**	—	**114,767**	**6**	**2,000**	**56**	**146,317**	**85**	**152,017**	**10,382**	**3,682,167**
Buildings and Facilities Account	—	**12,788**		—		—	—	—	—	—	—	—	—	—	—	—	—	—	—	**12,788**
Total Budget Authority, Pre-Transfer	**10,297**	**3,542,938**	**24**	**8,000**	**22**	**12,300**	**4**	**1,000**	—	**8,250**	—	**114,767**	**6**	**2,000**	**56**	**146,317**	**85**	**152,017**	**10,382**	**3,694,955**
Non-Field Activities	**5,613**	**1,981,387**	**24**	**8,000**	**12**	**9,594**	**4**	**1,000**	—	**6,358**	—	**68,702**	**4**	**1,504**	**44**	**95,158**	**112**	**76,179**	**5,725**	**2,057,566**
Field Activities	**4,684**	**1,227,968**	—	—	**10**	**2,706**	—	—	—	**1,892**	—	**46,065**	**2**	**496**	**12**	**51,159**	**-27**	**32,270**	**4,657**	**1,260,238**
Rent Activities, B&F, and White Oak	—	**333,583**	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	**-9,300**	—	**377,151**
21st Century Cures	**187**	**50,000**	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	**5,000**	**187**	**55,000**
Total Budget Authority with 21st Century Cures	**10,484**	**3,592,938**	**24**	**8,000**	**22**	**12,300**	**4**	**1,000**	—	**8,250**	—	**114,767**	**6**	**2,000**	**56**	**146,317**	**85**	**157,017**	**10,569**	**3,749,955**
HHS OIG transfer	—	**-1,500**	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	**-1,500**
Total Budget Authority, Post-Transfer	**10,484**	**3,591,438**	**24**	**8,000**	**22**	**12,300**	**4**	**1,000**	—	**8,250**	—	**114,767**	**6**	**2,000**	**56**	**146,317**	**85**	**157,017**	**10,569**	**3,748,455**

Figure 14 - Budget Authority Crosswalk 3/3

APPROPRIATION LANGUAGE

SALARIES AND EXPENSES (INCLUDING TRANSFERS OF FUNDS)

For necessary expenses of the Food and Drug Administration, including hire and purchase of passenger motor vehicles; for payment of space rental and related costs pursuant to Public Law 92–313 for programs and activities of the Food and Drug Administration which are included in this Act; for rental of special purpose space in the District of Columbia or elsewhere; in addition to amounts appropriated to the FDA Innovation Account, for carrying out the activities described in section 1002(b)(4) of the 21st Century Cures Act (Public Law 114–255); for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed $25,000; and notwithstanding section 521 of Public Law 107–188; $6,931,552,000: Provided, That of the amount provided under this heading, $48,050,000 shall remain available until September 30, 2026, for information technology stabilization and modernization activities, and for enterprise transformation activities: Provided, That of the amount provided under this heading, $1,450,545,000 shall be derived from prescription drug user fees authorized by 21 U.S.C. 379h, and shall be credited to this account and remain available until expended; $369,627,000 shall be derived from medical device user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended; $625,812,000 shall be derived from human generic drug user fees authorized by 21 U.S.C. 379j–42, and shall be credited to this account and remain available until expended; $31,731,000 shall be derived from biosimilar biological product user fees authorized by 21 U.S.C. 379j–52, and shall be credited to this account and remain available until expended; $34,170,000 shall be derived from animal drug user fees authorized by 21 U.S.C. 379j–12, and shall be credited to this account and remain available until expended; $25,500,000 shall be derived from generic new animal drug user fees authorized by 21 U.S.C. 379j–21, and shall be credited to this account and remain available until expended; $712,000,000 shall be derived from tobacco product user fees authorized by 21 U.S.C. 387s, and shall be credited to this account and remain available until expended: Provided further, That in addition to and notwithstanding any other provision under this heading, amounts collected for prescription drug user fees, medical device user fees, human generic drug user fees, biosimilar biological product user fees, animal drug user fees, and generic new animal drug user fees that exceed the respective fiscal year 2025 limitations are appropriated and shall be credited to this account and remain available until expended: Provided further, That fees derived from prescription drug, medical device, human generic drug, biosimilar biological product, animal drug, and generic new animal drug assessments for fiscal year 2025, including any such fees collected prior to fiscal year 2025 but credited for fiscal year 2025, shall be subject to the fiscal year 2025 limitations: Provided further, That the Secretary may accept payment during fiscal year 2024 of user fees specified under this heading and authorized for fiscal year 2026, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year 2026 for which the Secretary accepts payment in fiscal year 2025 shall not be included in amounts under this heading: Provided further, That none of these funds shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701: Provided further, That of the total amount appropriated: (1) $1,246,745,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $2,402,214,000* shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs; (3) $589,682,000* shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory*

Affairs; (4) $296,278,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $798,589,000* shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $80,590,000* shall be for the National Center for Toxicological Research; (7) $798,588,000 shall be for the Center for Tobacco Products and for related field activities in the Office of Regulatory Affairs; (8) $217,313,000 shall be for Rent and Related activities, of which $55,061,000 is for White Oak Consolidation, other than the amounts paid to the General Services Administration for rent; (9) $220,610,000 shall be for payments to the General Services Administration for rent; and (10) $369,183,000* shall be for other activities, including the Office of the Commissioner of Food and Drugs, the Office of Food Policy and Response, the Office of Operations, the Office of the Chief Scientist, and central services for these offices: Provided further, That not to exceed $25,000 of this amount shall be for official reception and representation expenses, not otherwise provided for, as determined by the Commissioner: Provided further, That any transfer of funds pursuant to, and for the administration of, section 770(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(n)) shall only be from amounts made available under this heading for other activities and shall not exceed $2,000,000: Provided further, That of the amounts that are made available under this heading for "other activities", and that are not derived from user fees, $1,500,000 shall be transferred to and merged with the appropriation for "Department of Health and Human Services—Office of Inspector General" for oversight of the programs and operations of the Food and Drug Administration and shall be in addition to funds otherwise made available for oversight of the Food and Drug Administration: Provided further, That funds may be transferred from one specified activity to another after notice to the Committees on Appropriations of both Houses of Congress.*

In addition, mammography user fees authorized by 42 U.S.C. 263b, export certification user fees authorized by 21 U.S.C. 381, priority review user fees authorized by 21 U.S.C. 360n and 360ff, food and feed recall fees, food reinspection fees, and voluntary qualified importer program fees authorized by 21 U.S.C. 379j–31, outsourcing facility fees authorized by 21 U.S.C. 379j–62, prescription drug wholesale distributor licensing and inspection fees authorized by 21 U.S.C. 353(e)(3), third-party logistics provider licensing and inspection fees authorized by 21 U.S.C. 360eee–3(c)(1), third-party auditor fees authorized by 21 U.S.C. 384d(c)(8), medical countermeasure priority review voucher user fees authorized by 21 U.S.C. 360bbb–4a, and fees relating to over-the-counter monograph drugs authorized by 21 U.S.C. 379j–72 shall be credited to this account, to remain available until expended.

**Note - Numbers in the FY 2025 Congressional Justification reflect the latest revisions that may not be in MAX database. Revisions to the numbers in appropriations language may be formally transmitted in a Budget corrections package after the Budget release*

Buildings and Facilities

For plans, construction, repair, improvement, extension, alteration, demolition, and purchase of fixed equipment or facilities of or used by the Food and Drug Administration, where not otherwise provided, $12,788,000, to remain available until expended.

Note - A full-year 2024 appropriation for this account was not enacted at the time the Budget was prepared; therefore, the Budget assumes this account is operating under the Continuing Appropriations Act, 2024 and Other Extensions Act (Division A of Public Law 118–15, as

amended). The amounts included for 2024 reflect the annualized level provided by the continuing resolution.

FDA Innovation Account, Cures Act (Including Transfers of Funds)

For necessary expenses to carry out the purposes described under section 1002(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes under the heading "Salaries and Expenses," $55,000,000, to remain available until expended: Provided, That amounts appropriated in this paragraph are appropriated pursuant to section 1002(b)(3) of the 21st Century Cures Act, are to be derived from amounts transferred under section 1002(b)(2)(A) of such Act, and may be transferred by the Commissioner of Food and Drugs to the appropriation for "Department of Health and Human Services Food and Drug Administration Salaries and Expenses" solely for the purposes provided in such Act: Provided further, That upon a determination by the Commissioner that funds transferred pursuant to the previous proviso are not necessary for the purposes provided, such amounts may be transferred back to the account: Provided further, That such transfer authority is in addition to any other transfer authority provided by law.

Salaries and Expenses (Legislative Proposal)

Contingent upon the enactment of authorizing legislation establishing fees under 21 U.S.C. 387s with respect to products deemed under 21 U.S.C. 387a(b) but not specified in 21 U.S.C. 387s(b)(2)(B), the Secretary shall assess and collect such fees, which shall be credited to this account and remain available until expended, in addition to amounts otherwise derived from fees authorized under 21 U.S.C. 387s.

Appropriation Language Analysis

Additional information on the proposals may be found within the A-19 appendix.

Language Provision	Explanation
Export Certification Fee	The Administration will propose legislation to allow FDA to increase the funding cap for the export certification fee from $175 per certification to $600 per certification for an estimated total of $9,536,000. This proposal, and the increased certification fee ceiling it promotes, is necessary to ensure that FDA can efficiently implement the export certification program, while ensuring that other public health programs do not suffer.
Tobacco Control Act Fee Increase	The Administration will propose legislation to increase the fees collected under the Tobacco Control Act. This will allow FDA to include all deemed products in the tobacco user fee assessments.

AMOUNTS AVAILABLE FOR OBLIGATION

Food and Drug Administration
Amounts Available for Obligation
(Dollars in Thousands)

(dollars in thousands)	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget
General Fund Discretionary Appropriation:			
Appropriation	3,591,438	3,591,438	3,748,455
Total Discretionary Appropriation	**3,591,438**	**3,591,438**	**3,748,455**
Mandatory Appropriation:			
CRADA	2,000	2,000	2,000
Total Mandatory Appropriation	**2,000**	**2,000**	**2,000**
Offsetting Collections:			
Non-Federal Sources:	3,128,632	3,296,150	3,466,705
Total Offsetting Collections	**3,128,632**	**3,296,150**	**3,466,705**
Total Obligations	**6,722,070**	**6,889,588**	**7,217,160**

*FY 2023, FY 2024 and FY 2025 levels reflect the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.

Figure 15 – Amounts Available for Obligation

SUMMARY OF CHANGES

Food and Drug Administration
Summary of Changes
(Dollars in millions)

FY 2023 Final	
Total estimated budget authority	$3,591.438
(Obligations)	
FY 2025 President's Budget	
Total estimated budget authority	$3,748.455
(Obligations)	
Net Change	+$157.017

	FY 2023 Final		FY 2025 President's Budget		FY 2025 +/- FY 2023	
	FTE	BA	FTE	BA	FTE	BA
Increases:						
Built-in:						
Commissioned corps pay increase	--	--	--	$6.994	--	+$6.994
Civilian pay increase	--	--	--	$107.773	--	+$107.773
Subtotal, Built-in Increases	**--**	**--**	**--**	**$114.767**	**--**	**+$114.767**
Infrastructure (WO & OR&RR) and B&F	--	$167.297	--	$168.897	--	+$1.600
Food Safety						
Human Foods Program	--	$1.605	--	$16.605	--	+$15.000
Medical Product Safety						
21st Century Cures	--	$50.000	--	$55.000	--	+$5.000
Crosscutting						
Modernization of Cosmetics	--	--	--	$8.000	--	+$8.000
Shortages and Supply Chain	--	--	--	$12.300	--	+$12.300
Foreign Office Expansion	--	--	--	$1.000	--	+$1.000
IT Stabilization & Modernization	--	$18.000	--	$26.250	--	+$8.250
Enterprise Transformation	--	--	--	$2.000	--	+$2.000
Subtotal, Program Increases	**--**	**$236.902**	**--**	**$290.052**	**--**	**+$53.150**
Total Increases	**--**	**$236.902**	**--**	**$404.819**	**--**	**+$167.917**
Decreases:						
Infrastructure (GSA Rent)	--	$166.286	--	$155.386	--	-$10.900
	--	--	--	--	--	--
Subtotal, Program Decreases	**--**	**$166.286**	**--**	**$155.386**	**--**	**-$10.900**
Total Decreases	**--**	**$166.286**	**--**	**$155.386**	**--**	**-$10.900**
Net Change	**--**	**$403.188**	**--**	**$560.205**	**--**	**+$157.017**

1/ The FY 2025 President's Budget also includes $338.1 million in user fee increases. Within this amount, $114.24 million is requested for an increase for the Tobacco Control Act to collect fees on all deemed products including e-cigarettes/other ENDS products and other deemed products. The remaining amount reflects statutorily authorized inflationary increases to user fees.

2/ FY 2023 Final and FY 2025 PB reflect $1.5 million transfer to HHS Office of the Inspector General to support oversight of FDA's expanded

3/ FY 2025 PB does not reflect the FDA Reauthorization Act Section 905 BA/UF shift.

Figure 16 – Summary of Changes

APPROPRIATIONS HISTORY

Salaries and Expenses

(dollars)	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
General Fund Appropriation*:				
FY 2016	4,889,642,000	4,579,118,000	4,589,562,000	4,651,392,000
FY 2017 2/	4,953,946,000	4,649,566,000	4,655,869,000	4,655,089,000
FY 2018	5,044,110,000	5,095,301,000	5,098,341,000	5,138,041,000
FY 2019	5,632,141,000	5,624,076,000	5,475,365,000	5,584,965,000
FY 2020				
Base	5,990,342,000	5,866,703,000	5,781,442,000	5,772,442,000
Supplemental #1 (P.L. 116-123)	---	---	---	61,000,000
Supplemental #3 (P.L. 116-136)	---	---	---	80,000,000
Supplemental #4 (P.L. 116-139)	---	---	---	22,000,000
FY 2021 /4				
Base	6,058,065,000	5,925,641,000	5,916,811,000	5,904,425,000
Supplemental #5 (P.L. 116-260)	---	---	---	55,000,000
Supplemental #6 (P.L. 117-2)	---	---	---	500,000,000
FY 2022				
Base	6,343,805,000	6,207,066,000	6,151,625,000	6,124,850,000
Supplemental #6 (P.L. 117-2)	---	---	---	222,500,000
FY 2023	6,490,145,000	6,514,527,000	6,382,312,000	3,593,149,000
FY 2024	7,127,913,000	6,598,042,000	6,663,618,000	---
FY 2025	6,964,450,000			

* Excludes Indefinite user fees.

1/ The FY 2015 Enacted level includes $25 million in emergency funding for FDA's role in the U.S. Government response to contain, treat, and prevent the spread of Ebola.

2/ The FY 2017 Omnibus Appropriation excludes $10 million in no-year funding to address Emerging Public Health Threats.

3/ Totals do not include funds for 21st Century Cures which are $20 million for FY 2017, $60 million for FY 2018, $70 million for FY 2019, $75 million for FY 2020, $70 million for FY 2021, $50 million for FY 2022, $50 million for FY 2023, $50 million for FY 2024 and $55 million for FY 2025.

4/ FY 2021 totals do not include $1 million for Seafood Safety Studies-GP Sec. 765 received in FY 2021.

5/ The Enacted levels requires the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.

Figure 17 – S & E Appropriations History

Buildings and Facilities

(dollars)	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
General Fund Appropriation:				
FY 2016	8,788,000	8,788,000	8,788,000	8,788,000
FY 2017	11,788,000	11,788,000	11,788,000	11,788,000
FY 2018	8,771,000	8,771,000	11,788,000	11,788,000
FY 2019	11,788,000	11,788,000	11,788,000	11,788,000
FY 2020	11,788,000	11,788,000	11,788,000	11,788,000
FY 2021	13,788,000	11,788,000	13,788,000	12,788,000
FY 2022	30,788,000	21,788,000	15,288,000	12,788,000
FY 2023	30,788,000	16,000,000	30,788,000	12,788,000
FY 2024	18,788,000	12,788,000	---	---
FY 2025	12,788,000			

*FY 2020 Appropriation excludes one-time $20 million provided in P.L. 116-94, section 780.

Figure 18 – B & F Appropriations History

BUDGET AUTHORITY BY ACTIVITY

(dollars in thousands)	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget
Salaries and Expenses Account:			
Foods	**1,196,097**	**1,185,989**	**1,246,745**
Center	401,867	404,806	434,560
Field	794,230	781,183	812,185
Human Drugs	**761,494**	**719,540**	**754,049**
Center	550,993	513,638	539,372
Field	210,501	205,902	214,677
Biologics	**272,215**	**267,130**	**279,986**
Center	224,165	219,828	229,508
Field	48,050	47,302	50,478
Animal Drugs and Feeds	**230,093**	**229,362**	**240,253**
Center	148,141	148,484	156,438
Field	81,952	80,878	83,815
Devices and Radiological Health	**449,597**	**444,534**	**465,778**
Center	356,362	352,697	366,695
Field	93,235	91,837	99,083
National Center for Toxicological Research	**76,919**	**77,505**	**80,590**
FDA Headquarters	**222,940**	**232,427**	**250,403**
FDA White Oak Consolidation	**48,414**	**52,498**	**52,498**
Other Rent and Rent Related	**106,095**	**154,879**	**156,479**
GSA Rental Payments	**166,286**	**166,286**	**155,386**
Subtotal, Salaries and Expenses Account	**3,530,150**	**3,530,150**	**3,682,167**
21st Century Cures	**50,000**	**50,000**	**55,000**
Buildings and Facilities Account	**12,788**	**12,788**	**12,788**
Total Budget Authority	**3,592,938**	**3,592,938**	**3,749,955**
HHS OIG Transfer	**-1,500**	**-1,500**	**-1,500**
Total Budget Authority, Post-Transfer	**3,591,438**	**3,591,438**	**3,748,455**
FTE	**10,484**	**10,458**	**10,569**

* FTE figures do not include an estimated 49 Reimbursable, 169 COVID-19 Supplemental, 4 FOIA, 31 PEPFAR, 25 HCFAC, 5 COVID-19 IDDA.

Figure 19 – FDA Budget Authority by Activity

LEGISLATIVE PROPOSALS

FDA FY 2025 LEGISLATIVE PROPOSALS

The FY 2025 budget includes several legislative proposals that better support Agency efforts to protect American consumers and patients. The proposals include enhanced authorities related to supply chain resiliency for drugs, medical devices, and foods. For example, requirements for manufacturers to notify FDA when they will be unable to supply an increase in demand and to provide manufacturing amount and supplier information; supporting innovation and competition, such as creating a new category for certain animal food substances to facilitate marketing of innovative products and 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 FDA-regulated commodities, and for destruction of products which present a significant public health concern. The Budget also proposes new authorities that would require animal drug sponsors to make post-approval safety changes and that would 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.

FACILITATING COMPETITION

Amend the 3-Year Exclusivity Provisions to Encourage Meaningful Innovation and Timely Competition

Under current law, new drugs can qualify for exclusivity that can block or delay competition from follow-on products even when the new drug applicant is not affirmatively seeking exclusivity, or when the new clinical investigation that is the basis of exclusivity fails to demonstrate the hypothesized effect of the drug. FDA is seeking to encourage competition for new drugs by proposing to amend the Hatch-Waxman 3-year exclusivity provisions to ensure that this exclusivity is limited to situations where the new drug applicant is actually seeking such exclusivity and where the data supporting the exclusivity demonstrates the hypothesized effect of the drug, and to prevent information on new safety risks from blocking competition. This approach would continue to reward innovation, while also allowing for earlier access to generic drugs in certain situations.

Create a Safe Harbor for "Skinny Labeling"

FDA is proposing that the provisions the Hatch-Waxman Amendments and the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) added to section 271 of title 35 of the U.S. Code be amended to create a safe harbor from patent infringement liability for human and animal generic drug applicants and 505(b)(2) applicants who market a drug with "skinny labeling," by excluding such labeling from the evidence that can be used to support a claim of patent infringement, and by clarifying that statements regarding therapeutic equivalence cannot be used as evidence to support an infringement claim. In GlaxoSmithKline LLC v. Teva Pharmaceuticals

USA, Inc., No. 18-1976, the majority Federal Circuit decision held that substantial evidence supported a jury verdict finding that Teva induced infringement of a patent-protected method of use for its generic version of Coreg (carvedilol) tablets, including during a period when Teva had carved out the corresponding condition of use from its labeling. While the majority decision indicates that the decision is narrow and fact dependent and should not upset the careful balance struck by the Hatch-Waxman Amendments regarding labeling carve-outs, FDA is concerned that this decision imperils an important statutory marketing pathway that allows earlier generic drug market entry for conditions of use of a drug not protected by a patent. FDA is concerned that the Federal Circuit's GSK v. Teva decision could significantly impact the timely availability of generic drugs.

Require Full Ingredient Disclosure for Drugs to Promote Generic Competition

Under current law, brand drugs are in many cases not required to disclose full ingredient information, including the amount of certain inactive ingredients, in their labeling. In such cases, FDA is generally prohibited by federal law from disclosing that information to members of the public, including potential generic drug sponsors. However, generic drugs, particularly non-oral dosage forms, often need to have the same ingredients (both active and inactive) in the same amount as the brand drug they are duplicating in order to meet the requirements for approval. To address this issue, FDA is seeking an amendment to the Federal Food, Drug, and Cosmetic (FD&C) Act to (1) require drug manufacturers to disclose full information about the name and amount of each inactive ingredient in their product in the product's labeling for applications (including supplements) submitted after the effective date of the legislative change, and (2) clarify that it is not an improper disclosure on FDA's part to provide a potential generic drug sponsor the names or amounts of inactive ingredients used in an approved reference listed drug's (RLD's) or reference listed new animal drug's (RLNAD's) formulation. FDA believes this change would effectuate timelier and more cost-efficient generic drug development, thereby increasing competition and access to generic drugs for American consumers, pet owners, and animal producers.

Amend the 180-day Forfeiture Provision Addressing Failure to Market

Under current law a first generic applicant may forfeit 180-day exclusivity if they fail to market within a certain time period, among other conditions. However, many first applicants are parking their exclusivity and delaying generic competition when there is no longer a patent-related impediment to generic market entry of either a first applicant or subsequent applicant. FDA is seeking to amend the 180-day exclusivity forfeiture provision regarding failure to market to specify that certain additional events can start the provision's 75-day period, possibly leading to forfeiture. Specifically, the amendments would specify that the provision's 75-day period can be triggered by the resolution of patent litigation without a finding of patent infringement or invalidity if there is no settlement agreement limiting the ability to market. Additionally, the amendments would provide that, when the terms of the resolution of patent litigation would allow the generic applicant to begin commercial marketing as of a certain date, the agreed-upon date would start the 75-day period leading to possible forfeiture. These amendments would allow the agency to use its authorities more effectively by addressing an exploitable loophole in the

failure to market provision. FDA believes that this change will help enhance generic competition and choice by improving FDA's ability to use the failure to market forfeiture provision effectively to limit a first applicant's ability to park exclusivity and block generic competition.

Eliminate **the Statutory Distinction Between the Approval Standard for Biosimilar and Interchangeable Biosimilar Products and Deem that Approved Biosimilars are Interchangeable**

The statutory distinction between biosimilars and interchangeable biosimilars has led to confusion and misunderstanding, including among patients and healthcare providers, about the safety and effectiveness of biosimilars and about whether interchangeable biosimilars are safer or more effective than other biosimilars. FDA is seeking to amend section 351 of the Public Health Service (PHS) Act to no longer include a separate statutory standard for a determination of interchangeability and to deem all approved biosimilars to be interchangeable with their respective reference products. This proposal would make the U.S. biosimilar program more consistent with current scientific understanding as well as with the approach adopted by other major regulatory jurisdictions such as the European Union where biosimilars are interchangeable with their respective reference products upon approval. Further, this proposal is expected to increase uptake of biosimilars, with potential downstream effects of increasing competition, access, and affordability.

Explicitly Address Generic Drug-Device Combination Products

Section 505(j) of the FD&C Act does not explicitly address abbreviated new drug applications (ANDAs) for drug-device combination products, and the lack of clarity in certain statutory provisions in this section – which was established nearly 40 years ago at a time when most products were simpler – make it difficult for companies to develop generic versions of these products and for FDA to efficiently approve ANDAs for these products. As a result, these products can be more expensive and less accessible to patients who need them. To address this, FDA is seeking to amend section 505(j) of the FD&C Act to explicitly address the submission and review of ANDA applications for drug-device combination products, as well as drug products submitted in an ANDA that are used with a device., FDA seeks amendments to clarify that FDA can request and review data for such applications, that certain differences between the device constituent parts of the reference listed drug (RLD) and the proposed generic are permissible, and that differences in labeling between the RLD and the proposed generic as a result of permissible differences in the device are also permissible.

Enhance Availability of Generic Animal Drugs

FDA is proposing that the FD&C Act be amended to clarify labeling requirements for generic animal drugs by explicitly including an exception from the requirement that a generic animal drug's labeling be the same as the labeling of a reference-listed new animal drug (RLNAD) where the RLNAD is approved in more than one "major species" as that term is defined in section 201(nn) of the FD&C Act. This exception would allow a generic sponsor to seek approval for only those major species on the RLNAD's labeling for which bioequivalence information has been provided, so long as the generic sponsor also sought approval for use in

any minor species for which the RLNAD has been approved for use. This proposal is intended to increase the availability of generic animal drugs particularly in situations where obtaining bioequivalence information for certain major species is impractical or scientifically challenging.

SUPPORTING INNOVATION

Provide a Structured and Tiered Risk-Based Framework for Biologic Products for Animals Subject to FDA Regulation

FDA is seeking to enact a structured and tiered risk-based statutory provision for FDA-regulated biologic products for animals. The current FDA statutory framework does not account for the unique attributes of these products. Partly as a result of the barriers inherent in the current statutory framework, FDA estimates that over 95% of animal products with characteristics of biologics are unapproved. A targeted statutory provision for FDA-regulated biologic products for animals would help protect human and animal health while encouraging significant innovation of these novel and promising products. The proposed amendments would help address safety concerns due to disease transmission, including zoonotic diseases, as well as provide appropriate quality standards. Of significant importance to stakeholders, this proposed pathway would also provide a path to market that entails minimal regulation for products that pose a low risk for adverse impact on human and animal health.

Regulate Certain Articles as Zootechnical Animal Food Substances

Products are legally regulated as food or drugs for animals depending on characteristics of the article, how the article is intended to be used, and what the article claims to do. Novel substances for animals are being developed that are added to animal food or water, that affect the structure or function of the animal through a means other than nutrition, but that act only within the animal's gastrointestinal (GI) tract. Under the FD&C Act these substances are new animal drugs. FDA is proposing to amend the FD&C Act to create a new category of animal food additives called zootechnical animal food substances (ZAFS). Certain substances would meet the definition of ZAFS if they are intended to be added to animal food or drinking water and have no nutritive value or technical effect on the animal food but have other important benefits, such as affecting the byproducts of digestion, reducing foodborne pathogens in food animals, or altering the animal's GI microbiome. This legislative change would give FDA increased flexibility to provide risk-based oversight and facilitate more timely availability of innovative animal food additives. Under this proposal, ZAFSs would be deemed to be food additives, and would not be animal drugs, despite having intended uses that could otherwise make them animal drugs under the FD&C Act.

ENHANCING DATA, INFORMATION, AND POSTMARKET SAFETY

Require Retention of Data and Records Supporting Marketed Medical Products and Marketed Medical Product Applications and Act Upon Submissions Containing Fraudulent or Unreliable Data

FDA is increasingly identifying instances of fraudulent or unreliable data provided in premarket submissions for medical devices and marketing applications for drug and biological products, including during inspections and remote regulatory assessments of manufacturing establishments. In many instances, the fraudulent or unreliable nature of the data is not discovered until after marketing authorization is granted. FDA is requesting express authority for the Agency to ensure that data supporting application and non-application medical products are reliable and verifiable for as long as the product may be legally marketed, including throughout the lifetime of the application or market authorization, and to ensure that FDA has appropriate tools to act on findings of fraudulent or unreliable data or information, including untrue statements of material fact. These new or clarified authorities would improve the reliability of data by encouraging applicants and manufacturers to more closely examine and monitor the information and data they submit to FDA and generate to support the marketing of FDA-regulated medical products. More importantly, it would protect the public from medical products that have not been shown to be safe and effective due to the fraudulent or unreliable nature of the data relied on.

Expand FDA's Ability to Disclose and Use Certain Information Related to Impurities in Drugs That Pose a Risk to the Public Health

FDA is seeking authority to confirm and expand FDA's ability to publicly disclose and use certain information from submissions to FDA related to impurities in drugs, including biological products, when such disclosure and use has been determined by FDA to be in the interest of public health. Early identification of impurities and disclosure of acceptable intake limits would enable the applicant or drug manufacturer to take quick corrective action (e.g., modify its manufacturing process or reformulate), which would help ensure continued availability of drug products and mitigate discontinuations in the marketing of affected products. This proposal would also provide a mechanism to enable FDA to quickly and readily disclose to sponsors such information, including in the form of recommendations, without additional steps and delay associated with current processes that may render information outdated. Further, the proposal would enable FDA to share safety-related information with international regulators more quickly and use certain information to develop internationally harmonized acceptable intake limits, where appropriate.

Require Site Master Files for Drug Manufacturing Facilities

FDA is seeking to amend the FD&C Act to explicitly require facilities at which human drugs (including both application and non-application products, drugs compounded under Section 503B, and biological products governed by section 351 of the Public Health Service Act that also meet the definitions of a drug under the FD&C Act) and animal drugs are manufactured to create, submit, and maintain Site Master Files (SMFs). SMFs typically contain specific

information about a firm's quality management policies and activities and the production or quality control of manufacturing operations carried out at the named site and identify any closely integrated operations at adjacent and nearby buildings. Currently, FDA has no explicit authority to require the submission of a SMF. Without a SMF, FDA may not capture ancillary changes within the covered manufacturing facilities that are not directly associated with an approved application or license, yet still potentially impact the safety of the approved or licensed products. SMFs can improve FDA understanding of quality management practices and supply chain management, which will improve overall supply chain resiliency. SMFs can further assist FDA when conducting risk identification for sites for surveillance and for-cause based inspections. In addition, FDA believes that requiring SMFs for facilities manufacturing would assist its preparation for inspections, thereby making inspections more efficient.

Expansion of FDA Tools to Provide Oversight of FDA-Regulated Products

FDA's authority to conduct mandatory records requests under section 704(a)(4) of the FD&C Act is limited to requests for records and other information in advance or in lieu of drug, device, and biomedical research monitoring (BIMO) inspections and FDA lacks authority to require establishments to participate in remote interactive evaluations. The agency relies on voluntary participation for remote regulatory assessments of establishments not covered under current mandatory authority but reliance on voluntary requests is not sufficient to achieve effective and efficient oversight, as for example, firms not subject to section 704(a)(4) can refuse to provide records or other information in advance of or in lieu of an inspection or to otherwise participate in remote regulatory assessments. This proposal is seeking to expand FDA's authority to request records or other information in advance of or in lieu of inspections to include all FDA-regulated products by revising section 704(a)(4) of the FD&C Act to explicitly include food, tobacco product, and cosmetic establishments. Additionally, this proposal would add explicit authority to require remote regulatory assessments of establishments, which may include remote interactive evaluations such as livestreaming video of operations, teleconferences, and screen sharing, so FDA may interact virtually with an establishment and assess its compliance with applicable laws and regulations. This proposal will promote regulatory compliance and help to protect the public health, particularly during a public health emergency like the COVID-19 pandemic where in-person inspections and investigations were limited. This proposal will expand FDA's authority to conduct certain oversight activities prior to arriving for or instead of an inspection, thus improving the efficiency of FDA resources and reducing FDA's on-site inspectional time. Further, this will help FDA to assess conditions at a facility without going onsite when an in-person visit is not feasible or deemed necessary by FDA.

Expanding Information Disclosure Authorities with States

State, local, and territorial governments play an important role in the protection of public health, particularly as FDA partners with them in the regulation of products, helping to ensure the safety and integrity of supply chains, and assisting in enforcement against products that are being unlawfully sold. FDA works closely with our state partners to employ complementary authorities to achieve fast and effective action to protect the public health during national public health emergencies such as the COVID-19 crisis, other state/local disaster declarations, outbreaks or

other public health events, and for routine regulatory oversight. FDA is proposing to amend the FD&C Act to allow for disclosure of non-public information to state, local, and U.S. territorial government agencies with counterpart functions related to FDA-regulated products while ensuring confidentiality of non-public information (such as confidential commercial information) provided by FDA. This proposal would advance an integrated food safety system and more effectively leverage the oversight capabilities and resources of FDA's state, local and territorial regulatory partners to allow for expanded mutual reliance related activities and other partnerships. The limitations on sharing certain regulated commodity information seamlessly and in real time with states prevents FDA from taking swift action to ensure a robust product supply and protect the integrity of supply chains. The Agency anticipates this authority will also benefit FDA partners conducting inspections and regulated industry by reducing the burden related to duplicative inspectional activities.

Evaluation of Non-Application Drug Manufacturers Before Marketing

FDA is seeking an amendment to authorities with respect to non-application drugs (finished dosage forms and active pharmaceutical ingredients (API)) to provide the agency a formal, designated opportunity to use a risk-based approach to determine if an inspection of the manufacturing facilities is necessary before the drug is first distributed, and to conduct the inspection if it is necessary. Under this proposal, a manufacturer that intends to distribute a non-application drug in interstate commerce from an establishment for the first time would be required to notify FDA of its intent at least six months prior to its first distribution. Additionally, manufacturers that intend to distribute sterile, non-application drugs in interstate commerce for the first time and have not previously been inspected for sterile manufacturing operations would be required to submit such a notice at least six months prior to their first distribution of a non-application sterile drug in interstate commerce, even if they already distribute other non-sterile drugs in interstate commerce. Under current law, for drugs that are not subject to premarket approval requirements, FDA typically does not have a formal, designated opportunity to inspect the manufacturing facilities before such products are first shipped to or distributed in the U.S. A recent focus on firms manufacturing non-application drugs has identified a high rate of non-compliance with current good manufacturing practice (CGMP) requirements, especially when a facility is first inspected. FDA believes that ensuring it has a designated opportunity for an inspection before distribution would help identify potential safety issues related to manufacturing before a drug product is distributed into interstate commerce and ultimately to patients.

Require Destruction of Imported Products that Pose a Significant Public Health Risk

FDA is seeking to amend section 801 of the FD&C Act to give FDA the authority to require an owner or consignee to destroy any FDA-regulated product(s) offered for import that has been refused entry and presents a significant public health concern, thus removing their option to export such product under current section 801(a). FDA believes this new authority would prevent the potential re-importation of such products and would deter owners and consignees from offering products they know to pose a significant public health risk for import into the United States. FDA also believes this authority would increase efficiency when Customs and Border Protection (CBP) seizes an FDA-regulated product. Under current practice, when CBP seizes an

FDA-regulated product, a violation of the FD&C or PHS Acts and/or FDA regulations is used to support the seizure. CBP then consults with FDA to confirm that the product seized violates the FD&C or PHS Acts and/or FDA regulations. Additionally, if the seizure is successful, the government will likely end up paying for the destruction. Under this proposal, FDA would order the destruction based on the Agency's admissibility review and evaluation of the significant public health concern presented by the products offered for import, thereby reducing the need for CBP consultations with FDA. Moreover, the importer of record would be required to pay the destruction costs up front so FDA and CBP do not have to file legal action to recoup the destruction costs.

Streamlining the Collection Process for FSMA Reinspection and Recall Fees

The Food Safety Modernization Act (FSMA) authorized FDA to collect fees to cover reinspection-related costs from domestic facilities, foreign facilities, and importers subject to reinspection for non-compliance related to a food safety requirement, and from a domestic facility and an importer who does not comply with a recall order. To date, FDA has not collected fees, in part due to the complexity of structuring a fee program in alignment with the statute. FDA is proposing to amend section 743 of the FD&C Act (21 U.S.C. 379j-31) to revise the Agency's reinspection and recall fee authority to allow the Agency to collect a fixed fee from the responsible party for each domestic facility, the U.S. agent for each foreign facility, and each importer subject to a reinspection to cover the estimated cost of conducting a reinspection for such facilities and importers and to collect a fixed fee from the responsible party for each domestic facility and importer who does not comply with a recall order issued under section 423 or 412(f) of the FD&C Act (21 U.S.C. 350l, 350a(f)) to cover the estimated cost of food recall activities associated with a recall order for such facilities and importers. FDA is also proposing to amend the definition of 'reinspection' to provide more clarity to industry. The proposed amendments would also provide flexibility for FDA to set and collect a reduced fee for small businesses. Streamlining the collection of reinspection and recall fees would strengthen the ability of FDA to collect these fees and enable the Agency to target resources currently being used for reinspection to other high-priority activities, such as securing the safety of the food supply.

Require Public Health Data Reporting Authority to Utilize Postmarket Health Information

While FDA can request public health data, including to request that IIS (immunization information systems), health plans, or healthcare providers voluntarily provide Protected Health Information (PHI), however, because we are operating under a voluntary system, we face significant delays or may never receive the data we request. Further, in some cases where we have sought information under this voluntary system, state or local entities have asserted that state laws prevent the state or local entities from sharing data or do not permit sharing patient-level data and only permit sharing aggregate data. FDA is seeking to amend the Public Health Service (PHS) Act to provide FDA with additional authority to require certain public health data reporting to more effectively utilize postmarketing health information to support medical product postmarketing safety and effectiveness monitoring, including preventive vaccines and therapeutic products. It would also help the Agency to more promptly identify adverse event

patterns and trends associated with the use of vaccines or other medical products (e.g., medical countermeasures (MCMs)), and more swiftly communicate with health care providers and patients about safety signals. In addition, this authority could potentially help FDA more quickly obtain death investigation reports with autopsy and post-mortem toxicology results in overdose cases of opioids and other substances involved in the opioid public health emergency.

Enhance Postmarket Safety of Animal Drugs

FDA is proposing that the FD&C Act be amended to authorize the Center for Veterinary Medicine (CVM) to require animal drug sponsors to make safety-related labeling changes based on new safety information that becomes available after approval of an animal drug; to require animal drug sponsors to develop and implement a Risk Evaluation and Mitigation Strategy (REMS), a drug safety program for drugs with serious safety concerns and for which interventions beyond FDA-approved labeling are necessary to ensure the safe use of the drug; and to require animal drug sponsors to conduct post-approval studies of animal drugs to assess a known or potential serious safety risk. Unlike for human drugs, FDA does not currently have these authorities for animal drugs. Additionally, these authorities would address the situation where multiple sponsors are marketing an animal drug or class of drugs with similar safety risks. In such cases, FDA has found the current process for negotiating changes in labeling or ensuring implementation of other voluntary, post-approval actions to mitigate risks to be lengthy and to create an uneven playing field as sponsors of similar drugs agree to different post-approval actions on different timelines, resulting in inconsistent practices and labeling information.

ADDRESSING MEDICAL PRODUCT SHORTAGES AND SUPPLY RESILIENCY

Lengthen Expiration Dates to Mitigate Critical Drug Shortages

Shortages of drugs that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition can be exacerbated when drugs are discarded because they exceed a labeled shelf-life. This proposal would expand FDA's authority to require, when likely to help prevent or mitigate a shortage, that a manufacturer evaluate existing data, submit studies to FDA, and label a product with the longest expiration date (shelf-life) that FDA agrees is scientifically supported. The proposal also seeks authority for FDA to levy a civil money penalty if a manufacturer fails to comply.

Expand FDA's Mandatory Recall Authority to Cover All Human and Animal Drugs

FDA is seeking to expand FDA's mandatory recall authority under the SUPPORT Act so that it covers all human and animal drugs. The SUPPORT Act, enacted in 2018, provided FDA with authority to mandate recalls for controlled substances in certain circumstances. FDA also has mandatory recall authority for biological products under the Public Health Service Act § 351(d) [42 U.S.C. § 262(d)], and recently received mandatory recall authority for cosmetics as part of the FDA Omnibus Reform Act. The agency lacks mandatory recall authority for other human and animal drugs. Currently, the great majority of companies agree to recall their human or animal drug products when asked to voluntarily do so by FDA. However, there are cases where a

company extensively delays initiating a recall or refuses to recall a violative drug product when asked to voluntarily do so. FDA believes that expanding its mandatory recall authority would help remove violative human and animal drugs more quickly thereby reducing harm to consumers due to exposure to dangerous products.

Require Drug Manufacturers to Notify FDA of an Increase in Demand

FDA is seeking an amendment to the FD&C Act to expand the notification requirements to include notifying FDA of an increase in demand for drugs described in section 506C(a) of the FD&C Act that the manufacturer likely will be unable to meet without meaningful shortfall or delay. Currently, FDA generally does not receive notice or adequate information from drug manufacturers regarding increases in demand that would position the Agency to assist in preventing or mitigating drug shortages driven by an increase in demand (in contrast to drug shortages driven by a disruption in supply due to manufacturing interruptions). FDA believes that receiving such notifications would better position FDA to take steps to prevent or mitigate shortages resulting from increased demand, such as those that occurred during the COVID-19 public health emergency for certain drugs needed to treat hospitalized patients.

Enhanced Drug Manufacturing Amount Reporting Information

FDA is seeking to enhance the manufacturing amount information required to be reported under section 510(j)(3) of the FD&C Act by adding an express requirement that registrants provide data identifying the suppliers they relied on to manufacture a listed drug and the extent of such reliance. Section 510(j)(3), which was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), requires drug manufacturers registered under section 510 of the FD&C Act to report annually to FDA the amount of each listed drug they manufactured, prepared, propagated, compounded, or processed ("manufactured") for commercial distribution. However, FDA still has gaps in its understanding of the drug supply chain. Notably, the information required to be submitted under section 510(j)(3) of the FD&C Act is insufficient to help FDA understand the extent of registrant reliance on suppliers used in the registrant's manufacture of its listed drugs. FDA believes the information from the proposed authority would help identify vulnerabilities in the supply chain that may be hidden due to the limited information in this respect provided to FDA under section 510(j)(3) and, for application products, in the approved applications.

Remove the Temporal Limitation on FDA's Medical Device Shortages Authorities and Require Manufacturers to Maintain and Share Risk Management Plans

Under the CARES Act, FDA received new authority relating to device shortages codified in section 506J of the FD&C Act. By the end of the COVID-19 public health emergency (PHE), FDA received 477 potential and actual shortage signals, which translates to hundreds of thousands of device units that have been or could have been in shortage. We used the information we collected under these new authorities to help mitigate approximately 359 of the 477 shortages. Unfortunately, the requirement for manufacturers to provide this critical information is temporally limited as it is only required to be provided to FDA during or in

advance of a PHE. However, shortages of critical medical devices have persisted even after the COVID-19 PHE ended. Medical device shortages occur in many situations that fall outside of or are unrelated to PHEs, including natural or human-made disasters, recalls, geopolitical conflicts, production shutdowns, and cybersecurity incidents. Each of these events and others that fall outside of a PHE can lead to device shortages that significantly impact patient care and jeopardize healthcare worker safety. Moreover, as we saw with the onset of COVID-19, by the time there is an emergency, it is often too late to prevent or mitigate shortages. The PREVENT Pandemics Act clarified the ability of FDA to receive voluntary notifications from manufacturers about certain device discontinuances and interruptions, but the lessons of this pandemic have demonstrated that relying solely on voluntary information-sharing deprives FDA and the public of critical supply chain information. To protect patients, build a more resilient domestic supply chain, and help reduce dependence on foreign sources, it is critical that Congress remove the temporal limitation in section 506J that only requires manufacturers to notify FDA about interruptions or discontinuances in the manufacture of certain devices during or in advance of a PHE. Furthermore, COVID-19 also showed us that manufacturers are not always prepared for situations where their ability to manufacture product may be disrupted or may be insufficient to meet increases in demand, especially where they are dependent on one source for a critical raw material or component that was in shortage. Providing FDA clear authority to review risk management plans (RMPs) would help ensure manufacturers have plans in place to build resiliency and mitigate future supply chain disruptions.

Require Labeling to Include the Original Manufacturer and Supply Chain Information

FDA is proposing to amend section 502 (21 U.S.C. 352) of the FD&C Act to provide that active pharmaceutical ingredients (APIs) are misbranded if they are introduced into interstate commerce and the original manufacturer and unique facility identifier are not included on the API label (i.e., label of the bulk drug substance), other labeling, and on the certificate of analysis. FDA also is proposing to amend 502 to deem finished drug products misbranded if the original manufacturer isn't included on the finished drug product label, and if certain additional supply chain information is not included in the broader finished drug product labeling. Finally, FDA is proposing to amend section 502 to require that the label for certain excipients designated as high-risk by the Secretary identify the name and address of the excipient's original manufacturer. FDA believes there is a lack of supply chain accountability and transparency due to APIs and finished drug products, including repackaged and relabeled APIs, lacking information regarding the original manufacturer of the API. End purchasers of repackaged API may therefore be unaware of whether the API they purchase is adulterated (for example if it was originally manufactured by a firm that has not met drug current good manufacturing practice requirements). In FDA's experience, lack of supply chain oversight of APIs and finished drug products can cause serious vulnerabilities in the supply chain since FDA and other supply chain stakeholders are not always able to identify the source of the drugs to address manufacturing or safety concerns and may thus lead to patient safety issues. FDA believes this proposal would allow compounders, conventional drug manufacturers, and the FDA itself to quickly identify the original manufacturer of an API or finished drug product that is found to be adulterated or misbranded and take appropriate action to address poor quality products from

circulation. Requiring the same transparency for high-risk excipients would allow FDA to ensure adequate oversight to help prevent contaminated products from entering the U.S. drug supply.

Prevent Animal Drug Diversion and Misuse

Diversion and misuse of animal drugs has led to increasingly high-profile incidents where there is serious harm to humans, and which also threaten the availability of critical animal drugs (either directly by the diversion or misuse itself reducing inventory or indirectly due to stakeholders' reactions). FDA is aware of a wide range of diversion and misuse of animal drugs including: APIs or finished products; approved or unapproved animal drugs; OTC (e.g., ivermectin) or prescription animal drugs (e.g., xylazine); and animal drugs that are at risk of diversion while in the supply chain (e.g., xylazine API) or animal drugs that are primarily misused after legal retail sale (e.g., ivermectin). The human drug supply chain authorities (e.g., the Drug Supply Chain Security Act) do *not* cover animal drugs and are not adaptable to solve this problem because they are designed primarily to address a different problem, in this instance counterfeit human drugs, rather than diversion/misuse of legitimate animal drugs by humans. FDA seeks new authority under the FD&C Act to prevent the diversion and/or misuse of animal drugs (including those containing xylazine) by humans to decrease the potential for harm to humans by these animal drugs while protecting the legitimate veterinary drug supply. This proposal will achieve certain parts of the Fentanyl Adulterated or Associated with Xylazine Response Plan that are under FDA's jurisdiction.

Prevent Food Shortages, Including Critical Foods

FDA is seeking authority to clarify that we can impose additional conditions on notifications submitted by manufacturers of critical foods when there is a permanent discontinuance or interruption in manufacture that is likely to lead to a meaningful disruption in the U.S. supply, including requirements to submit specific information as part of the notification. Critical foods are of public health importance, as they often are the sole or substantial source of nutrition for those who consume them, and this new authority will provide FDA with additional tools to help mitigate and prevent future shortages. Additionally, FDA is seeking new authority to designate additional categories of foods for which notification of anticipated interruptions in the supply chain is appropriate during a declared public health emergency. The COVID-19 pandemic demonstrated the need for timely and accurate information about confirmed or likely supply chain challenges to help ensure the continuity of the food supply so that consumers have access to a safe and adequate food supply during public health crises. Such information would help FDA better ensure the continuity of the food supply and avoid shortages of nutritionally important food products.

Modernize the Tobacco User Fees Framework to Apply to All Regulated Tobacco Products

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) authorizes FDA to assess and collect tobacco user fees from domestic manufacturers and importers of six classes of products: cigars, pipe tobacco, cigarettes, snuff, chewing tobacco, and roll-your-own tobacco, as well as the total amount of tobacco user fees FDA must assess and collect each year.

For the first ten years of the FDA tobacco program, the total amount of user fee collections increased each year; however, beginning in FY 2019, the authorized amount of $712 million is fixed for each subsequent fiscal year and is not indexed to inflation. Moreover, because electronic nicotine delivery systems (ENDS) were a relatively new product category when the Tobacco Control Act was enacted to give FDA authority to regulate tobacco products in 2009, the authorized funding did not take into account the resources required for the regulation of ENDS; since that time, these products have become the most used tobacco product category by youth. This presents two issues: 1) Manufacturers and importers of regulated tobacco products outside of the six product classes listed above, including ENDS, do not pay tobacco user fees for their regulatory oversight, and 2) FDA has had to spend a significant portion of the $712 million in user fees it collects annually from the existing six product classes to properly regulate tobacco products outside of the six product classes listed above, especially ENDS. This means fewer funds are available to be spent on important efforts related to those six product classes. For example, the Agency has been forced to constrict funding for research, limit enforcement and compliance efforts and divert funds from efforts related to smoked and smokeless tobacco products. This proposal is seeking to amend Section 919 of the FD&C Act to: authorize the Agency to assess user fees on, and collect such fees from, each manufacturer and importer of any products subject to Chapter 9 of the FD&C Act, promoting a fair distribution of tobacco user fee assessments to all regulated tobacco products, including ENDS; increase the current limitation on total tobacco user fee collections by $114 million; and index all future collections to inflation.

Request Improved Hiring Authority for FDA's Center for Tobacco Products

FDA is seeking to extend the agile hiring authorities and salary flexibility of the 21st Century Cures Act for the Center for Tobacco Products (CTP) to improve its ability to recruit, hire, and retain personnel with the needed skills to effectively meet its public health mandate. FDA estimates that at least an additional 400 staff members, mostly in scientific and compliance and enforcement positions, are needed to fully complete its tobacco program mission. CTP believes that securing the Cures Act authorities would permit CTP to competitively compensate and retain experienced scientists and other personnel to avoid delays or impact to mission critical activities.

MODERNIZING FOODS AUTHORITY

Modernize **Regulation of Critical Foods and Other Foods Marketed for Consumption by Infants and Young Children**

A modern regulatory framework is critical for FDA to help ensure the safety of foods consumed by vulnerable populations. Under current law, FDA has limited tools to effectively regulate foods marketed for consumption by infants and young children. FDA is seeking new authority to establish binding contamination limits in foods, including those consumed by infants and young children, via an administrative order process. This new authority would provide a faster way to set binding limits and update limits as new scientific information becomes available. Additionally, FDA is seeking to amend the FD&C Act to grant authority to: (1) require industry to conduct testing of final products, including those marketed for consumption by infants and

young children, for contaminants and maintain such records of these testing results for FDA inspection; (2) remotely access records of these test results and to review these test results whenever necessary in a more streamlined fashion; and (3) require a mandatory recall when FDA determines through any means that there is a reasonable probability that an article of infant or toddler food (other than infant formula) bears or contains a contaminant that renders the product adulterated. This would help FDA better understand levels of contaminants in foods, allow FDA to monitor industry progress in reducing levels over time, and identify where FDA should devote more time and resources. FDA also seeks new authority to require industry to report all product positive test results for relevant pathogens in critical foods (i.e., infant formula or medical foods) and conduct more frequent environmental monitoring in their facilities to identify the presence of relevant pathogens on surfaces from which the risk of critical food contamination is the greatest and maintain the results of such testing for FDA inspection, either in person or remotely. The combination of these new authorities would empower FDA to work with firms in real time to resolve issues around product positive findings and better ensure the safety of critical foods entering the market.

Modernize the Dietary Supplement Health and Education Act (DSHEA)

Since the Dietary Supplement Health and Education Act of 1994 (DSHEA) was enacted 30 years ago, the dietary supplement market in the U.S. has grown from approximately 4,000 products to well over 100,000 products. FDA is seeking to modernize DSHEA to provide for a more transparent marketplace, help facilitate a risk-based regulation of dietary supplements and clarify FDA's authorities relating to products marketed as "dietary supplements." Specifically, FDA is seeking to amend our authorities to: (1) require all dietary supplements to be listed with FDA, including by providing the product label and other basic information; and (2) clarify FDA's authorities over products marketed as dietary supplements. These amendments would help FDA to know when new products are introduced and quickly identify dangerous or illegal products on the market to take appropriate action to protect consumers when necessary.

OTHER

Provide Medical Assistance and Evacuation Insurance for the Department of Health and Human Services (HHS) Employees

Existing HHS authorities do not permit HHS or FDA to purchase medical assistance and evacuation insurance coverage for full-time federal, uniformed, and intermittent HHS or FDA employees on official government foreign travel. As a result, travel-related medical assistance insurance when needed in an emergency is considered a personal expense and must therefore be borne by the employee. Absent this coverage, the employee must cover the costs of medical emergencies when on official travel overseas – which can be substantial. Factors such as the employee covering unforeseen foreign medical expenses and foreign travel insurance affect morale and affect an employee's willingness to conduct foreign travel to support mission requirements. In addition, these factors may also deter outside candidates from joining the Federal Government. Specifically, as it relates to HHS/FDA, we are seeking this authority to permit the purchase of medical assistance and evacuation insurance coverage for FDA

employees on official government foreign travel. The ability to provide medical assistance and evacuation insurance for FDA's employees, especially those investigators conducting foreign inspections on multiple week trips on multiple occasions during a calendar year, will better support employees by providing points of contact for medical emergencies, ensuring that the employee receives appropriate medical care, and ensuring that expenses are paid when needed in a timely fashion. For example, at FDA, during the decade leading up to the COVID-19 pandemic, foreign inspections almost quadrupled (from 1,102 in FY 2010 to 3,766 in FY 2019). More specifically, in FY 2019 there were 1,189 foreign trips by employees from FDA's Office of Regulatory Affairs (ORA) with most of these inspectors going overseas approximately once or twice a year for 3-4 weeks. In addition, this insurance can serve as a retention tool for staff fulfilling mission requirements and act as a recruitment tool for those conducting foreign healthcare missions.

Change in Agency Regulatory Oversight Responsibility for Certain New Animal Drug Products

FDA is proposing that the definition of "new animal drug" in section 201(v) of the FD&C Act be amended to provide the ability to exclude certain products or classes of products that FDA and EPA agree are more appropriately regulated by EPA as pesticides; and that section 512 of the FD&C Act be amended to facilitate an orderly transfer of regulatory responsibility from EPA to FDA of specified products that are currently registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that FDA and EPA agree are more appropriately regulated by FDA as animal drugs. The first change would allow FDA, in consultation with EPA, to determine whether to exclude certain products from the definition of "new animal drug" so as to allow EPA to regulate these products as pesticides. The second change would eliminate the need for duplicative safety and effectiveness studies for certain parasiticides currently marketed as pesticides that are transferred to regulation by FDA as animal drugs. In 1975, Congress sought to reduce the regulatory burden of obtaining approval from both the EPA and FDA by amending the definition of "pesticide" in FIFRA to exclude "new animal drugs." This change has complicated FDA's and EPA's ability to regulate products in a way that both agree is appropriate and limits the way FDA can direct sponsors to the appropriate regulatory agency. The proposed changes to the FD&C Act would remove regulatory uncertainty and provide clarity to sponsors about which agency intends to regulate a given product or type of products.

STRENGTHENING BIODEFENSE TO PROTECT AGAINST 21ST CENTURY BIOTHREATS

The COVID-19 pandemic highlighted FDA's unique and cross-cutting role central to the whole-of-government response to protect and promote public health. The Budget provides $670 million to improve FDA's core capabilities and regulatory capacity to respond rapidly and effectively to future biothreats. To maintain FDA's gold standard for science-based product review and regulatory decision-making, the Budget will help modernize FDA's regulatory capacity, information technology, and laboratory infrastructure.

These funds will support the Agency's biodefense efforts, domestic and globally, by bolstering FDA's cadre of medical product reviewers and strengthening foundational processes. It would also increase FDA's capacity to leverage a One Health approach to respond to emerging threats in recognition of the interconnectedness of human, animal, and environmental health. The Budget also will improve FDA's laboratory facilities so that FDA has modern and safe physical spaces necessary to conduct our regulatory pandemic preparedness and response work.

Lastly, these resources would help strengthen underlying technology platforms to improve electronic information exchange among stakeholders. The funding will further build FDA's data infrastructure capabilities such as advanced predictive modeling data analytics capacity, real-world data analysis tools, and business continuity systems. With these resources, FDA will have the opportunity to build on lessons learned and provide transformational investments to help ensure that FDA can respond quickly and effectively to emerging biothreats.

For more information on the Department-wide biodefense proposal, please find the detailed narrative in HHS's Public Health Social Services and Emergency Fund budget justification.

NARRATIVE BY ACTIVITY

FOODS

PURPOSE STATEMENT

The Foods Program protects and promotes human health by ensuring the safety of the American food supply, dietary supplements, and cosmetics, as well as the proper labeling of food and cosmetics. The Foods Program began with the passage of the 1906 Pure Food and Drugs Act.

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Federal Import Milk Act (21 U.S.C. 142-149); Public Health Service Act (42 U.S.C. 201, et seq.); Food Additives Amendment of 1958; Color Additives Amendments of 1960; The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); Safe Drinking Water Act (21 U.S.C. 349); Saccharin Study and Labeling Act; Infant Formula Act of 1980; Drug Enforcement, Education, and Control Act of 1986; Nutrition Labeling and Education Act of 1990; Dietary Supplement Health and Education Act of 1994; Food Quality Protection Act of 1996; Federal Tea Tasters Repeal Act (42 U.S.C. 41); Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349); Food and Drug Administration Modernization Act of 1997; Antimicrobial Regulation Technical Corrections Act of 1998; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Food Allergen Labeling and Consumer Protection Act of 2004; Sanitary Food Transportation Act of 2005; Food and Drug Administration Amendments Act of 2007; Food and Drug Administration Food Safety Modernization Act of 2011 (Public Law 111-353); Dietary Supplement and Nonprescription Drug Consumer Protection Act (21 U.S.C. 379aa-1)

Allocation Methods: Direct Federal/intramural; Contract; Competitive grant

BUDGET REQUEST

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
Foods	**1,099,001**	**1,131,315**	**1,207,864**	**1,197,992**	**1,258,987**	**51,123**
Budget Authority	***1,098,973***	***1,131,315***	***1,196,097***	***1,185,989***	***1,246,745***	***50,648***
User Fees	***28***	***---***	***11,767***	***12,003***	***12,242***	***475***
Center	343,289	367,150	402,768	405,725	435,497	32,729
Budget Authority	343,289	367,150	401,867	404,806	434,560	32,693
User Fees	---	---	901	919	937	36
Field	755,712	764,165	805,096	792,267	823,490	18,394
Budget Authority	755,684	764,165	794,230	781,183	812,185	17,955
User Fees	28	---	10,866	11,084	11,305	439
FTE	**4,037**	**3,939**	**3,969**	**3,944**	**3,977**	**8**

Figure 20 – Foods Funding History Table

The FY 2025 President's Budget for the Foods Program is $1,258,987,000 of which $1,246,745,000 is budget authority and $12,242,000 is user fees. The budget authority increases by $50,648,000 compared to the FY 2023 Final Level; user fees increase by $475,000. The amount in the request for the Center for Food Safety and Applied Nutrition (CFSAN) is $435,497,000. The amount requested for the Office of Regulatory Affairs (ORA) is $823,490,000.

The FY 2025 Budget makes significant investments in CFSAN. Despite CFSAN's mandate to oversee nearly 80 percent of food, all cosmetics, and all dietary supplements sold in the United States, the Center's funding has failed to keep up with the dramatic growth of the industries it

oversees. This funding shortfall means CFSAN's operational capacity has not grown to meet 21st century challenges or to stay current with evolving industry and food production practices.

CFSAN will utilize the additional funding to make progress towards addressing the gap between the scope of its oversight and the resources currently available. New resources will allow CFSAN to invest in the tools, information, and staff it needs to meet the challenges it faces and further its mission to promote and protect the public's health, including advancing nutrition science and microbiological food safety.

BUDGET AUTHORITY

FY 2025 President's Budget: Foods *Budget Authority - Dollars in Thousands*			
	Center	**Field**	**Total**
FY 2023 Final	**401,867**	**794,230**	**1,196,097**
FY 2025 Budget Authority Changes	**32,693**	**17,955**	**50,648**
Requested Increases	**29,558**	**30,619**	**60,177**
Human Foods Program	13,700	1,300	15,000
Public Health Employee Pay Costs	14,156	28,000	42,156
Enterprise Transformation	139	298	437
IT Stabilization & Modernization	479	1,021	1,500
Shortages and Supply Chain-Agency-wide	1,084	-	1,084
Other Adjustments	**3,135**	**(12,664)**	**(9,529)**
ORA Transfer to HQ/OGPS	-	(16,214)	(16,214)
FY 2024 Comparability Adjustment	2,939	3,167	6,106
FY 2025 Comparability Adjustment	196	383	579
FY 2025 Budget Net Total: Foods	**434,560**	**812,185**	**1,246,745**

Figure 21 - Foods Budget Authority

Total Requested Increase: +$60.2 million / +33 FTE

Public Health Employee Pay Costs: +$42.2 million

Center: +$14.2 million

Field: +$28.0 million

The FY 2025 President's Budget includes $114.8 million in new budget authority to fund approximately 72 percent of the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 and FY 2025 Cost of Living Adjustments (COLA). For FY 2025 this assumes a 2.0 percent for Civilian and 4.5 percent Military pay increase for FTE funded through budget authority. Within the Foods program, $42.2 million is provided for pay costs, including $14.2 million for CFSAN and $28.0 million for ORA.

Enterprise Transformation: +$437,000 / 2 FTE

Center: +$139,000

Field: +$298,000 / 2 FTE

The FY 2025 President's Budget provides $2.0 million for Enterprise of Transformation, which includes $437,000 for the Foods Program to coordinate and lead several crosscutting agency-wide projects to analyze and implement common business processes and data optimization. Benefits of this funding will include improved communication and data sharing across the life cycle of an inspection, increased access to relevant data to facilitate risk-based decision-making, and the introduction of more modern mobile technology for field work to improve the user experience. The office also seeks to standardize the Freedom of Information (FOI) business processes across the Agency and create effective governance to enable successful process and technology changes.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

Human Foods Program: +$15.0 million / 29 FTE

Center: +$13.7 million / 27 FTE

Field: +$1.3 million / 2 FTE

The FY 2025 President's Budget provides $15.0 million for the Human Foods Program, including $13.7 million to CFSAN and $1.3 million to ORA. The Budget will help strengthen and modernize the Agency's capacity to protect and promote a safe, nutritious U.S. food supply. While structural and process changes are in progress, this new funding will reinforce existing activities and support new initiatives to ensure the Agency remains on the cutting edge of the latest advancements in nutrition science and food safety.

The Budget provides new resources for microbiological activities to prevent foodborne illness. Funds will support strengthening state and federal mutual reliance and collaboration with academic partners to advance knowledge and understanding of foodborne pathogens, preventive controls, and prevention measures. The Budget will further support microbiological methods and sampling improvements to support more rapid and effective mitigation of produce-borne outbreaks related to *Salmonella* and *shigatoxigenic E. coli* in the pre-harvest produce production environment. This body of work will strengthen root-cause investigations essential to FDA's outbreak prevention strategy for produce.

Funding will also be used to grow the nutrition program within the planned Nutrition Center of Excellence. With an emphasis on early childhood nutrition, this request assists FDA in addressing the enormous public health burden of diet-related chronic diseases and supports continued action to realize the gains of the President's National Strategy for Hunger, Nutrition, and Health. Early childhood is a key period for establishing healthy dietary patterns that may influence the trajectory of eating behaviors and health throughout the course of life. Proper nutrition in early childhood can decrease the risk of obesity as well as the development of diet related- chronic diseases, such as heart disease, type two diabetes, high blood pressure, cancer, osteoporosis, dental caries, and iron deficiency. FDA will develop regulations and guidance that will empower parents and caregivers—including those in families of color, those living in rural and urban communities, and low-income families—in making informed choices in foods they purchase for their families to help establish healthy eating patterns early in life. For example, FDA will onboard new scientists, epidemiologists, and biostatisticians to develop regulations and guidance for labeling of toddler drinks, including products marketed and sold online. FDA will also develop Reference Amounts Customarily Consumed (RACC) for foods and beverages

consumed by infants and toddlers to support standard serving sizes in the Nutrition Facts labeling for these products. These efforts will support and extend important work on infant formula that FDA is already engaged in, without diverting or diluting resources critical to assuring a continued robust and diverse supply of safe and nutritionally adequate infant formula.

Through administration of its pre-market food additive authorities outlined in the Food Drug and Cosmetics Act FDA evaluates safety data and information provided in submissions from manufacturers and, from internal and externally available sources to determine if a food additive, food contact material, or Generally Recognized as Safe (GRAS) substance is safe under the intended conditions of use. The pre-market safety evaluation results in generally applicable authorizations for the conditions of safe use for food additives, or a final letter for use of GRAS substances posted publicly to our web inventory. However, advancements in science, food technology, manufacturing innovation, and consumer preferences can drive changes that may signal the need for a reevaluation to ensure the continued safe use of a substance or support necessary regulatory action to limit or remove existing approvals. The FY 2025 budget will support the implementation of a systematic post-market reassessment of intentionally added ingredients and authorized substances present in food due to their use in food, in food packing, or in food manufacturing. FDA will improve information gathering, detection of signals, safety assessment processes and reporting systems to enhance transparency and stakeholder engagement on the safety and status of review for ingredients and chemicals in food. Additionally, funds requested in FY 2025 will strengthen the compliance program to incentivize industry compliance in its use of the GRAS program for food additives and compliance for food contact materials.

Achieving a more effective risk prioritization approach to managing emerging issues and food innovation for the Human Foods Program is key to making the proposed advancements in microbiological, chemical, and nutrition efforts. The Budget will build staffing and technical infrastructure necessary to complete and integrate risk analyses of hazards across the Human Foods portfolio, enabling FDA to prioritize activities based on the potential or real impacts of risks and the effectiveness of strategies available to manage them. For example, the Budget will focus on preventing foodborne illness by advancing outbreak response and prevention activities and better informing post-outbreak root cause analyses. With this additional support, FDA will increase historical outbreak data-trending analyses and leverage outbreak data modeling that directly contributes to creating prevention strategies; increase publications to further communicate findings to industry and stakeholders; and enhance surveillance assignments, work plans, routine inspections, import sampling, and monitoring based on outbreak data trending and analyses.

IT Stabilization & Modernization: +$1.5 million

Center: +$479,000

Field: +$1.0 million

The FY 2025 President's Budget provides $8.3 million for IT Stabilization & Modernization, including $1.5 million for the Foods Program to further build FDA's centralized enterprise data modernization capabilities and to strengthen FDA's common data infrastructure, data exchange, and IT analytic services, talent, and tools. With these resources, FDA will continue to improve data exchange and underlying technology platforms in support of FDA's programs and mission critical- responsibilities – to better meet the challenges of emerging threats, support needs for

real-time evaluation, and more continuously access, analyze, and aggregate multiple sources of information, such as for recalls, adverse events, outbreaks, and pandemics.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

Shortages and Supply Chain: +$1.1 million / 2 FTE

Center: +$1.1 million / 2 FTE

The FY 2025 President's Budget provides $12.3 million for Shortages and Supply Chain, including $1.1 million for the Foods Program to advance FDA's capabilities to help prepare for, build resilience to, and respond to shortages that are supply-driven and/or demand-driven through improved analytics to identify shortage threats and vulnerabilities as well as regulatory approaches to address disruptions and shortages.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

In collaboration with FDA's ORA, CFSAN, enhances public health through innovative and modern approaches to preventing foodborne illness, reducing diet-related chronic disease, and reducing exposure to harmful toxic elements and chemicals in food and cosmetics.

The Office of Food Policy and Response (OFPR) provides executive leadership, management, and strategic direction for FDA's foods initiatives. OFPR also directs integration of the programs, policies, and budgets of CFSAN, ORA, and the Center for Veterinary Medicine (CVM), ensuring the optimal use of all available FDA resources.

The following accomplishments demonstrate the Foods Program's delivery of its regulatory and public health responsibilities.

Strengthen Science and Effective Risk-Based Decision Making

Outbreaks of foodborne illness and contamination events have a substantial impact on public health. An estimated 48 million foodborne illnesses occur every year,[3] causing an estimated 128,000 hospitalizations and 3,000 deaths. Foodborne illnesses cost an average of $3,630 per case, resulting in more than $36 billion per year in medical costs, lost productivity, and other burdens to society.[4]

The Foods Program prioritizes the prevention of foodborne and feed-borne illness of both known and unknown origins through the implementation of the FDA Food Safety Modernization Act (FSMA) and other legislative authorities. The Program addresses food safety risks at multiple points of the food supply chain through regulations, guidance, technical assistance, training, outreach, consumer information, and model codes for food service establishments.

Nutrition-related priorities are another focus area of the Foods Program. Poor diet is a key risk factor for chronic diseases–the leading cause of death and disability in the United States. Many chronic diseases and conditions–such as heart disease, stroke, cancer, diabetes, obesity, and

[3] https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html *Center of Disease Control and Prevention (CDC) 2011 Estimates and Findings. A comparable analysis cannot be made between CDC's 2011 estimates and findings from earlier years due to a new methodology being used in 2011.*

[4] https://www.cdc.gov/chronicdisease/about/costs/index.htm

arthritis–are among the most common, costly, and preventable of all health problems in the United States today. Approximately 90 percent of the nation's health care expenditures are for people with one or more chronic medical conditions.[5]

The Foods Program ensures that nutrition labeling is informative and accurate. The program promotes a nutritionally healthy food supply to reduce the hundreds of thousands of deaths each year attributable to poor diet.

In addition to the high-priority initiatives listed above, the Foods Program conducts other important activities related to proper nutrition and food and cosmetics safety. These include:

- Premarket review of infant formula notifications and regulation of ingredients and packaging, such as the review of food additive and color additive petitions
- Postmarket monitoring for chemical contaminants
- Authorization of nutrient content and health claims
- Regulation of dietary supplements
- Cosmetics safety and labeling

Continued Efforts to Secure National Infant Formula Supply

In early 2022, a large-scale recall was engaged to mitigate an outbreak of *Cronobacter sakazakii* illnesses associated with the consumption of powdered infant formula. This critical situation led to a national shortage of infant formula and shaped FDA's actions throughout 2022.

Throughout 2022, FDA took numerous measures to improve the resiliency of the U.S. infant formula supply and to restore consumers' confidence that the formula they feed their children is safe and nutritious. Such measures include:

- Increasing flexibilities regarding the importation of certain infant formula products to bolster the availability of infant formula while protecting the health of infants.[6]
- Making educational resources available for parents and caregivers about using the hundreds of millions of bottles worth of imported infant formula headed to the U.S.
- Announcing new guidance that helps provide a pathway for infant formulas operating under enforcement discretion in the U.S. to remain on the market.[7]
- Releasing an outline of a prevention strategy under development to prevent *Cronobacter sakazakii* illnesses associated with consumption of powdered infant formula.[8]

[5] *Centers for Disease Control and Prevention. "Chronic Disease Prevention and Health Promotion: Chronic Disease Overview."* https://www.cdc.gov/chronicdisease/about/index.htm

[6] https://www.fda.gov/news-events/press-announcements/fda-encourages-importation-safe-infant-formula-and-other-flexibilities-further-increase-availability

[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-transition-plan-exercise-enforcement-discretion

[8] https://www.fda.gov/food/new-era-smarter-food-safety/outline-fdas-strategy-help-prevent-cronobacter-sakazakii-illnesses-associated-consumption-powdered

In March 2023, FDA released an Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market.[9] The strategy follows a months-long infant formula shortage sparked by unsanitary conditions at one of the nation's largest infant formula facilities, which led to a significant voluntary recall and a multiple-month production shutdown.[10]

This strategy, with input from the National Academy of Science, Engineering and Medicine (NASEM),[11] represents a first step toward issuing a long-term national strategy in 2024 to improve preparedness against infant formula shortages by outlining methods to improve information-sharing, recommending measures for protecting the integrity of the infant formula supply chain, and preventing contamination. The long-term strategy will also explore new approaches to help facilitate entry of new infant formula manufacturers to increase supply and mitigate future shortages and recommend other necessary authorities to gain insight into the supply chain and risks for shortages.

In May 2023, FDA released a number of materials to help consumers and other stakeholders better understand *Cronobacter sakazakii*, the pathogen that has been at the center of a number of recent recalls of powdered infant formula. These materials included a blog,[12] a new webpage,[13] and an infographic.[14]

Additionally, in August 2023, FDA sent three warning letters[15] to infant formula firms to reinforce the importance of instituting and maintaining appropriate corrective actions when pathogens are detected to ensure compliance with FDA's laws and regulations.

And in October 2023, FDA announced updates to its infant formula compliance program.[16] These include additional background on the risks associated with *Salmonella* and *Cronobacter* in infant formula products, and the conditions that could lead to environmental contamination within the manufacturing facilities. The program also provides guidance for firms, including instructional material for conducting environmental samples for these pathogens and for how to notify FDA of any positive findings.

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[9] https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/immediate-national-strategy-increase-resiliency-us-infant-formula-market

[10] https://www.fda.gov/food/cfsan-constituent-updates/fda-publishes-immediate-national-strategy-increase-resiliency-us-infant-formula-market

[11] https://www.nationalacademies.org/our-work/challenges-in-supply-market-competition-and-regulation-of-infant-formula-in-the-united-states

[12] https://www.fda.gov/news-events/fda-voices/demystifying-cronobacter-and-actions-fda-taking-keep-food-supply-safe

[13] https://www.fda.gov/food/resources-you-food/infant-formula

[14] https://www.fda.gov/media/167688/download

[15] https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-three-infant-formula-manufacturers

[16] https://www.fda.gov/media/71695/download?attachment

FDA remains committed to ensuring that consumers have confidence that the formula they feed their children is safe and nutritious.

Addressing Diet-Related Chronic Diseases and Improving Health

FDA helps to ensure that Americans of all ages and backgrounds can reduce their risk of diet-related chronic diseases and improve nutrition.

In March 2023, FDA issued draft guidance to provide industry with the Agency's current thinking on how and when to use Dietary Guidance Statements in food labeling, as well as to ensure that Dietary Guidance Statements promote good nutrition and nutritious dietary practices.[17] Dietary Guidance Statements are used on food labels to provide consumers with information about foods or food groups that can contribute to a nutritious dietary pattern in order to help consumers make healthier choices more easily.[18]

The draft guidance provides the Agency's best thinking about the use of statements such as "make half your grains whole grains," and "eat a variety of vegetables." The draft guidance recommends that foods with Dietary Guidance Statements contain a meaningful amount of the food or category of foods that is the subject of the statement and that they also not exceed certain amounts of saturated fat, sodium, and added sugars. The recommendations in the guidance can enhance consistency in the use of such statements and consumer understanding.

This guidance is part of FDA's overall effort to improve dietary patterns in the United States, help reduce the burden of nutrition-related chronic diseases, and advance health equity. It is also part of the National Strategy presented at the White House Conference on Hunger, Nutrition, and Health held on September 28, 2022.

The FDA Food Safety Modernization Act

FDA is transforming the nation's food safety system from a reactive system to a proactive system by implementing FSMA to focus on preventing food safety problems before they occur. FSMA engages all domestic and foreign participants in the food system to do their part to minimize the likelihood of harmful contamination.

As part of FSMA, FDA issued a final rule on food traceability in November 2022.[19] This rule is designed to facilitate faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and deaths. The key requirement of the 2022 final rule is that persons who manufacture, process, pack, or hold food on the related Food Traceability List maintain records, including key data elements related to critical tracking events.

In May and June of 2023, FDA published additional guidance and resources for small entities—including farms and small businesses—and industry to educate on the rule's requirements and

[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-about-dietary-guidance-statements-food-labeling

[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-about-dietary-guidance-statements-food-labeling

[19] https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods#:~:text=The%20Food%20Traceability%20Rule%20requires,in%20the%20food%27s%20supply%20chain.

facilitate compliance with applicable recordkeeping policies.[20] This aligns with the Agency's efforts to ensure all required food facilities meet the rule's compliance date of January 20, 2026.[21]

Advanced Goals of the New Era of Smarter Food Safety Blueprint

The New Era of Smarter Food Safety blueprint, released in July 2020, outlines the work FDA plans to undertake over the next decade to modernize its food safety approaches and bend the curve of foodborne illness by reducing the number of illnesses.[22]

It includes work to enhance traceability, improve predictive analytics, respond more rapidly to outbreaks, address new business models, reduce contamination of food, and foster the development of a stronger food safety culture.

In December 2022, FDA, in coordination with USDA and CDC, collaborated with the Conference of Food Protection (CFP) to release food safety best practices for third-party delivery services.[23] These recommendations focus on key parameters companies should consider when delivering food to consumers.

Addressing the safety of foods ordered online and delivered directly to consumers is a priority outlined in the New Era of Smarter Food Safety blueprint. Consumers are increasingly ordering food from a variety of online retailers. The best practices document identifies mitigating measures to potential food safety vulnerabilities, including those that may arise in the "last mile" of delivery.

In line with these efforts, FDA also issued a Request For Information (RFI) in April 2023 to learn more from industry, consumer advocacy group and consumers about the content, format, and accuracy of food labeling information provided through online grocery shopping platforms.[24]

Online grocery sales in the U.S. exploded during the COVID-19 pandemic, growing from $62 billion in 2019 to $96 billion in 2020. This number continues to grow, with online grocery orders expected to make up more than 20 percent of all U.S. grocery sales this year.

The RFI aligns with the Biden-Harris Administration's National Strategy on Hunger, Nutrition, and Health. The RFI also aims to ensure that consumers can find and view labeling information online, which can help them to make more informed and healthier food choices.

[20] https://www.fda.gov/food/cfsan-constituent-updates/now-available-small-entity-compliance-guide-food-safety-modernization-act-fsma-food-traceability

[21] https://www.fda.gov/food/cfsan-constituent-updates/fda-publishes-new-faqs-and-additional-tools-food-traceability-rule

[22] https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint

[23] http://www.foodprotect.org/guides-documents/guidance-document-for-direct-to-consumer-and-third-party-delivery-service-food-delivery/

[24] https://www.federalregister.gov/public-inspection/2023-08543/request-for-information-food-labeling-in-online-grocery-shopping

Improved Outbreak Response

The Coordinated Outbreak Response & Evaluation (CORE) Network coordinates the Agency's efforts to find, stop, and work to prevent outbreaks of illness related to FDA-regulated foods. This office coordinates activities across FDA's subject matter experts, FDA field offices, and state and local partners. CORE works with other federal agencies, such as CDC and USDA, to ensure timely and effective resolution of foodborne illness outbreaks.

In calendar year 2023, the CORE Signals Team evaluated a total of 69 events and 25 events transferred to a CORE Response Team. Of the 25 events coordinated by a Response Team, nine investigations resulted in a public advisory. Public advisories issued by CORE provide specific, actionable steps for consumers to take to protect themselves.

In April 2023, FDA released an Outbreak Investigation Report (OIR) on its investigation of a *Salmonella Typhimurium* outbreak caused by contaminated cantaloupe.[25] OIRs provide an overview of factors contributing to contamination in foodborne outbreaks. These reports summarize the outbreak and investigation and provide conclusions and recommendations to assist in future prevention efforts. The cantaloupe OIR focused on an outbreak that caused 87 reported illnesses and 32 hospitalizations in the U.S. between July and September 2022, but also addressed historical outbreak and laboratory findings to the cantaloupe growing region in question.

FDA identified *Salmonella* species in on-farm, post-harvest, and off-farm environments due to outbreak response activities. The sampling analyses explained in the report suggest that *Salmonella* presence is a recurring issue which may impact the safety of melons grown in the region. In light of the investigational findings, the OIR highlighted several recommendations and requirements applicable to firms, such as growers of melons and similar produce, that may help prevent similar outbreaks in the future.

OIRs are important communication tools developed by CORE to allow FDA to share outbreak investigation findings with stakeholders to help limit or prevent future outbreaks. The information shared within an OIR goes beyond what is included in the public advisories. OIRs build on the foundational work established by FSMA while leveraging data enhancements and modern approaches included in FDA's New Era of Smarter Food Safety.

In addition to OIRs, CORE leads other publication efforts with the goal of sharing investigational findings to help inform prevention. In 2023, CORE contributed to 17 publications,[26] (peer-reviewed journal articles, magazine articles, and other reports) and more than 35 presentations. In January 2024, CORE published its first ever Annual Report which highlights the overall work done by CORE in 2022 and the public health impact of the work. [27] Annual Reports from CORE will continue moving forward. CORE-led OIRs, publications, and reports are important tools for sharing outbreak findings with stakeholders and they advance the goals set forth in FDA's Foodborne Outbreak Response Improvement Plan.

[25] https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-cantaloupe-implicated-outbreak-salmonella-typhimurium

[26] https://www.fda.gov/food/outbreaks-foodborne-illness/core-publications

[27] https://www.fda.gov/food/outbreaks-foodborne-illness/core-annual-reports

Improved Pathogen Detection and Traceability

FDA initiated the GenomeTrakr network in 2012 to accelerate the use of whole-genome sequencing within food safety. The network has grown to include national and international federal, state, hospital, and academic labs, all of whom perform genomic surveillance of foodborne pathogens. FDA continues to facilitate opportunities that expand the adoption of genomic tools by public and private laboratories. This effort aligns with the goals of the New Era of Smarter Food Safety Blueprint, which includes facilitating opportunities to speed up the sequencing of pathogens. In addition, the Foods Program and GenomeTrakr are advancing FDA's One Health paradigm.[28]

The GenomeTrakr network, now in its eleventh year, contributes to a public repository that has amassed more than 1.2 million foodborne pathogen bacterial genome sequences (including more than 590,000 *Salmonella*). These genome sequences are stored in a publicly accessible database at NIH. FDA developed outbreak traceback methodology based on whole bacterial genomes that can precisely determine the source of many outbreaks down to the farm or facility level.

Applying genomic technology to foodborne pathogen surveillance helps the Foods Program to better protect public health by:

- Enhancing surveillance capabilities and allowing quicker, more responsive, and more precise investigations of outbreaks.
- Providing for better recall scoping and prioritization by accurately tying facility inspection findings to both previous facility findings and clinical findings.
- Improving cooperation between federal and state agencies and facilitating usage of genome technology by public health labs via cloud computing analysis platforms, such as GalaxyTrakr.[29]
- Identifying emerging antimicrobial resistance threats in the food supply.
- Supporting research to improve preventive controls and good agricultural practices and leveraging data for use in Agency risk assessments.
- Sample collection and sequence cataloging from food production sites can help monitor and ensure compliance with FDA's rules on safe food-handling practices.

The Foods Program applies whole genome sequencing regularly to trace foodborne outbreaks for Shiga toxin-producing *E.coli* (STEC), *Salmonella*, and *Listeria monocytogenes*.

In 2023, FDA collected samples as a regular part of foodborne outbreak investigations and compliance actions; FDA also performs routine surveillance of the genomic database, and 216 separate genomic analyses were performed to support those activities. To date, more than 1,200 such analyses have been performed.

- **Domestic**: Genomic data determined that the *Listeria* strain found in an ice cream manufacturing facility matched an outbreak strain leading to the manufacturer's recall.
- **International**: In 2023, genomic analysis helped international agencies associate product and clinical cases of Salmonellosis associated with cantaloupes.

[28] https://www.fda.gov/animal-veterinary/animal-health-literacy/one-health-its-all-us

[29] https://galaxytrakr.org/

- **Recall and Import Scoping**: Genomic analysis elucidated the magnitude of the issue of *Listeria* in enoki mushrooms and informed the scope of recalls and the country-wide import restrictions.
- **Infant Formula**: More robust genomic surveillance of the pathogen *Cronobacter sakazakii* from powdered infant formula facilities, products, and ill infants would have helped better inform public health officials and the public.[30]
- **Good Agricultural Practices**: Genomic analysis played a key role in understanding and moderating risks from environmental pathogens in agricultural practices in Arizona, California, and most recently southwest Indiana.

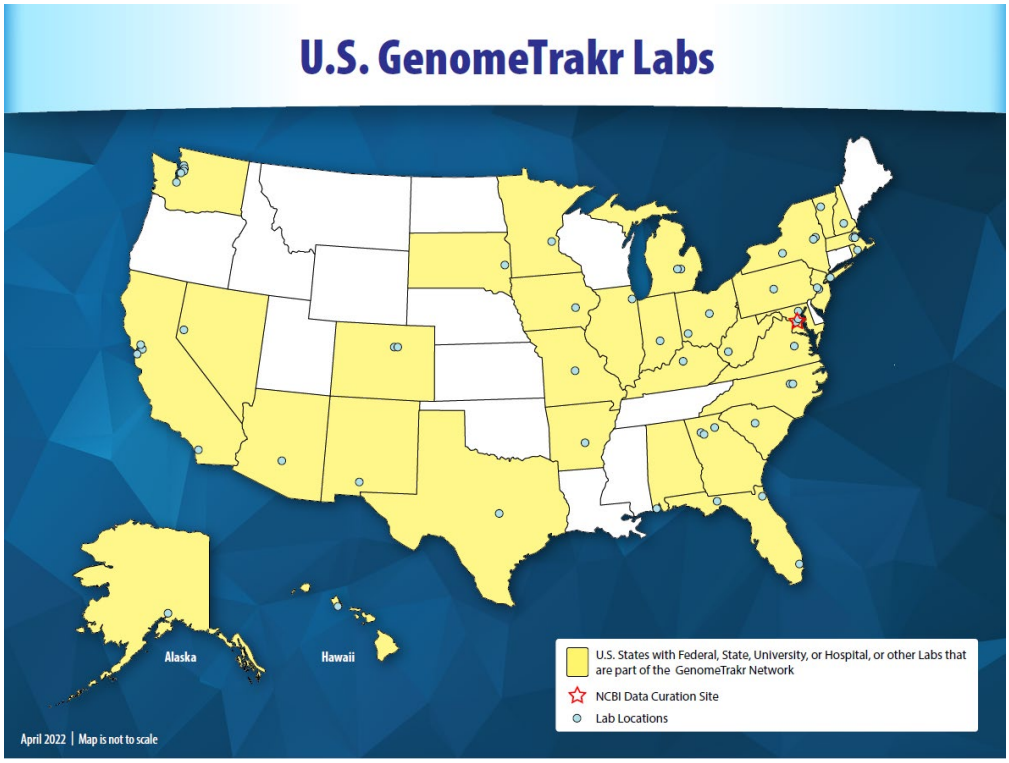

Figure 22 - U.S. Map of GenomeTrakr Labs

Published Timely Food Additive, Color Additive, Generally Recognized as Safe (GRAS), and Food Contact Substance Reviews

The Foods Program has statutory responsibility for the following premarket review activities that help to foster competition and innovation and fall within FDA's goals of improving and safeguarding access:

- Review and approval of all petitions for direct food additives or for color additives.
- Review and approval of all new food contact substances, food contact materials, packaging, antimicrobials, and other indirect food additives.

[30] https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022

- Review of Generally Recognized as Safe (GRAS) ingredients and products of biotechnology related to food.

FDA has the primary legal responsibility for determining the safe use of food additives and color additives. To market a new food additive, color additive, or food contact substance—or before using an additive already approved for one use in another manner not yet approved—a manufacturer or other sponsor must first obtain regulatory approval. A manufacturer or other sponsor may petition for a food additive or a color additive or inform a notification program for food contact substances and GRAS food ingredients. In FY 2023, FDA ensured safe access to the food supply by reviewing four Food Additive or Color Additive Petitions, 65 GRAS notifications, and 70 premarket notifications for Food Contact Substances.

FDA Issues Update on Recent Activities Pertaining to PFAS in Food

In May 2023, FDA shared testing results for per- and polyfluoroalkyl substances (PFAS) in 186 samples from two regional collections from the Total Diet Study (TDS).[31] PFAS was detected in two cod and two shrimp samples, and one sample each of tilapia, salmon, and ground beef. For the samples where PFAS was detected, each type of PFAS for which there are toxicological reference values (TRVs) was assessed individually. FDA has concluded that exposure to the PFAS at the levels measured in the seven samples are not likely to be a health concern for young children or the general population.

These data are consistent with previous TDS testing results; no PFAS have been detected in over 97 percent (701 out of 718) of the fresh and processed foods tested from the TDS. At least one type of PFAS was detected in 44 percent (14 out of 32) of the TDS seafood samples and in 74 percent (60 out of 81) of the samples from the 2022 targeted seafood survey.

FDA is committed to maintaining the availability of safe seafood, as it provides key nutrients for children and adults. The Agency will continue to engage with industry and apply the latest science to increase our understanding of the levels of PFAS in seafood, the reasons for the differences within and across types of seafood, and to help identify strategies that can reduce PFAS in seafood. In addition, FDA is available to provide technical assistance to industry as laboratories work to expand their analytical capabilities to test for PFAS in seafood.

Since 2019, FDA has expanded its testing methodology from 16 to now 30 types of PFAS in 2023. The Agency is also expanding its research effort by using high resolution mass spectrometry (HRMS). This will allow FDA to determine which additional types of PFAS, beyond those tested for with the current method, are present in foods and should be included in targeted methods going forward.

As part of FDA's technical assistance to states, the Agency is contributing to research to understand how PFAS is taken up by plants, and how PFAS concentrations vary between plants and parts of a plant. This is an area of research that may help make significant reductions in PFAS exposure from food. For example, by studying PFAS uptake, researchers may help identify plants that can be safely grown in contaminated soil without PFAS uptake to the edible portion of the plant.

[31] https://www.fda.gov/food/science-research-food/fda-total-diet-study-tds

Implementing the Closer to Zero Action Plan and Safeguarding Foods for Babies and Young Children

In April 2021, FDA announced a comprehensive plan to further reduce levels of toxic elements such as lead cadmium, mercury, and arsenic in foods for babies and young children. The "Closer to Zero: Action Plan for Baby Foods" identifies actions FDA will take to reduce exposure to toxic elements from foods eaten by babies and young children to as low as possible. FDA has

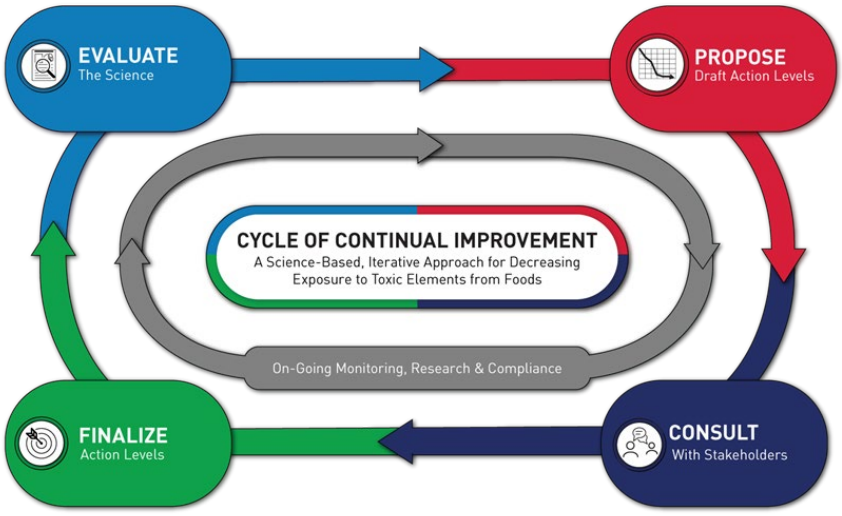

Figure 23 - Closer to Zero Action Plan's Cycle of Continual Improvement

prioritized babies and young children because their smaller body sizes and metabolism make them more vulnerable to the harmful effects of these contaminants. [32]

In January 2023, FDA issued for public comment "Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry."[33] As FDA outlined in "Closer to Zero" action plan, the agency expects over time for this guidance, together with other activities, to result in industry progressively reducing levels of lead in foods to as low as possible. The draft guidance supports FDA's goal of reducing dietary exposure to lead, arsenic, cadmium, and mercury, and the associated health effects, while maintaining access to nutritious foods.[34]

In June 2023, FDA announced the availability of a final guidance for industry entitled "Action Level for Inorganic Arsenic in Apple Juice."[35] The final guidance identifies for industry the action level of 10 parts per billion (ppb) for inorganic arsenic in apple juice, issued in draft by

[32] https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods

[33] https://www.federalregister.gov/public-inspection/2023-01384/guidance-action-levels-for-lead-in-food-intended-for-babies-and-young-children

[34] https://www.federalregister.gov/documents/2023/01/25/2023-01384/action-levels-for-lead-in-food-intended-for-babies-and-young-children-draft-guidance-for-industry

[35] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-apple-juice

the agency in 2013. The guidance supports FDA's goal to reduce exposure to environmental contaminants from foods commonly consumed by babies and young children.[36]

FDA expects that the 10 ppb action level, though non-binding, will encourage manufacturers to reduce levels of inorganic arsenic in apple juice. FDA will continue its current practice of monitoring arsenic in apple juice samples and if testing identifies inorganic arsenic in apple juice above 10 ppb, FDA will consider this action level, in addition to other factors, to determine whether to take enforcement action.

Partnering with other federal agencies, academia and other stakeholders, FDA will continue its ongoing surveillance sampling of these products to monitor progress levels over time and to better understand the variability of toxic element levels in different foods and the potential impacts.

Encouraged the Safe Production of Dietary Supplements

In FY 2023, FDA's regulatory activities for dietary supplements focused on protecting consumers from unsafe or otherwise unlawful products and ensuring product integrity. This includes warning several firms for selling dietary supplements with claims to treat cardiovascular disease, publicly raising concerns about probiotic products sold for use in preterm infants and issuing consumer alerts for certain weight loss products substituted with toxic botanicals. In March 2023, FDA unveiled its new Dietary Supplement Ingredient Directory, a webpage where the public can look up ingredients used in products marketed as dietary supplements and quickly find what the FDA has said about that ingredient. The Ingredient Directory is intended to help manufacturers, retailers, and consumers stay informed about ingredients and whether they are appropriate for use in dietary supplements.

FDA's oversight activities in FY 2023 included conducting over 500 inspections at dietary supplement facilities, both domestic and foreign. These facility inspections, along with other oversight activities, resulted in:

- 37 warning letters
- 1,797 import refusals
- Two injunctions (filed)
- One seizure
- Nine criminal convictions

Additionally, FDA posted 45 public notifications for products that have been found to be tainted with undeclared drugs, many of which are marketed as dietary supplements.

FDA responded to 44 new dietary ingredient notifications in FY 2023 with 27 notifications being acknowledged with no objection. FDA objected to 17 notifications, seven of which raised safety or identity concerns, another seven notifications were incomplete, and three did not pertain to a dietary ingredient or dietary supplement. Throughout FY 2023, FDA received more than 2,000 adverse event reports associated with dietary supplements. The reports are evaluated by clinical reviewers in CFSAN to monitor the safety of consumer products, an integral part of FDA's post-market surveillance for dietary supplements.

[36] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-apple-juice

PERFORMANCE

The Foods Program's performance measures focus on premarket application review, incidence of foodborne pathogens, regulatory science activities, and postmarket inspection and import screening activities to ensure the safety and proper labeling of the American food supply and cosmetics, as detailed in the following table.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 +/- FY 2024
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. (Output)	FY 2022: 57% Target: 80% (Target Not Met)	80%	80%	Maintain
214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. (Outcome)	FY 2023: 959 enrolled Target: 927 (Target Exceeded)	974	989	+15
212415: Foodborne Illness - Reduce the incidence of laboratory-diagnosed, domestically-acquired Shiga toxin-producing Escherichia coli (STEC) infections. (Outcome)	CY 2022: 4.6 cases/100,000 Target: 4.3 (Target Not Met)	4.2	4.1	-0.1
212416: Foodborne Illness - Reduce the incidence of laboratory-diagnosed, domestically-acquired Listeria monocytogenes infections. (Outcome)	CY 2022: 0.26 cases/100,000 Target: 0.25 (Target Not Met)	0.25	0.25	Maintain
212417: Foodborne Illness - Reduce the incidence of laboratory-diagnosed, domestically-acquired Salmonella infections. (Outcome)	CY 2022: 14.5 cases/100,000 Target: 14.0 (Target Not Met)	13.7	13.4	-0.3

Figure 24 - Foods Performance Table 1/2

214337: Accuracy rate for confirmation of presumptive STEC positives from leafy green samples. (Output)	FY 2023 : 40% Target: 40% (Target Met)	50%	60%	+10%
214221: Percentage of Human and Animal Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 98.9% Target: 80% (Target Exceeded)	80%	80%	Maintain
214222: Percentage of Human and Animal Food follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 76.0% Target: 65% (Target Exceeded)	65%	65%	Maintain
214206: Maintain accreditation for ORA labs. (Outcome)	FY 2023: 12 labs Target: 12 labs (Target Met)	12 labs	12 labs	Maintain
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). (Outcome)	FY 2023: 3,200 rad & 2,600 chem Target: 3,200 rad & 2,600 chem (Target Met)	3,200 rad & 2,600 chem	3,200 rad & 2,600 chem	Maintain

Figure 25 - Foods Performance Table 2/2

The following selected items highlight notable results and trends detailed in the performance table.

Food Additive and Color Additive Petition Review

The Foods Program conducts an extensive review as part of its Food Additive and Color Additive Petition review process, which includes a Chemistry, Toxicology, and Environmental evaluation. The current measure is for FDA to complete review and action on the safety evaluation of direct and indirect food and color additive petitions within 360 days of receipt. FDA did not meet the target in FY 2022, completing 57 percent of the petitions within 360 days of receipt. Delayed review times for petitions in FY 2022 are due to increased complexity of recent submissions that lead to additional time needed to review larger and more complex data sets. Additionally, with the exception of environmental scientists, the staff responsible for reviewing and managing petitions also oversee other premarket review programs which are experiencing an increase in review volume and have stricter timeframes for completion. Despite the factors that led to not meeting the FY 2022 target, recent hiring efforts will facilitate the return to previous review levels, so for now FDA will maintain FY 2024 and FY 2025 targets at 80% and monitor the potential need to adjust going forward.

Voluntary National Retail Food Regulatory Program Standards

Strong and effective regulatory programs at the state, local, tribal, and territorial (SLTT) level are needed to prevent foodborne illness and reduce the occurrence of foodborne illness risk factors in retail and foodservice operations. The voluntary use of the Retail Program Standards by a food inspection program reflects a commitment toward continuous improvement and the application of effective risk-based strategies for reducing foodborne illness. The FY 2023 actual

enrollment number of SLTT in the Retail Program Standards reflects an annual increase of 47 enrollments from the year-end FY 2022 total enrollments (912). Awareness of the value of using the Retail Program Standards to drive program improvement continues to grow, particularly among local health departments. In addition, more retail food regulatory programs are recognizing that FDA cooperative agreement funds are available to jurisdictions that enroll in the Retail Program Standards and commit to achieving key milestones. The FY 2024 and FY 2025 targets reflect increases in the number of enrollees by 15 above the previous year's actual number of enrollees or target.

Key Pathogens

Consistent with the Healthy People 2030 objectives, FDA is tracking a set of performance measures related to the incidence rates of infection for Shiga toxin-producing E. coli (STEC), Salmonella, and Listeria monocytogenes. These organisms remain significant from a public health perspective in terms of the number and severity of illnesses they cause, and outbreaks are frequently attributed to FDA-regulated products. Therefore, there is a continued need to invest resources into prevention activities to reduce illness caused by these pathogens. In CY 2020, there was a significant decrease in the incidence rate of infection for each of these three pathogens. According to the CDC, there was a 26 percent decrease in incidence of infections caused by all pathogens transmitted commonly through food during 2020, which was the largest single-year variation in incidence during 25 years of FoodNet surveillance.[37] Widespread public health interventions implemented to prevent SARS-CoV-2 transmission might have contributed to this decrease in detection of illnesses. In CY 2022, the incidence of infections caused by pathogens transmitted commonly through food generally return to levels observed during the pre-pandemic period, 2016-2018. [38] Continued surveillance might improve the understanding of how the pandemic affected foodborne illness and might help identify prevention measures and strategies that FDA, industry, and other public health partners can use to target particular pathogens and foods. CFSAN is keeping the FY 2024 and 2025 targets in place consistent with planned progress toward Healthy People 2030 objectives and will monitor the potential need to adjust targets going forward.

STEC Pathogen Detection Improvement Metric

Leafy greens are among the most widely consumed vegetables and an important part of an overall healthy diet. However, while millions of servings are consumed safely every day, leafy greens have been repeatedly associated with illnesses caused by Shiga toxin-producing *E. coli* (STEC), the most common of which is *E. coli* O157:H7. FDA is committed to breaking this cycle of reoccurring outbreaks. FDA microbiologists will improve the microbiological analytical workflow for STEC testing of leafy greens enabling the FDA to more accurately and quickly detect, characterize, and assess the public health risk associated with this highly variable group

[37] *Ray LC, Collins JP, Griffin PM, et al. Decreased Incidence of Infections Caused by Pathogens Transmitted Commonly Through Food During the COVID-19 Pandemic — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2017–2020. MMWR Morb Mortal Wkly Rep 2021;70:1332–1336. DOI: http://dx.doi.org/10.15585/mmwr.mm7038a4*

[38] Delahoy MJ, Shah HJ, Weller DL, et al. Preliminary Incidence and Trends of Infections Caused by Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2022. MMWR Morb Mortal Wkly Rep 2023;72:701–706. DOI: http://dx.doi.org/10.15585/mmwr.mm7226a1.

of pathogens. The new workflow will greatly increase the accuracy of confirmation and improve the ability to isolate pathogenic STECs when they are present. FDA is investing in a new STEC specific-agar, a gelatinous substance used for biological culture media, for the confirmation step to enhance our current presumptive positive confirmation rate from around 30 percent to upwards of 70 percent over the next few years. The target is an increase of 10 percent confirmation for presumptive positives each year for FY 2024 and 2025. This increase will strengthen confidence in initial screening results and increase the likelihood of obtaining an isolate when STECs are present. As a result, FDA's testing protocol for produce-borne STEC in leafy greens and other short shelf-life produce commodities will significantly improve the quality of STEC detection and confirmation and enable regulators to more confidently and proactively identify potential problems with leafy greens before they reach consumers.

ORA Field Performance Measures

ORA's performance goals measure topics such as our commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to ORA regulatory impact on violators, and are tracked on a 3-year rolling basis. Due to the nature of regulatory actions and subsequent follow-up conducted by FDA, the duration of these events can vary considerably. After regulatory action, FDA also works to schedule follow-up after a reasonable time has passed to allow the firm to correct for the original violations. A 3-year rolling timeline also ensures tracking of all significant violations that require attention and allows for a more robust analysis.

ORA Laboratory Accreditation

ORA's Philadelphia Laboratory was closed at the end of FY 2022, though the accreditation remained active though the end of the fiscal year, allowing ORA to meet this performance goal. Starting in FY 2023, the target for this goal will be lowered to 12 to reflect the continuation of accreditation at ORA's remaining 12 laboratories.

Performance Activity Data

Foods Program Activity Data

CFSAN Workload and Outputs	FY 2023 Final	FY 2024 CR	FY 2025 PB
Food and Color Additive Petitions			
Petitions Filed [1]	7	7	7
Petitions Reviewed [2]	6	6	6
Premarket Notifications for Food Contact Substances			
Notifications Received	65	65	65
Notifications Reviewed [3]	70	70	70
Infant Formula Notifications			
Notification Reviews Completed [4]	22	22	22
Notification Reviews Completed Within 180 Days of Filing [5]	12	12	12
FDA Review Time [6]	180 days	180 days	180 days
New Dietary Ingredient Notifications			
Notification Reviews Completed	44	44	44
Notification Reviews Completed Within 75 Days of Filing [7]	44	44	44
FDA Review Time	75 days	75 days	75 days

[1] This number is for the cohort of petitions filed in the FY.

[2] Number reviewed includes petitions approved, withdrawn, or placed in abeyance due to deficiencies during the FY.

[3] Number reviewed includes notifications that became effective or were withdrawn.

[4] A notification may include more than 1 infant formula.

[5] Number of submissions reviewed includes some submissions that were received in the previous FY.

[6] In January 2021, due to the increasing complexity of new infant formula submissions received in late 2020, FDA determine that it would not be able to complete its review of submissions within 90 days after filing dates and notified industry it would be adding up to an additional 60 days (i.e., 150 days total) to the review period for new submissions moving forward. In November 2021, FDA determined that it would need an additional 30 days (i.e., 180 days total) in order to complete reviews of submissions moving forward and notified industry. This change was fully implemented during the next reporting cycle which occurred in Q2 of fiscal year 2022.

[7] Number of submissions received in current FY includes some received late in the FY that are expected to be completed in the next FY when the due date occurs.

Figure 26 - Foods PAD Table

HUMAN DRUGS

PURPOSE STATEMENT

FDA's Human Drugs Program is responsible for ensuring the safety and efficacy of prescription and over-the-counter (OTC) drug products, including generic drugs, and therapeutic biological products, including biosimilar and interchangeable biosimilar products; monitoring the safety of marketed drugs; and overseeing drug quality to prevent and detect substandard or counterfeit drugs in the U.S. market. The Center for Drug Evaluation and Research (CDER) and Office of Regulatory Affairs (ORA) field drugs program comprise FDA's Human Drugs Program, which operates with funding from budget authority and user fees.

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Public Health Service Act of 1944 (42 U.S.C. 201); Federal Advisory Committee Act (FACA) of 1972 as amended; Orphan Drug Act of 1983 (21 U.S.C. 360ee); Drug Price Competition and Patent Term Restoration Act of 1984 (Section 505(j) 21 U.S.C. 355(j)) (a.k.a. "Hatch Waxman Act"); Prescription Drug Marketing Act (PDMA) of 1987 (21 U.S.C. 353); Anti-Drug Abuse Act of 1988; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Orphan Drug Amendments of 1988; Generic Drug Enforcement Act of 1992; Prescription Drug User Fee Act (PDUFA) of 1992; FDA Export Reform and Enhancement Act of 1996; Food and Drug Administration Modernization Act (FDAMA) of 1997; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Best Pharmaceuticals for Children Act (BPCA) of 2002; Freedom of Information Act (FOIA) as amended in 2002 (5 U.S.C. § 552); Pediatric Research Equity Act (PREA) of 2003; Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3); Food and Drug Administration Amendments Act (FDAAA) of 2007; Public Health Service Act of 2010 (42 U.S.C. 262); Protecting Patients and Affordable Care Act of 2010 (P.L. 111-148); Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) (P.L. 112-144) ; Drug Quality and Security Act (P.L. 113-54); Sunscreen Innovation Act (P.L. 113-195); Adding Ebola to the FDA Priority Review Voucher Program Act (P.L. 113-233); 21st Century Cures Act (CURES Act) (P.L. 114-255); Food and Drug Administration Reauthorization Act of 2017 (FDARA) (P.L. 115-52); Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) (P.L. 115-271); Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (P.L. 116-136); Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (PL 117-180); and Consolidated Appropriations Act, 2023 (P.L. 117-328).

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
Human Drugs	**2,006,214**	**2,058,404**	**2,283,747**	**2,335,869**	**2,403,402**	**119,655**
Budget Authority	***688,844***	***706,524***	***761,494***	***719,540***	***754,049***	***-7,445***
User Fees	***1,317,370***	***1,351,880***	***1,522,253***	***1,616,329***	***1,649,353***	***127,100***
Center	1,768,212	1,803,931	1,999,525	2,053,725	2,110,936	111,411
Budget Authority	509,915	518,116	550,993	513,638	539,372	-11,621
User Fees	1,258,297	1,285,815	1,448,532	1,540,087	1,571,564	123,032
Field	238,002	254,473	284,222	282,144	292,466	8,244
Budget Authority	178,929	188,408	210,501	205,902	214,677	4,176
User Fees	59,073	66,065	73,721	76,242	77,789	4,068
FTE	**6,725**	**6,743**	**6,953**	**7,580**	**7,589**	**636**

Figure 27 - Human Drugs Funding History Table

The FY 2025 President's Budget for the Human Drugs Program is $2,403,402,000, of which $754,049,000 is budget authority and $1,649,353,000 is user fees. The budget authority decreased by $7,445,000 compared to the FY 2023 Final Level; user fees increase by $127,100,000. The Center for Drug Evaluation and Research (CDER) amount in the request is $2,110,936,000. The Office of Regulatory Affairs (ORA) amount is $292,466,000.

The Human Drugs Program will continue activities to uphold its public health mission of ensuring the safety and efficacy of new, generic, biosimilar, and OTC drug products. The program will continue to advance its mission and strategic efforts to further strengthen our programmatic foundation. These efforts accompanied by the necessary funding will allow the FDA to further our goal to help ensure that human drugs are safe and effective for their intended use, that they meet established quality standards, and that they are available to patients.

The FY 2025 Budget will enable FDA to continue to carry out rigorous science-based premarket drug reviews of new, generic, and biosimilar biological drug products. Identifying and developing new scientific methods, models, and tools to improve the quality, safety, predictability, and efficiency of new drug development is a core mission of FDA. The Agency will continue to promote patient and health professional awareness of drug benefits and risks through effective communication of drug information.

The FY 2025 Budget will also enable CDER to advance capabilities to help prepare for, build resilience to, and respond to medical product shortages. Funding will support optimization of activities targeted at the prevention, mitigation, and monitoring of drug shortages.

BUDGET AUTHORITY

FY 2025 President's Budget: Human Drugs *Budget Authority - Dollars in Thousands*	Center	Field	Total
FY 2023 Final	**550,993**	**210,501**	**761,494**
FY 2025 Budget Authority Changes	**(11,621)**	**4,176**	**(7,445)**
Requested Increases	**25,407**	**8,634**	**34,041**
Public Health Employee Pay Costs	16,956	8,125	25,081
Enterprise Transformation	609	84	693
IT Stabilization & Modernization	3,075	425	3,500
Shortages and Supply Chain-Agency-wide	4,767	-	4,767
Other Adjustments	**(37,028)**	**(4,458)**	**(41,486)**
ORA Transfer to HQ/OGPS	-	(3,630)	(3,630)
FDARA Sec. 905 BA Shift	(39,667)	(2,002)	(41,669)
FY 2024 Comparability Adjustment	2,312	1,033	3,345
FY 2025 Comparability Adjustment	327	141	468
FY 2025 Budget Net Total: Human Drugs	**539,372**	**214,677**	**754,049**

Figure 28 - Human Drugs Budget Authority

Total Requested Increases: +$34.0 million / 5 FTE

Public Health Employee Pay Costs: +$25.1 million

Center: +$17.0 million

Field: +$8.1 million

The FY 2025 President's Budget includes $114.8 million in new budget authority to fund approximately 72 percent of the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 and FY 2025 Cost of Living Adjustments (COLA). For FY 2025 this assumes a 2.0 percent for Civilian and 4.5 percent Military pay increase for FTE funded through budget authority. Within the Human Drugs program, $25.1 million is provided for pay costs, including $17.0 million for CDER and $8.1 million for ORA.

Enterprise Transformation: +$693,000 / 2 FTE

Center: +$609,000 / 2 FTE

Field: +$84,000

The FY 2025 President's Budget provides $2.0 million for Enterprise Transformation, which includes $693,000 for the Human Drugs Program to coordinate and lead several crosscutting agency-wide projects to analyze and implement common business processes and data optimization. Benefits of this funding will include improved communication and data sharing across the life cycle of an inspection, increased access to relevant data to facilitate risk-based decision-making, and introduction of more modern mobile technology for field work to improve

the user experience. The office also seeks to standardize the FOIA business processes across the Agency and create effective governance to enable successful process and technology changes.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

IT Stabilization & Modernization: +$3.5 million

Center: +$3.1 million

Field: +$425,000

The FY 2025 President's Budget provides $8.3 million for IT Stabilization & Modernization, including $3.5 million for the Human Drugs Program to further build FDA's centralized enterprise data modernization capabilities and to strengthen FDA's common data infrastructure, data exchange, and IT analytic services, talent, and tools. With these resources, FDA will continue to improve data exchange and underlying technology platforms in support of FDA's programs and mission-critical responsibilities – to better meet the challenges of emerging threats, support needs for real-time evaluation, and more continuously access, analyze, and aggregate multiple sources of information, such as for recalls, adverse events, outbreaks, and pandemics.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

Shortages and Supply Chain: +$4.8 million / 3 FTE

Center: +$4.8 million / 3 FTE

The FY 2025 President's Budget provides $12.3 million for Shortages and Supply Chain, including $4.8 million for the Human Drugs Program to advance FDA's capabilities to help prepare for, build resilience to, and respond to shortages that are supply-, and demand driven- through improved analytics to identify shortage threats and vulnerabilities as well as regulatory approaches to address disruptions and shortages.

CDER requests funding for keys areas that maintain and advance efforts to combat drug shortages. These include Drug Shortage Data and Analytics to continue to support the surveillance system built during the pandemic, and support for work to address nitrosamine impurities. Prior to the COVID-19 pandemic, most new drug shortages were the result of manufacturing issues triggered by lack of investment due to economic challenges with new technology and processes to prevent disruptions in manufacturing. However, during the pandemic there has also been substantial increase in demand for products used to treat COVID-19 or its symptoms in hospitalized patients, resulting in additional shortages. The COVID-19 pandemic has not only resulted in many new drug shortages but has also increased concerns around the lack of transparency and data on the pharmaceutical supply chain and its potential vulnerabilities.

Industry notifications of supply disruptions have increased from a baseline of approximately 500 notifications per year in 2019 and prior years, to 744 in 2021 and 1267 in 2022. CDER's Drug Shortage Staff (DSS) evaluates each potential for shortage notification based on manufacturer information, market data and availability of alternatives, then takes all appropriate and available actions to prevent and mitigate shortages. This requires extensive outreach to industry to monitor

supplies and encourage other companies to enter a market. DSS has been able to successfully prevent over 500 shortages since 2021 however additional resources are required to continue these efforts, as well as appropriately track, monitor, and report on supplies, availability, and actions taken.

A significant amount of data is needed for activities targeted at the prevention, mitigation, and monitoring of drug shortages. In a report released by the U.S. Government Accountability Office (GAO) on January 29, 2021,[39] GAO highlighted the lack of data available to federal agencies as a key challenge for strengthening domestic drug manufacturing and supply chains. While close communication and coordination with manufacturers, including their reporting requirements, are critical, these activities are not sufficient to adequately prevent and mitigate drug shortages, therefore further capacity must be developed in this space.

Manufacturers are required to submit data with their applications on their drug formulation and manufacturing facilities. Most recently, the Coronavirus Aid, Relief, and Economic Security Act (CARES) mandated that manufacturers provide information on the volume of the drug substances produced, both the active pharmaceutical ingredient and the finished dosage form. While there are some gaps in this data, including lack of insight into the relative reliance on each manufacturing facility and data related to drug distribution, FDA is one of the only agencies with access to much of the information needed to support illumination of the supply chain. The COVID-19 Critical Drug Supply Chain Surveillance team began the work to integrate these data into a single, cloud-based, highly secured system to support the various workstreams related to proactively working to prevent drug shortages and quickly addressing any shortages that occur. However, this work was primarily funded through one-time COVID-19 supplemental funding and does not have dedicated funding to sustain these efforts in the future. CDER needs resources to maintain the systems that bring together data that optimize our response to shortages, including capturing structured data from stakeholders.

Additionally, the ongoing nitrosamine impurity issues contribute to drug shortages either because of removal of drugs with nitrosamine levels above an acceptable level or delays in review and approval of new applications as they are assessed for nitrosamine risk. Nitroso drug substance related impurities (NDSRIs) and other small molecule nitrosamines have also directly caused drug shortages (e.g., losartan, varenicline, ketamine and others). As more NDSRIs are found, more potential drug shortages may occur as manufacturers or regulators stop distribution or take other actions to address the concern and develop plans to mitigate the issue. Often there is a lack of knowledge about the potency of novel nitrosamine such as NDSRIs to cause DNA mutations that could lead to human cancer. The studies being performed at NCTR are part of a global effort to provide an improved scientific underpinning to determine acceptable intake (AI) limits for human drugs. Ongoing work has focused on optimizing Ames testing to make sure the test is predictive of the potential mutagenicity of different nitrosamine and new in vitro model systems

[39] https://www.gao.gov/products/GAO-21-265

to assess nitrosamine genotoxicity. FDA needs continued funding to work towards a speedy resolution of this threat to US drug supply.

At this level of funding, CDER would not be able to further develop framework that can be used to evaluate a drug manufacturing establishment's level of quality management maturity (QMM) as an enduring solution to help mitigate drug shortages. The QMM program, a priority for the Administration, has the capability to help mitigate shortages that are supply- and demand driven-, which ultimately benefits patients and consumers who will have greater and more reliable access to quality drug products when they need them.

Finally, the U.S. drug supply chain has become increasingly complex as it reaches beyond U.S. borders and faces additional threats such as counterfeiting, diversion, cargo theft, and importation of unapproved or substandard drugs, that could result in unsafe and ineffective drugs in the U.S. drug supply chain. While congressionally mandated, the activities mandated under the Drug Supply Chain Security Act (DSCSA) remain unfunded. Without funding for drug supply chain activities, FDA will not be able to fully implement its product tracing program which will significantly enhance FDA's ability to detect and remove potentially dangerous drugs from the drug supply chain and protect consumers from exposure to illegitimate harmful drugs.

USER FEES

Current Law User Fees: +$127.0 million

Center: +$123.0 million

Field: +$4.0 million

The Human Drugs Program request includes an increase of $127.0 million for user fees, compared to FY 2023 Final Level, which will allow FDA to fulfill its mission of promoting and protecting the public health by ensuring safety and efficacy of FDA-regulated products.

PROGRAM DESCRIPTIONS AND ACCOMPLISHMENTS

FDA's Human Drugs Program is responsible for ensuring the safety and efficacy of prescription and over-the-counter (OTC) drug products. This includes not only approval of new drugs and therapeutic biological products but also generic drugs, and biosimilars, including interchangeable biosimilar products; monitoring the safety of marketed drugs; and overseeing drug quality to prevent and detect substandard or counterfeit drugs in the U.S. market. The Center for Drug Evaluation and Research (CDER) and Office of Regulatory Affairs (ORA) field drugs program comprise FDA's Human Drugs Program, which operates with funding from budget authority and user fees.

Looking ahead to FY 2025, CDER is implementing strategic efforts to further strengthen our programmatic foundation, including focusing on innovation; rare disease drug development; health equity; harnessing real world evidence; advanced manufacturing; international harmonization and regulatory convergence; substance abuse and overdose prevention; and drug safety and compounding. Ultimately, these efforts, accompanied by the necessary funding, will allow the Center to further our goals of helping to ensure that human drugs are safe and effective

for their intended use, that they meet established quality standards, and that they are available to patients. The narrative provides greater detail about CDER programs and activities and our recent accomplishments.

Innovation

New Drug Review

FDA is committed to advancing drug approvals to meet patients' needs. Of the 55 novel drugs approved in 2023, 35 (64 percent) were approved first in the United States. Of these novel drugs, 20 (36 percent) were first-in-class. Additionally, 36 (65 percent) of the 2023 novel drug approvals were designated in one or more of the following expedited programs: fast track, breakthrough therapy, priority review, and accelerated approval.[40]

To facilitate drug development, in FY 2023, CDER's Office of New Drugs published 30 guidances, 22 of which focused on disease specific areas of drug development in pediatric and adult populations including first draft guidance for industry on designing clinical trials for psychedelic drugs.

Drug Development Tools

FDA has taken actions to improve the qualification process and accessibility of Drug development tools (DDTs), including launching a publicly accessible DDT database (searchable for qualification submissions, reviews, and determinations across the FDA DDT programs) on our website.41 In addition, the programs awarded a total of eight research grants to support ongoing qualification efforts. Highlights of regulatory science efforts and selected accomplishments include:

Biomarker Qualification Program

As of the end of FY 2023, the Biomarker Qualification Program currently had over 50 biomarker projects under development with industry, academic, and consortia requesters. The program also hosted two public workshops to discuss translation of biomarkers into clinical programs and complexity of composite biomarkers.

Digital Health Technologies in Drug Development

Advances in digital health technologies (DHTs), including electronic sensors, computing platforms and information technology, provide new opportunities to obtain clinical trial data directly from patients. In FY 2023, FDA published the final guidance on use of DHTs in clinical investigations and our Framework for the use of DHTs in Drug and Biological Product Development details activities for FDA's DHT Program.

Clinical Outcome Assessment Qualification Program

The CDER Clinical Outcome Assessment (COA) Qualification Program manages the qualification process for COAs intended to address critical measurement gaps related to unmet

[40] *https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022*

[41] https://force-dsc.my.site.com/ddt/s/

public health needs. The program currently has 67 projects in various stages of qualification and 3 letters of intent (LOIs) under review.

Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program

Since January 2022, ten new applications have been submitted to the ISTAND pilot program, including the first-ever Qualification Plan for this program.

Fit-for-Purpose Initiative

FDA has established qualification programs to support DDT development. One such program, the FDA the fit-for-purpose program (FFP) initiative provides a pathway for regulatory acceptance of dynamic tools and analytical methods that are intended to enable more efficient, effective, and informative drug development. In FY 2023, FDA received two Full Qualification Packages for disease focused clinical trial simulation tools that are currently undergoing review and four briefing package submissions to which FDA responded with recommendations for further development of each drug development tool.

Improving the Efficiency of Medical Product Development and Regulation with In Silico Tools

CDER uses in silico tools to generate critical evidence to support alternative drug-dosing strategies; alleviate the need for additional clinical trials; aid in assessing how concomitant medications or organ impairment effects drug exposure in the absence of dedicated trials; and inform clinical management strategies.

Patient-Focused Drug Development

CDER patient-focused drug development continues to advance patient input by issuing final guidance on methods to identify what is important to patients and draft guidance on selecting, [42] developing, or modifying fit-for purpose clinical outcome assessments.[43]

Artificial Intelligence (AI)

In May 2023, CDER, in collaboration with CBER and CDRH, published a discussion paper, "Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products," that aims to foster dialogue on the use of Artificial Intelligence (AI) and Machine Learning (ML) in drug and biological product development, and the development of medical devices to use with these treatments.[44] To specifically address the use of AI in drug manufacturing, CDER also issued a discussion paper in May 2023, titled "Artificial Intelligence in Drug Manufacturing,"[45] as part of the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative.

[42] *https://www.fda.gov/media/131230/download*

[43] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-selecting-developing-or-modifying-fit-purpose-clinical-outcome

[44] https://www.fda.gov/media/167973/download?attachment

[45] https://www.fda.gov/media/165743/download

Complex Innovative Trial Design

In October 2022, FDA announced the continuation of the complex innovative design (CID) paired meeting program with a goal of facilitating and advancing the use of complex adaptive, Bayesian, and other novel clinical trial designs. Throughout FY 2023, CDER focused on training, outreach, and stakeholder engagement.

Model-Informed Drug Development

Model-informed drug development (MIDD) represents the development and application of exposure-based, biological, and statistical models derived from preclinical and clinical data sources in drug development and regulatory review. MIDD approaches can improve clinical trial efficiency, increase the probability of regulatory success, and optimize drug dosing/therapeutic individualization in the absence of dedicated trials.

The MIDD Paired Meeting Program became a formal meeting program in FY 2023.[46] In FY 2023, nine meetings have been conducted with sponsors.

Advancing Alternative Methods for Regulatory Use

In FY 2023, FDA/CDER continued to act on plans on how the agency can enhance its existing approaches to support the development, qualification, and implementation of alternative methods for regulatory use that can address the "3Rs" and improve predictivity of nonclinical testing. An example of an alternative method is an "organ-on-a-chip" or microphysiological system, which can be used for drug testing using cells and tissues in the laboratory to emulate organ functions.

Rare Disease Drug Development

In May 2022, CDER announced the launch of the new Accelerating Rare disease Cures (ARC) Program.[47] The vision of CDER's ARC Program is to accelerate and increase the development of effective and safe treatment options that will address the unmet needs of patients with rare diseases. In 2023, we have continued our outreach and engagement with the rare disease drug development community soliciting input through a public docket to inform our Learning and Education to Advance and Empower Rare Disease Drug Developers (LEADER 3D) program. CDER's ARC program has additionally supported the launch of critical pilot programs for rare disease drug development such as the Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program.[48]

The ARC Program has accomplished tremendous engagement to advance rare disease drug development in the past year including: more than 25 public speaking engagements; a combined 42 rare disease patient-listening sessions and patient focused- drug development meetings with CDER staff; over 10,000 subscribers to the CDER ARC listserv highlighting agency rare disease

[46] https://www.fda.gov/drugs/development-resources/model-informed-drug-development-paired-meeting-program

[47] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cders-arc-program

[48] https://www.fda.gov/news-events/press-announcements/fda-launches-pilot-program-help-further-accelerate-development-rare-disease-therapies

news and initiatives; and multiple workshops to engage and educate stakeholders on rare disease drug development. As part of FDA's activities in implementing the Act for ALS, the Office of Orphan Product Designations funded multiple natural history and biomarker studies and two contracts related to endpoints for ALS and brain-controlled communication in ALS under the Rare Neurodegenerative Disease Grant Program.

In addition, FDA will continue to work with NIH through the Critical Path for Rare Neurodegenerative Disease (CP-RND) public partnership will continue to work with stakeholders to identify drug development tools to accelerate development of therapeutics for rare neurodegenerative diseases.

Health Equity

FDA is committed to helping achieve diverse participation in research used to support marketing applications for FDA-regulated medical products. In November, FDA in collaboration with the Clinical Trials Transformation Initiative, held a two-day workshop on enhancing clinical study diversity and will publish a report from that workshop.

The Agency seeks to promote innovative trial designs and technologies as approaches that can enhance enrollment of diverse populations; facilitate the development of drugs, biological products, and devices; and improve efficiencies.[49] In May 2023, FDA issued a draft guidance, "Decentralized Clinical Trials for Drugs, Biological Products, and Devices,"[50] which should reduce barriers to trial participation and increase the breadth and diversity of participants trials.

Harnessing Real World Evidence

FDA continues to work to expand the use of fit-for-purpose, real-world data (RWD) to generate real-world evidence (RWE) in regulatory decision making regarding medical product effectiveness. In 2023, FDA approved a new dosing regimen for Vimpat (lacosamide)[51] to treat pediatric patients with certain types of seizures, based on a non-interventional study utilizing data from EHR's in the PEDSnet clinical research network. FDA has published a series of foundational draft guidances regarding the use of RWD. FDA has also published final guidances on regulatory considerations for use of RWE and considerations for use of registries and data standards for submissions containing RWD. [52] In addition to publishing these final guidances,

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[49] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial* *and* *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies*

[50] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices

[51] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022253s050,022254s040,022255s032lbl.pdf

[52] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-world-data-assessing-electronic-health-records-and-medical-claims-data-support-regulatory*; *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-drug-and-biological-product-submissions-containing-real-world-data; https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-world-data-assessing-registries-support-regulatory-decision-making-drug-and-biological-products*; and

FDA published the first RWE study design guidance, "Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products" in August 2023.[53]

The Agency also established our new PDUFA Advancing RWE Program. This program provides another pathway for sponsors who are selected into the Program to meet with Agency staff, before protocol development or study initiation, to discuss the use of RWE in medical product development.

Advanced Manufacturing

Advanced manufacturing remains a high priority for CDER because it should help address significant challenges related to drug manufacturing and maintaining robust supply chains by limiting quality-related manufacturing interruptions.

CDER established the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) initiative to prepare a regulatory framework to support the adoption of advanced manufacturing technologies that could start to bring benefits to patients over the next 5-10 years. As part of this initiative, in addition to publishing a discussion paper on AI in drug manufacturing, FDA has published a discussion paper on distributed manufacturing of drugs and point-of-care manufacturing.

CDER's Emerging Technology Program (ETP), has facilitated the approval of 21 applications that use advanced manufacturing (some including continuous manufacturing) for a variety of purposes.

In addition, FDA's 18,000 square foot advanced pharmaceutical manufacturing research facility in Ammendale, MD was completed in 2023. This facility will improve CDER's capability to conduct mission-relevant testing, research, and training for FDA staff in emerging technologies.

International Harmonization and Regulatory Convergence

International efforts to develop consistent global pharmaceutical standards are vital to realizing the benefits of safe, effective, high-quality, and accessible medicines. As a founding member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH),[54] FDA is continuing to advance harmonization projects. This year, FDA announced the availability of the draft ICH guideline on Good Clinical Practice (GCP), which encourages innovation in trial design while maintaining quality and ensuring participant safety. In addition, FDA is active in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) charged with developing and promoting global convergence in Good Manufacturing, Clinical, and Pharmacovigilance Practices, primarily through its inspectorate training.

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https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-real-world-data-and-real-world-evidence-support-regulatory-decision-making-drug

[53] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-design-and-conduct-externally-controlled-trials-drug-and-biological-products

[54] *https://www.ich.org/*

FDA has expanded its Mutual Recognition Agreements (MRAs) to include one with Switzerland.[55] In addition to inspections, FDA and the European Medicines Agency (EMA) recently completed the first collaborative assessment of a proposed post-approval change for a critical oncology biologic.

Promoting Public Health
Substance Use and Overdose Prevention

The nation continues to face a multifaceted drug overdose crisis that has evolved beyond prescription opioids. In recent years, illicit opioids largely driven by fentanyl and its analogues have become key contributors to the overdose crisis. Other controlled substances, including benzodiazepines and stimulants (particularly methamphetamine), are also being used in combination with opioids, as are emerging substances of concern, such as xylazine.

Doing our part to ensure the safe use of prescription opioids and other controlled substances and ameliorate the overdose crisis is among FDA's highest priorities.

In alignment with HHS's Overdose Prevention Strategy, FDA has identified four specific Overdose Prevention Priorities: support primary prevention; encourage harm reduction; advance evidence-based treatments for substance use disorders; and protect the public from unapproved, diverted, or counterfeit drugs presenting overdose risks.[56] Recent accomplishments include:

- Final approval and implementation of safety labeling changes for opioid pain medications
- Announced a requirement for manufacturers of opioid analgesics dispensed in outpatient settings to make prepaid mail-back envelopes available to outpatient pharmacies and other dispensers as an additional opioid analgesic disposal option for patients.
- Issued a Drug Safety Communication and a statement announcing updates for amphetamine and methylphenidate products, a class of stimulant medications used to treat attention deficit/hyperactivity disorder (ADHD) and other disorders, to standardize information regarding risks associated with misuse, abuse, addiction, and overdose.
- Approved the first branded over-the-counter naloxone nasal spray, thereby expanding access and availability of the first-line treatment used to reverse opioid overdose.
- Announced issuance of its first draft guidance titled Stimulant Use Disorders: Developing Drugs for Treatment for development of drugs and biologics to support treatment of moderate to severe cocaine use disorder, methamphetamine use disorder and prescription stimulant use disorder.
- Issued six warning letters to website operators illegally offering for sale unapproved and misbranded prescription-controlled- substances, including opioids, benzodiazepines, and schedule II stimulants, to U.S. consumers in violation of the Federal Food, Drug, and Cosmetic Act.

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[53] https://www.fda.gov/international-programs/international-arrangements/switzerland-mutual-recognition-agreement

[56] *https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework#:~:text=FDA's%20Overdose%20Prevention%20Framework%20Priorities,treatments%20for%20substance%20use%20disorders*.

- Announced an action to restrict the unlawful entry of xylazine active pharmaceutical ingredients and finished dosage form drug products into the country.

Drug Safety and Compounding

Sentinel

In response to the FDA Amendments Act of 2007 (FDAAA), FDA established the Sentinel System, one of the world's premier real-world data (RWD) platforms. The Sentinel System remains one of the largest multi-site, privacy-preserving, medical product safety surveillance systems with highly curated data in the world. Sentinel captures over 1 billion person-years of longitudinal data and more than 112 million patients actively accruing new data.

Strengthening the Compounding Program

FDA's compounding program aims to protect patients from unsafe, ineffective, and poor-quality compounded drugs, while preserving access to lawfully marketed compounded drugs for patients who have a medical need for them. In FY 2023, FDA conducted 41 inspections, issued 11 warning letters and 25 referral letters to state agencies, oversaw 35 recalls, and obtained 1 injunction. Also in FY 2023, FDA issued three compounding guidance documents, including two immediately-in-effect guidances to help increase supply of certain drugs products that were experiencing an increase in demand.

Nitrosamines

In August 2023, FDA issued a new guidance for immediate implementation, "Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs),"[57] which provides drug manufacturers and applicants with a recommended framework for a risk-based safety assessment of NDSRIs that could be present in approved and marketed drug products, as well as products under review by the FDA. This guidance finalized recommendations originally outlined in the 2021 guidance, "Control of Nitrosamine Impurities in Human Drugs."[58]

Ensuring Patient Access

Access to Biosimilars

Innovative biological products have provided new therapies in areas such as cancer, blood disorders, and certain autoimmune diseases. Biosimilars provide more treatment options, which may increase access to lifesaving medications and may lower health care costs through competition. The Biosimilar User Fee Amendments (BsUFA) support the review process for biosimilar product applications.[59] To date, FDA has approved 44 biosimilars, including 7 interchangeable biosimilars, including interchangeable biosimilars to insulin glargine, ranibizumab, adalimumab, and ustekinumab. As of October 2023, 95 programs were in the

[57] https://www.fda.gov/media/170794/download

[58] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/control-nitrosamine-impurities-human-drugs

[59] *https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars*

Biosimilar Product Development Program and CDER has received formal meeting requests to discuss the development of biosimilar products for 54 different reference products.

Generic Drug Review

Many Americans face challenges accessing drug products due to rising prescription drug prices. Bringing more drug competition to the market through our generic drug program is a top priority. In FY 2023 FDA approved over 900 new generics published 174 new revised product-specific guidances describing FDA's current thinking on how to develop specific complex generic drugs, updated informational web pages, held public workshops, and assisted generic drug applicants early in the product development phase through pre-ANDA meetings and controlled correspondences. FDA also seeks to highlight drugs for which there is no generic competition and updated the List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic in FY 2023 twice.[60]

Drug Shortages

Drug shortages continue to pose a real challenge to public health, particularly when the shortage involves a critical drug, for example to treat cancer, infections to provide parenteral nutrition, or to address another serious medical condition, such as drugs indicated for ADHD. Drug shortages can occur for many reasons and FDA continues to work closely with manufacturers to prevent shortages and to resolve those that occur.[61] There were 49 new shortages in CY 2022, but FDA worked with manufacturers to successfully to prevent 222 shortages. Actions taken in CY 2022 include expedited review of close to 200 submissions to prevent or mitigate shortages and prioritization of 30 inspections to address drug shortages.

[60] https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/list-patent-exclusivity-drugs-without-approved-generic

[61] *https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages*

PERFORMANCE

The Human Drugs Program's performance measures focus on premarket and postmarket activities, generic drug review actions, and drug safety to ensure that human drugs are safe and effective and meet established quality standards, as detailed in the following table.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 +/- FY 2024
223210: Review and act on 90 percent of standard NME NDA and original BLA submissions within 10 months of the 60-day filing date. (Output)	FY 2022: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
223211: Review and act on 90 percent of priority NME NDA and original BLA submissions within 6 months of the 60-day filing date. (Output)	FY 2022: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
223212: Review and act on 90 percent of standard non-NME original NDA submissions within 10 months of receipt. (Output)	FY 2022: 98% Target: 90% (Target Exceeded)	90%	90%	Maintain
223213: Review and act on 90 percent of priority non-NME original NDA submissions within 6 months of receipt. (Output)	FY 2022: 91% Target: 90% (Target Exceeded)	90%	90%	Maintain
223216: Review and act on 90 percent of priority original Abbreviated New Drug Application (ANDA) submissions within 8 months of receipt. (Output)	FY 2022: 95% Target: 90% (Target Exceeded)	90%	90%	Maintain
223235: Review and act on 90 percent of standard original Abbreviated New Drug Application (ANDA) submissions within 10 months of receipt. (Output)	FY 2022: 93% Target: 90% (Target Exceeded)	90%	90%	Maintain
224221: Percentage of Human and Animal Drug significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 85.5% Target: 80% (Target Exceeded)	80%	80%	Maintain
224222: Percentage of Human and Animal Drug follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 45.7% Target: 55% (Target Not Met)	55%	55%	Maintain
292203: Number of medical product analyses conducted through FDA's Sentinel Initiative. (Output)	FY 2023: 65 Target: 65 (Target Met)	65	65	Maintain

Figure 29 - Human Drugs Performance Table

The following selected items highlight notable results and trends detailed in the performance table.

Review Goals
New Drug Review

The New Drug Review performance measures focus on ensuring that the public has access to safe and effective new treatments as quickly as possible. The goal of the PDUFA program is to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval. The agency met all four of the PDUFA performance goals in FY 2022 and will continually work to meet or exceed the review performance goals in the future.

Generic Drug Review

The goal of the GDUFA program is to enhance the efficiency of the generic drug review process, promote transparency between FDA and generic drug sponsors, and enhance access to high quality-, lower cost generic drugs. The value of this investment in the Generic Drug Review program is reflected by FDA's performance on its review goals under GDUFA and FDA's commitment to meet shorter review goals (8 months) for priority submissions.

Sentinel

The Sentinel Initiative is FDA's active surveillance program that enables the FDA to evaluate the safety of regulated medical products and informs regulatory decision making. This program provides vital information to patients and providers about the safety of drugs and vaccines by contributing to multiple drug safety communications and labeling changes, supporting FDA Advisory Committee Meetings, highlighting potential ways to intervene in the opioid crisis, and influencing regulatory decisions. The Sentinel Initiative consists of multiple components including the Sentinel System, and its Active Risk Identification and Analysis (ARIA) program. The Sentinel System remains one of the world's largest multi-site, privacy-preserving, medical product safety surveillance systems capturing over 1.1 billion person-years of longitudinal data, more than 110 million patients actively accruing new data, and more than 10 million live-birth deliveries with a mother-infant linkage to support assessments of medication use in pregnancy. In 2023, the Sentinel System completed 65 medical product analyses, including 14 related to COVID-19 themes. Sentinel has proven to be a vital source of safety information that informs regulatory decision-making and expands our knowledge of how medical products perform when widely used in medical practice.

ORA Field Performance Measures

ORA's performance goals measure topics such as our commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to ORA regulatory impact on violators, and are tracked on a 3-year rolling basis. Due to the nature of regulatory actions and subsequent follow-up conducted by FDA, the duration of these events can vary considerably. After regulatory action, FDA also works to schedule follow-up after a reasonable time has passed to allow the firm to correct for the original violations. A 3-year rolling timeline also ensures tracking of all significant violations that require attention and allows for a more robust analysis.

ORA missed one of its eleven measures, associated with follow-up inspections of Human and Animal Drug firms. This measure is an outcome goal, which depends on the corrective actions made by the firms to bring themselves into compliance, for which ORA has no role or control. Center components may work with firms to provide them guidance and evaluate corrective actions to help enable the firm to achieve compliance. Many violations found at a firm may take significant time and action before compliance can be reached. In some instances, firms do not come into compliance or other issues arise leading to another OAI finding upon re-inspection. While ORA believes this is an important outcome measure to encourage and measure firms' corrective actions, and expects to meet the targets going forward, it is important to recognize that ORA has limited ability to drive compliance, and the ultimate responsibility to comply rests with the firm itself.

Program Activity Data

Human Drugs Program Activity Data (PAD)			
CDER Workload and Outputs	**FY 2023 Final**	**FY 2024 CR**	**FY 2025 PB**
New Drug Review			
Workload – Submissions/Filings/Requests			
New Drug Applications/Biologic Licensing Applications (NDA/BLA)	143	130	144
Efficacy Supplements	214	208	198
Manufacturing Supplements	2,262	2,389	2,327
Commercial INDs (Drugs and Biologics) with Activity	9,445	10,447	11,028
Sponsor Requests: IND-Phase Formal Meetings	3,342	3,707	3,793
Sponsor Requests: Review of Special Study Protocols	137	137	137
Submissions of Promotional Materials	135,291	149,000	154,000
Outputs – Reviews/Approvals			
Reviews: Priority NDA/BLA	65	65	65
Reviews: Standard NDA/BLA	133	133	133
Approvals: Priority NDA/BLA	48	48	48
Approvals: Standard NDA/BLA	74	74	74
Median time from Receipt to Approval: Priority NDA/BLAs (in months)	8	8	8
Median Time from Receipt to Approval: Standard NDA/BLAs (in months)	15	15	15
Reviews: NDA Supplemental	2,806	2,806	2,806
Reviews: Clinical Pharmacology/ Bio-Pharmaceutic	5,936	6,233	6,544
Biologic Therapeutics Review			
Workload – Submissions/Filings/Requests			
Receipts: Commercial IND/IDE (Biologics Only)	261	261	261
Receipts: IND/IDE Amendments (Biologics Only)	34,373	34,373	34,373
Outputs – Reviews/Approvals			
Reviews: Total Original License Application (PLA/ELA/BLA)	39	39	39
Approvals: PLA/BLA	23	23	23
Reviews: License Supplement (PLA/ELA/BLA)	597	597	597
Generic Drug Review			
Workload – Submissions/Filings/Requests			
Receipts: Abbreviated New Drug Applications (ANDA)	733	790	790
Outputs – Reviews/Approvals			
Actions – ANDA	2,561	2,200	2,000
Approval Actions - ANDA (both Tentative and Full Approvals)	954	875	850
Median Review Time from ANDA Receipt to Approval (months)	23	25	25
Actions - ANDA Supplementals (Labeling and Manufacturing)	12,750	11,550	11,550
Over-the-Counter Drug Review[1]			
OTC Monographs Under Development	9	8	6
OTC Monographs Published	11	3	8
Best Pharmaceuticals for Children Act			
Labels Approved with New Pediatric Information	15	19	19
New Written Requests Issued	6	8	8
Pediatric Exclusivity Determinations made	16	14	12
Post Exclusivity Safety Report	4	4	4

Figure 30 - Human Drugs PAD Table 1/2

Patient Safety			
Workload – Submissions/Filings/Requests			
Submissions: Adverse Event Reports	2,252,095	2,284,810	2,287,264
Electronic Submissions: % of Total Adverse Drug Reaction Reports	98%	98%	98%
Electronic Submissions: % of Serious/Unexpected Adverse Drug Reaction Reports	100%	100%	100%
Submissions: Drug Quality Reports	21,859	24,000	26,000
Outputs – Reviews/Approvals			
Safety reviews completed by Office of Surveillance & Epidemiology	9,347	10,095	10,902
Number of drugs with Risk Communications	104	100	110
Administrative/Management Support			
Workload			
Number of Advisory Committee Meetings	31	35	35
Number of FOI Requests	2,795	2,400	2,700
Number of FOI Requests Processed	2,501	2,425	2,750
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	63	67	67
Number of Citizen Petitions Pending on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)	143	149	149
Number of Citizen Petitions Completed (excluding suitability petitions and OTC monograph-related petitions)[2]	82	81	81

[1] *On March 27, 2020, the President signed the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The CARES Act includes statutory provisions that reform and modernize the way OTC monograph drugs are regulated in the United States. The CARES Act replaces the rulemaking process with an administrative order process for issuing and revising OTC monographs. Data beginning in FY 2021 reflect this change; and include OTC monographs deemed by Congress in the CARES Act and subsequently posted by FDA.*

[2] *Citizen Petitions completed may include petitions filed in prior years.*

Figure 31 - Human Drugs PAD Table 2/2

BIOLOGICS

PURPOSE STATEMENT

The Biologics Control Act of 1902 established the Biologics Program in the Department of Treasury's Hygienic Laboratory, which became part of the National Institutes of Health (NIH) in 1930. In 1972, the Biologics Program transferred from NIH to FDA and is currently comprised of the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs' (ORA) biologics field program.[62] CBER's mission is to ensure the safety, purity, potency, and effectiveness of biological products including vaccines, allergenics, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury. Through its mission, CBER also seeks to protect the public against the threats of emerging infectious diseases and bioterrorism. CBER uses sound science and regulatory expertise to:

- Protect and improve public and individual health in the United States and, where feasible, globally
- Facilitate the development, approval of, and access to safe and effective products and promising new technologies
- Strengthen CBER as a preeminent regulatory organization for biologics

Authorizing Legislation: Public Health Service Act; Federal Food, Drug, and Cosmetic Act; Medical Device Amendments of 1976; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Safe Medical Devices Act of 1990; Medical Device Amendments of 1992; FDA Export Reform and Enhancement Act of 1996; Food and Drug Administration Modernization Act of 1997; Medical Device User Fee and Modernization Act of 2002; Public Health Security and Bioterrorism Preparedness Response Act of 2002; Project Bioshield Act of 2004; Medical Device User Fee Stabilization Act of 2005; Food and Drug Administration Amendments Act of 2007 (FDAAA); Patient Protection and Affordable Care Act of 2010; Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA); Drug Quality and Security Act of 2013; Pandemic and All-Hazards Preparedness Reauthorization Act of 2013; 21st Century Cures Act of 2016 (Cures Act); Food and Drug Administration Reauthorization Act of 2017 (FDARA); Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019; and Further Consolidated Appropriations Act, 2020; Consolidated Appropriations Act 2022; and Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023.

Allocation Methods: Direct Federal; Intramural

[62] ORA's accomplishments can be found in ORA's section of the budget justification.

BUDGET REQUEST

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
Biologics	**441,809**	**459,405**	**490,465**	**570,632**	**589,682**	**99,217**
Budget Authority	***254,031***	***259,935***	***272,215***	***267,130***	***279,986***	***7,771***
User Fees	***187,778***	***199,470***	***218,250***	***303,502***	***309,696***	***91,446***
Center	399,304	414,302	440,329	520,972	536,798	96,469
Budget Authority	212,026	215,120	224,165	219,828	229,508	5,343
User Fees	187,278	199,182	216,164	301,144	307,290	91,126
Field	42,505	45,103	50,136	49,660	52,884	2,748
Budget Authority	42,005	44,815	48,050	47,302	50,478	2,428
User Fees	500	288	2,086	2,358	2,406	320
FTE	**1,503**	**1,551**	**1,467**	**1,643**	**1,651**	**184**

Figure 32 – Biologics Funding History Table

The FY 2025 President's Budget for the Biologics Program is $589,682,000 of which $279,986,000 is budget authority and $309,696,000 is user fees. The budget authority increases by $7,771,000 compared to the FY 2023 Final Level; user fees increase by $91,446,000. The Center for Biologics Evaluation and Research (CBER) amount in the request is $536,798,000. The Office of Regulatory Affairs (ORA) amount is $52,884,000.

The FY 2025 Budget allows the Biologics Program to advance public health through thoughtful and innovative regulation that promotes the safety, purity, potency, effectiveness, and timely delivery of biological products including vaccines, allergenics, blood and blood products, and cell, tissues, and gene therapies to the American public. CBER aims to increase preparedness for emerging threats and promote global public health. CBER continues to support FDA's mission to provide timely regulatory recommendations and scientific advice to vaccine manufacturers to support continued response efforts, including considerations for future doses of COVID-19 vaccines and the process for COVID-19 vaccine strain selection to address current and emerging variants as necessary. CBER facilitates the development and availability of safe and effective medical products through the integration of advances in science and technology through enhanced FDA-sponsor communications in its user fee programs, the continued use of its expedited programs, and streamlined regulatory pathways. CBER is developing a regulatory program for individualized (bespoke) therapies and fostering global regulatory convergence for cell and gene therapies. FDA will continue to work with stakeholders to facilitate end-to-end solutions for key issues limiting the development and application of gene therapies, including manufacturing challenges that make these therapies cost-prohibitive and present commercial difficulties.

CBER will protect public health from infectious diseases by facilitating the availability of safe and effective vaccines and by working to reduce the risk of infectious disease transmission through blood or tissues. CBER monitors the impact of Emerging Infectious Diseases (EIDs) on the safety and availability of the blood supply and is working to advance pathogen reduction technologies. CBER also aims to improve the availability of vaccines to immunize the public prior to EID exposure, decreasing the number of infections or complications from infection. CBER works with other federal agencies and industry, through the Public Health Emergency Medical Countermeasure Enterprise, on a broad array of products aimed at making the U.S. better prepared for chemical, biological, radiological, and nuclear threats, and emerging disease through the development of new countermeasures. The regulatory science and research programs

will continue to engage in forward-looking priority setting to allocate resources towards efforts that best support FDA's ability to respond to current and emerging public health needs and meet ever-changing scientific and technological advancements. CBER's cadre of scientific experts will conduct research to inform guidance and support development of new tools, models, standards, and methods, harnessing new technologies to expedite product development. To further support advanced manufacturing, CBER will continue to conduct intramural research and make extramural awards to study and recommend improvements for the advanced manufacturing of biological products, including vectors for gene therapies and vaccines for emerging infectious diseases.

To ensure that biologic products are safe and effective, FDA conducts compliance and surveillance activities to ensure the quality of products through their entire lifecycle. FDA will continue to initiate regulatory action to address non-compliance with relevant statutes and regulations, including those manufacturers, clinics, or health care providers who may be offering unapproved regenerative medical products. CBER continues to use real world data and real-world evidence to monitor postmarket safety, life-threatening adverse events, and regulatory decisions, such as informing donor blood eligibility or assessing the safety and effectiveness of preventative vaccines. FDA also strategizes methods to harmonize existing regulatory standards and works with international scientific efforts to establish and maintain reference materials and standards for biologics.

BUDGET AUTHORITY

FY 2025 President's Budget: Biologics *Budget Authority - Dollars in Thousands*			
	Center	**Field**	**Total**
FY 2023 Final	**224,165**	**48,050**	**272,215**
FY 2025 Budget Authority Changes	**5,343**	**2,428**	**7,771**
Requested Increases	**9,566**	**3,142**	**12,708**
Public Health Employee Pay Costs	7,577	2,211	9,788
Enterprise Transformation	163	25	188
IT Stabilization & Modernization	608	92	700
Shortages and Supply Chain-Agency-wide	1,218	814	2,032
Other Adjustments	**(4,223)**	**(714)**	**(4,937)**
ORA Transfer to HQ/OGPS	-	(968)	(968)
FDARA Sec. 905 BA Shift	(5,761)	(55)	(5,816)
FY 2024 Comparability Adjustment	1,424	275	1,699
FY 2025 Comparability Adjustment	114	34	148
FY 2025 Budget Net Total: Biologics	**229,508**	**50,478**	**279,986**

Figure 33 – Biologics Budget Authority

Total Requested Increases: +$12.7 million / 4 FTE

Public Health Employee Pay Costs: +$9.8 million

Center: +$7.6 million

Field: +$2.2 million

The FY 2025 President's Budget includes $114.8 million in new budget authority to fund approximately 72 percent of the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 and FY 2025 Cost of Living Adjustments (COLA). For FY 2025 this assumes a 2.0 percent for Civilian and 4.5 percent Military pay increase for FTE funded through budget authority. Within the Biologics program, $9.8 million is provided for pay costs, including $7.6 million for CBER and $2.2 million for ORA.

Enterprise Transformation: +$188,000

Center: +$163,000

Field: +$25,000

The FY 2025 President's Budget provides $2.0 million for Enterprise of Transformation, which includes $188,000 for the Biologics Program to coordinate and lead several crosscutting agency-wide projects to analyze and implement common business processes and data optimization. Benefits of this funding will include improved communication and data sharing across the life cycle of an inspection, increased access to relevant data to facilitate risk-based decision-making, and introduction of more modern mobile technology for field work to improve the user experience. The office also seeks to standardize the FOIA business processes across the Agency and create effective governance to enable successful process and technology changes.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

IT Stabilization & Modernization: +$700,000

Center: +$608,000

Field: +$92,000

The FY 2025 President's Budget provides $8.3 million for IT Stabilization & Modernization, including $700,000 for the Biologics Program to further build FDA's centralized enterprise data modernization capabilities and to strengthen FDA's common data infrastructure, data exchange, and IT analytic services, talent, and tools. With these resources, FDA will continue to improve data exchange and underlying technology platforms in support of FDA's programs and mission-critical responsibilities – to better meet the challenges of emerging threats, support needs for real-time evaluation, and more continuously access, analyze, and aggregate multiple sources of information, such as for recalls, adverse events, outbreaks, and pandemics. FDA is also requesting two-year budget authority (FY 2025 – FY 2026) for this funding to provide more flexibility and ensure the most effective use of these resources.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

Shortages and Supply Chain: +$2.0 million / 4 FTE

Center: +$1.2 million / 1 FTE

Field: +$814,000 / 3 FTE

The FY 2025 President's Budget provides $12.3 million for Shortages and Supply Chain, including $2.0 million for the Biologics Program to advance FDA's capabilities to help prepare for, build resilience to, and respond to shortages that are supply-driven and/or demand-driven

through improved analytics to identify shortage threats and vulnerabilities as well as regulatory approaches to address disruptions and shortages.

Because shortages of medical products can pose a significant public health threat that can delay, and in some cases even deny, critically needed care for patients, shortages remain a top priority for FDA. FDA must continue to prioritize our efforts on this important public health issue, working to ensure the American public is protected against outbreaks of emerging infectious diseases, such as COVID-19, as well as chemical, biological, radiological, and nuclear threats, and to ensure the availability of necessary drugs and biological products for the American public.

Given the importance of preventing and mitigating shortages, and the high-profile nature of FDA's response to shortages and supply chain questions/issues, CBER needs a robust, fully functional, and updated shortage surveillance solution with modern technologies and long-term support compatible with CBER's current IT modernization plan and in line with the Agency's focus towards Enterprise Solutions. With this funding, CBER will begin to make investments for a shortage surveillance solution that leverages work already done in other FDA Centers to identify, manage, and track potential and actual shortages.

USER FEES

Current Law User Fees: +$91.4 million

Center: +$91.1 million

Field: +$320,000

The Biologics Program request includes an increase of $91.4 million for user fees, compared to FY 2023 Final Level, which will allow FDA to fulfil its mission of promoting and protecting the public health by ensuring safety and efficacy of FDA-regulated products.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

CBER's 2021-2025 strategic plan outlines the goals, objectives, and strategies designed to further its mission and vision during the term of the strategic plan. The plan aligns with Department of Health and Human Services (HHS) priorities, FDA priorities, and new authorities provided through the 21st Century Cures Act. The following selected accomplishments by priority area demonstrate the Biologics Program's delivery of its regulatory and public health responsibilities through medical product review. These priorities are in line with presidential, HHS, and FDA priorities, and CBER's strategic plan goals.[63]

Protecting Public Health Through Scientific Advancement

CBER is committed to helping advance novel products by providing guidance to industry and, when appropriate, expediting the development and evaluation of new biological products for a broad range of diseases, including infectious diseases and complex, life-threatening, and rare diseases. The increasing sophistication and complexity of biological products requires scientific and regulatory expertise to facilitate innovation and prevent unintended harm. FDA protects the public health by using effective and smart regulation to make decisions based on a rigorous evaluation of current data and scientific evidence. CBER supports FDA's public health agenda

[63] *Additional information on the CBER 2021-2025 Strategic Plan can be found at: https://www.fda.gov/media/81152/download.*

which includes public health and consumer protection; modernization to keep pace with evolving science and technology; and emergency preparedness and response.

To help ensure that the regulatory process is effective and thoughtful, especially for innovative products that incorporate state-of-the-art science, CBER develops and updates policies and guidance for scientific and regulatory oversight. The goal is to create clear recommendations, frameworks, and pathways that allow beneficial novel technologies to efficiently reach the public while maintaining standards for product safety and effectiveness. CBER also meets with prospective developers of Advanced Manufacturing (AM) technologies and innovative investigational products at early stages to provide informal consultation. Mechanisms for these interactions include the CBER Initial Targeted Engagement for Regulatory Advice on CBER products (INTERACT) program and the CBER Advanced Technologies Team (CATT) meeting program.

FDA uses existing programs to expedite the development and evaluation of innovative products to treat or prevent serious conditions, when appropriate. As of the end of September 2023, CBER granted 69 Breakthrough Therapy designations, with 31 of the products having Orphan Drug Designation. Since the program's inception in December 2016, FDA has granted 91 Regenerative Medicine Advanced Therapy (RMAT) Designations agency-wide, with 41 having Orphan Drug Designation.

To facilitate the availability of FDA-regulated products, CBER works with manufacturers and uses all available tools to help prevent or mitigate shortages. Potential actions include identifying the extent of the shortfall and determining if other manufacturers are willing and able to increase production to make up the gap; expediting FDA's inspections and reviews of submissions submitted by affected manufacturers attempting to restore production; expediting the release of lots of certain licensed biological products regulated by CBER, and working with the affected manufacturers to ensure adequate investigations into the root cause of the shortages. In FY 2023, CBER documented 1 resolved shortage, 23 new product shortages, 12 prevented shortages, 3 ongoing shortages, and 70 notifications from 25 different manufacturers.[64]

CBER's regulatory science program addresses knowledge gaps and maintains deep familiarity with how new science and technology are applied to FDA-regulated products. Research is a critical component to advancing CBER's initiatives related to individualized therapies, AM, pathogen reduction, the microbiome, vaccines, and preparedness efforts to bring needed treatments and preventative measures to the public. FDA research facilitates the design of better methods to predict and evaluate the safety, purity, potency, and effectiveness of biological products early in their lifecycle, allowing adoption of the most advanced science and risk management tools to inform policy. FDA's research program also supports development of new tools, models, and standards, harnessing new technologies to expedite product development and provide effective scientific and regulatory responses for public health emergencies.

Infectious Disease Preparedness and Response

CBER uses every tool available to the Agency to quickly and creatively help the American public gain timely access to promising safe and effective biological products while facilitating

[64] *See https://www.fda.gov/media/169302/download?attachment. Additional information on CBER Regulated Products: Shortages and Discontinuations can be found at: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-shortages-and-discontinuations*

research to evaluate their safety and effectiveness. CBER monitors the impact of Emerging Infectious Diseases (EIDs) on the safety and availability of the blood supply and is working to advance pathogen reduction technologies. In addition to protecting the blood supply from infectious diseases, CBER aims to improve the availability of vaccines to immunize the public prior to EID exposure. To this end, CBER collaborates with federal partners and other stakeholders to monitor and address infectious diseases and is committed to expediting the development and evaluation of new products for EIDs. The Center's demonstrated efforts have increased public health preparedness and response to health security threats.

Additionally, many of the products that FDA regulates address infectious disease threats that are not unique to the U.S.; therefore, international engagements are an important component of how FDA carries out its regulatory responsibilities. CBER's international activities include regulatory harmonization, regulatory capacity building, pharmacovigilance capacity building, information sharing, international standards setting, and collaborative research. CBER partners with a range of organizations in undertaking these efforts. CBER's relationships with the World Health Organization (WHO) and the Pan American Health Organization (PAHO) are cornerstones to these efforts, as evidenced by CBER's status as a PAHO/WHO Collaborating Center for Biological Standardization. FDA actively participates in the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the Coalition for Epidemic Preparedness Innovation (CEPI) meetings. CBER continues to take a leadership role in the International Coalition of Medicines Regulatory Authorities (ICMRA) to facilitate global alignment regarding COVID-19 vaccine development and data required for regulatory decision-making.[65]

Annual influenza vaccination remains the best way to prevent influenza disease and its complications, as well as mitigating the impact on hospitalization and healthcare resource utilization. CBER conducts research to increase the diversity of vaccine manufacturing methods and capacity for influenza vaccine production. Every year, FDA, WHO, CDC and other public health experts collaborate to review influenza disease surveillance and laboratory data collected internationally, identifying influenza strains that are likely to cause the most illness for the upcoming influenza season. FDA then convenes the Vaccines and Related Biological Products Advisory Committee (VRBPAC), consisting of outside experts, to discuss the WHO recommendations and to consider which flu viruses are expected to circulate in the U.S. In March 2023, the VRBPAC recommended the strains for inclusion in the influenza vaccines for the 2023-2024 U.S. influenza season. As an Essential Regulatory Laboratory in WHO's Global Influenza Surveillance and Response System, CBER contributes to production of seasonal and pandemic vaccine seed stocks and reagents required for manufacture and release of influenza vaccines.

Respiratory Syncytial Virus (RSV) is a highly contagious, seasonal respiratory virus that causes infections of the lungs and breathing passages in individuals in all age groups. In adults 65 years of age and older, RSV is a common cause of lower respiratory tract disease (LRTD), and RSV infection leads to approximately 60,000-120,000 hospitalizations and 6,000-10,000 deaths each year in the United States. In May 2023, FDA approved the first RSV vaccine for use in the United States, Arexvy, for the prevention of LRTD caused by RSV in individuals 60 years of age

[65] *Additional information on CBER's Regulatory Harmonization and Convergence can be found at: https://www.fda.gov/vaccines-blood-biologics/international-activities/regulatory-harmonization-and-convergence*

and older. In the same month, FDA also approved Abrysvo, the second vaccine approved for use in the United States for the prevention of LRTD caused by RSV in individuals 60 years of age and older. In August 2023, FDA approved Abrysvo, the first vaccine for use in pregnant individuals to prevent LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age.

Following the expiration of the COVID-19 public health emergency (PHE) on May 11, 2023, CBER has implemented a focused response toward COVID-19 by facilitating the availability of vaccines for the prevention of COVID-19 that meet FDA's scientific and regulatory standards for safety and effectiveness. These vaccines continue to save lives by preventing disease, hospitalizations, and deaths. As of November 3, 2023, CBER has reviewed 2,039 EUA amendments to authorized COVID-19 vaccines and for the approved COVID-19 vaccines, Comirnaty and Spikevax, CBER has reviewed 828 and 313 submissions respectively. Since the start of the pandemic, CBER intramural research scientists have conducted over 40 COVID-19 laboratory research studies, which have produced more than 200 publications addressing topics with wide-ranging implications for evaluating anti-COVID-19 antibody and vaccine effectiveness. Moreover, ongoing research will inform future therapeutic and vaccine development and regulation. COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies remains authorized for emergency use for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. In October 2023, CBER revised the guidance document entitled "Investigational COVID-19 Convalescent Plasma" to provide continued recommendations to blood establishments that collect COVID-19 convalescent plasma under the EUA and to ensure the authorized product is available for patients when indicated.

Additionally, FDA remains committed to providing timely regulatory recommendations and scientific advice to vaccine manufacturers to support continued response efforts, including considerations for future doses of COVID-19 vaccines and the process for COVID-19 vaccine strain selection to address current and emerging variants. In October 2023, FDA published revised guidance on the "Development and Licensure of Vaccines to Prevent COVID-19" to assist the Agency and sponsors in the clinical development and licensure of vaccines for the prevention of COVID-19. To maintain an open and transparent scientific review process, FDA convenes its VRBPAC as warranted to discuss the data pertaining to the safety and effectiveness of COVID-19 vaccines for various populations and future COVID-19 vaccine strain composition. In June 2023, VRBPAC unanimously voted to update the composition to a monovalent COVID-19 vaccine with an XBB-lineage of the Omicron variant. Based on the totality of the evidence, FDA has advised manufacturers who will be updating their COVID-19 vaccines that they should develop vaccines with a monovalent XBB 1.5 composition.

On September 11, 2023, FDA approved and authorized for emergency use updated mRNA COVID-19 vaccines. Specifically, FDA approved Comirnaty to include the 2023-2024 formula and a change to a single dose for individuals 12 years of age and older, approved Spikevax to include the 2023-2024 formula and a change to a single dose for individuals 18 years of age and older and approval of a single dose for individuals 12 through 17 years of age. Also, Moderna COVID-19 Vaccine was authorized for emergency use in individuals 6 months through 11 years of age to include the 2023-2024 formula and lower the age eligibility for receipt of a single dose from 6 years to 5 years of age and Pfizer-BioNTech COVID-19 Vaccine was authorized for emergency use in individuals 6 months through 11 years of age to include the 2023-2024

formula. On October 3, 2023, FDA authorized Novavax COVID-19 Vaccine, Adjuvanted for emergency use in individuals 12 years of age and older to include the 2023-2024 formula.

In addition to seasonal respiratory viruses, pertussis (also known as whooping cough) is a common respiratory disease in the United States, resulting in frequent outbreaks. Most serious pertussis cases, hospitalizations, and deaths occur in infants younger than two months of age who are too young to be protected by the childhood pertussis vaccine series. In January 2023, FDA approved a second vaccine, Adacel, for immunization during the third trimester of pregnancy to prevent pertussis in infants younger than two months of age. Adacel is also approved as booster immunization against tetanus, diphtheria, and pertussis in individuals 10 through 64 years of age.

Clostridioides difficile (*C. difficile*) is a bacterium that can cause *Clostridioides diff.* infection (CDI), a potentially life-threatening disease resulting in diarrhea and significant inflammation of the colon. In the United States, CDI is associated with 15,000-30,000 deaths annually, and there are few treatment options. Furthermore, factors such as age older than 65 years, hospitalization, a weakened immune system, and a previous history of CDI can increase the risk for CDI. The administration of fecal microbiota is thought to facilitate restoration of the gut flora to prevent further episodes of CDI. In November 2022, FDA approved Rebyota, the first fecal microbiota product approved by the agency. It is approved for the prevention of recurrence of CDI in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI and is administered rectally. As the first FDA-approved fecal microbiota product, it is an advance in caring for patients who have recurrent CDI. In April 2023, FDA approved Vowst, the first fecal microbiota product that is taken orally. Vowst is approved for the prevention of recurrence of CDI in individuals 18 years of age and older, following antibacterial treatment for recurrent CDI. The availability of a fecal microbiota product that can be taken orally is a significant step in advancing patient care. A full list of CBER product approvals, including significant products related to infectious disease, may be found at FDA's website: Biological Approvals.

Biologics Safety and Pharmacovigilance

CBER continues to monitor the safety and effectiveness of regulated biological products, including the use of vaccines in the real-world setting. Clinical trials may not be large enough to detect all adverse reactions, especially those that occur infrequently, or designed to evaluate safety and effectiveness in all subpopulations. Real World Evidence (RWE) is the clinical evidence about the usage and potential benefits or risks of a medical product, derived from analysis of patient health information. This information can be collected through multiple sources, such as Electronic Health Records (EHR), insurance claims, reports, and public health databases.[66] FDA uses RWE and multiple other tools to detect potential safety issues early and mitigate them, as well as to answer critical questions pertaining to effectiveness of vaccines, such as duration of protection and the impact of SARS-CoV-2 variants. CBER is also exploring the potential use of Real-World Data (RWD) and RWE to inform the discovery of new therapies for patients, to understand the risks and benefits in practice, and to inform which therapies may be best for which patients.

The CBER Biologics Effectiveness and Safety (BEST) Program leverages a variety of data partners and methods, tools, expertise, and infrastructure to conduct surveillance and

[66] *Center for Biologics Evaluation and Research & Center for Drug Evaluation and Research Real-World Evidence | FDA*

epidemiologic studies of biological products. BEST is a part of the FDA Sentinel Initiative and provides access to EHRs for over 50 million persons and access to medical claims data for over 100 million persons to conduct robust, rapid safety and effectiveness studies of biological products. FDA co-manages the Vaccine Adverse Event Reporting System (VAERS) with CDC, which collects data reported from healthcare providers, vaccine recipients, and parents of pediatric vaccine recipients and through active surveillance of EHR and medical claims databases. Further, FDA collaborates with CMS to utilize Medicare and Medicaid databases for surveillance of biologics. These data systems leverage high-quality data, analytics, and innovation to enhance surveillance, real-world evidence generation, and clinical practice that benefits patients, which is used in protocol and manuscripts issued by the CBER BEST Program for biological products.

Safe and Adequate Blood Supply

Blood products are critical to public health and offer potentially life-saving benefits for a variety of acute and chronic conditions. CBER works closely with other parts of HHS to identify and respond to potential threats to blood safety; to develop safety recommendations; to monitor the blood supply and help promote the importance of blood donation; and to collaborate with other government and nongovernment partners in ensuring an adequate supply of safe, pure, and potent blood products. Internationally, CBER serves on the WHO Advisory Group for Blood Regulation, Availability and Safety, a forum for international blood regulatory authorities. Participation in this advisory group allows CBER to share insights and support policies and strategies to strengthen blood systems, and advance global access to safe, effective, and quality-assured blood products.

Additionally, the Transfusion Transmissible Infections Monitoring System (TTIMS), a collaborative effort with the National Heart, Lung, and Blood Institute, HHS Office of the Assistant Secretary of Health, and blood establishments in the U.S., gathers and uses donor data to help ensure the continued safety of the U.S. blood supply and monitor the effects of FDA's policy changes regarding donor deferral. TTIMS monitors approximately 60 percent of the U.S. blood supply for human immunodeficiency virus (HIV), hepatitis B virus, hepatitis C virus, and syphilis incidence and prevalence.

In December 2022 Congress passed important new authority in the Food and Drug Omnibus Reform Act to streamline FDA's ability to receive voluntary information from blood donors or potential blood donors.[67] Specifically, section 3631 of FDORA exempts from the Paperwork Reduction Act collections of information to which a response is voluntary from blood donors or potential blood donors to support the development of recommendations concerning blood donation. This exemption was applied to the renewal of the data collection for the "Donor Risk Assessment Questionnaire for the FDA/National Heart, Lung, and Blood Institute - Sponsored Transfusion-Transmissible Infections Monitoring System - Risk Factor Elicitation" survey for TTIMS.

[67] *Food and Drug Omnibus Reform Act of 2022. Sec. 3631. Streamlining blood donor input.*

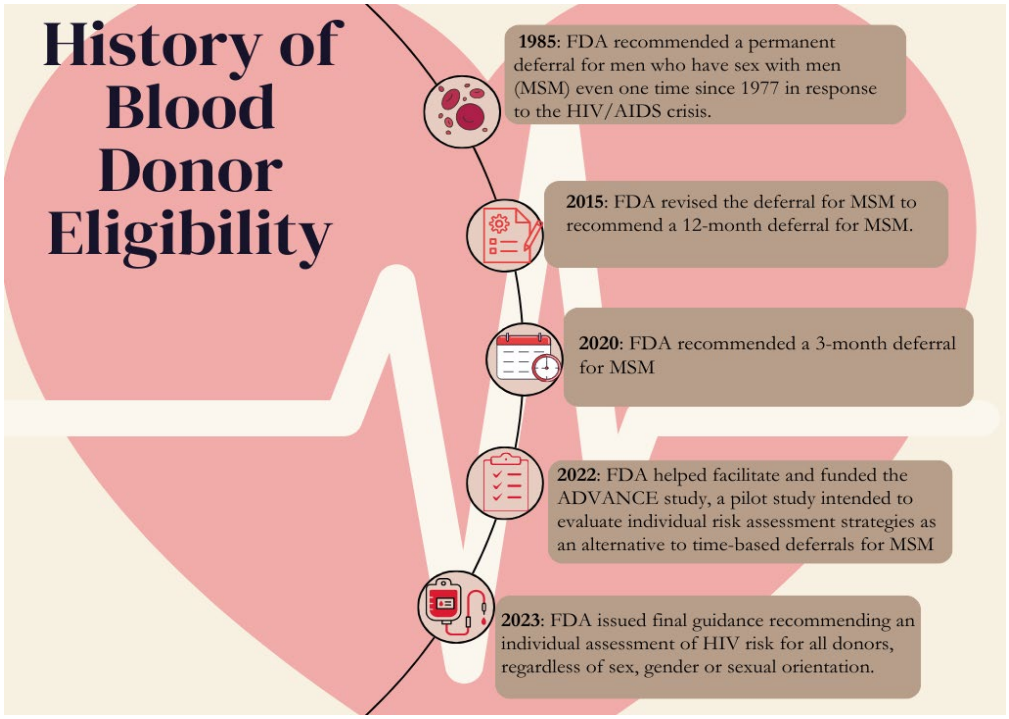

Figure 34 - History of Blood Donor Eligibility

In May 2023, CBER published a guidance that provides recommendations for evaluating blood donor eligibility using individual risk-based questions. This guidance was informed by results of the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study which examined the rates of HIV risk factors, such as anal sex, and rates of HIV infection, as well as the usage of medications to treat or prevent HIV infection, among men who have sex with men (MSM) study participants. This guidance provides blood establishments that collect blood or blood components, including Source Plasma, with FDA's revised donor deferral recommendations for individuals with increased risk for transmitting HIV infection. Based on our review of the available data, the guidance recommends eliminating the screening questions specific to MSM and women who have sex with MSM, and instead recommends assessing donor eligibility using the same individual risk-based questions relevant to HIV risk for every donor regardless of sex or gender. The updated policy is in line with policies in countries with similar HIV epidemiology as the United States, including the United Kingdom and Canada.

Cell and Gene Therapy

Cell and gene therapies have potential to treat serious diseases and conditions, including cancer, genetic diseases, and infectious diseases, with many such products being developed to address unmet medical needs in patients with rare diseases. The number of cell and gene therapy submissions is rising sharply, and this increase is expected to continue in the near future. The number of new gene therapy Research Investigational New Drug applications (INDs) has more than doubled in recent years, as shown in Figure 34. CBER has been supporting the fast pace of products advancing in clinical development, with an increasing number yielding marketing applications.

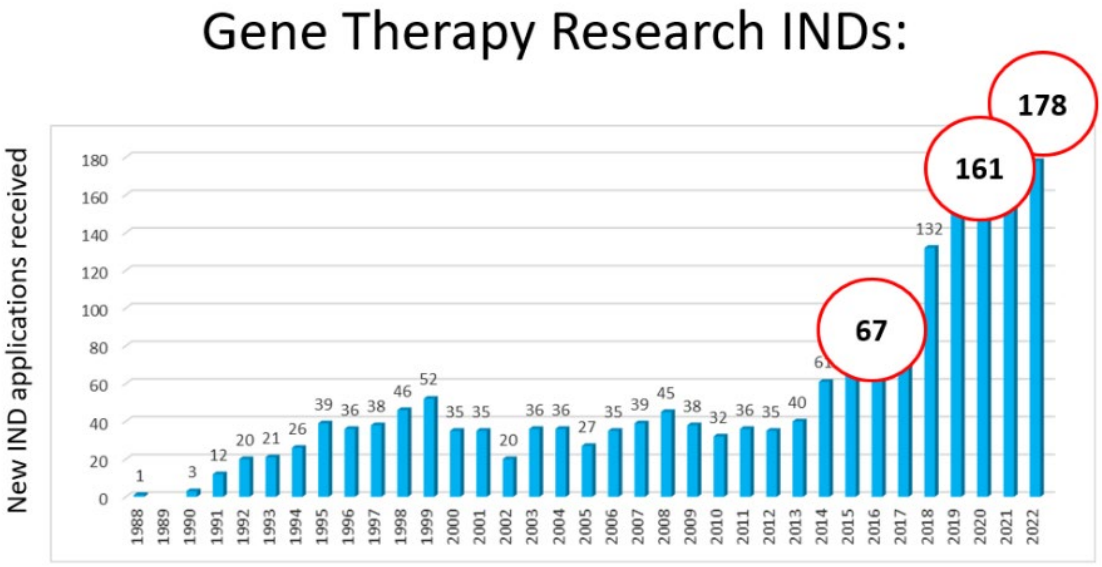

Figure 35 - New Gene Therapy IND applications received over time. (Schultz, Kimberly. "Review Management Updates". May 19, 2023.)

A full list of CBER's cellular and gene therapy product approvals may be found at FDA's website: Approved Cellular and Gene Therapy Products. Recent key approvals for cell and gene therapy include:

- ADSTILADRIN (nadofaragene firadenovec-vncg), the first gene therapy for the treatment of adults with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non--muscle -invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors (December 2022)
- VYJUVEK (beremagene geperpavec-svdt), indicated for treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene (May 2023)
- ELEVIDYS (delandistrogene moxeparvovec-rokl), for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene (June 2023)
- LANTIDRA (donislecel-jujn), indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education (June 2023)

CBER provides extensive scientific and regulatory advice to product manufacturers throughout the medical product lifecycle. Advice starts at either the INTERACT or pre-IND stage, or both for cutting edge cell and gene therapies and includes feedback on manufacturing, preclinical, and clinical topic areas. CBER also develops policy and guidance on novel clinical, scientific, and manufacturing challenges for these products. The guidance documents explain FDA's interpretation and policy for a regulatory issue, and are primarily for industry, but also for other stakeholders and internal staff. A full list of CBER guidances may be found at FDA's website: Biologics Guidances. Recent key CBER guidance documents include:

- Draft Guidance for Industry: Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products (FDA-2023-D-2436), which provides recommendations regarding product comparability and the management of manufacturing changes for investigational and licensed cell and gene therapy products (July 2023)

CBER continues to engage with stakeholders on topics on the cutting edge of medicine and drug development. In September 2022, CBER launched the Office of Therapeutic Products (OTP) Virtual Town Hall Series to engage with product development stakeholders and researchers in a question-and-answer format. OTP has hosted five town hall events thus far and answered questions from cell and gene therapy stakeholders across an array of disciplines. In March 2023, CBER held the Advanced Manufacturing and Analytical Technologies (AMAT) for Regenerative Medicine Therapies (RMT) Workshop for FDA staff and cell and gene therapy stakeholders. This workshop was held to discuss innovative manufacturing technologies and alternative testing methods, and share experiences, challenges, and best practices critical for chemistry, manufacturing, and controls (CMC) of cellular and gene therapies and tissue engineered medical products.

CBER also continues to support Agency-wide efforts to advance patient engagement and patient focused medical product development. Programs at the Center include CBER's Science of Patient Input (SPI) initiative and CBER's Rare Disease program. SPI initiative activities include supporting studies on methods and tools to obtain robust patient input to support biological product regulatory reviews and providing CBER reviewers with assistance in the regulatory review of patient input and patient-reported outcomes data. CBER's Rare Disease program also incorporates patient engagement, including the RegenMedEd workshop and webinar series, which hosted a workshop in April 2023 and webinar in October 2023 to discuss foundational information about gene and cell therapy products and ways in which patients and advocates can help advance product development.

FDA's regenerative medicine framework clarifies how it interprets existing regulatory definitions and describes FDA's compliance and enforcement policy. Compliance actions on human cell, tissue, and cell and tissue-based product manufacturers taken by FDA in FY 2023 include the issuance of seven Untitled Letters for marketing of unapproved regenerative medicine products and six Warning Letters for either unapproved or adulterated regenerative medicine products or both to treat various diseases or conditions.

CBER's Rare Disease Program advances development of biologics for rare diseases through various activities that engage staff across the Center and may involve collaboration with rare disease partners at FDA such as CDER's Rare Diseases Team and the Office of Orphan Products Development. Several activities support user fee commitments and include reviewer training, stakeholder engagement, and ensuring consideration of flexible and feasible approaches in review. As a new commitment under PDUFA VII and the Food and Drug Omnibus Reform Act, CBER, in collaboration with CDER, is implementing the Rare Disease Endpoint Advancement (RDEA) Pilot Program. Sponsors whose proposals are admitted into this pilot will have the opportunity to collaborate with FDA throughout the efficacy endpoint development process. CBER anticipates receiving proposals from cell and gene therapy sponsors for consideration in this pilot program, which will run through FY 2027.

Advanced Manufacturing

CBER encourages development and adoption of AM technologies to support fewer interruptions in production, fewer product failures, and greater assurance that biologic products will provide the expected clinical performance. The CBER Advanced Technologies Team offers pre-submission regulatory support to meet with prospective innovators and developers of AM technologies to provide informal consultation during early-stage development. CBER also works closely with FDA's ORA on new inspection strategies. To address manufacturing challenges, CBER has made several extramural awards to support research projects that promote the development and adoption of innovative approaches. Results have been communicated to stakeholders in over 17 scientific publications.

In FY 2023, CBER awarded a contract to a research group at MIT to develop tools to advance the manufacture of exosome therapeutics. Exosomes are nanoscale, extracellular vesicles, that are emerging as a therapeutic modality with significant potential to address unmet needs. Their clinical application includes diverse areas such as tissue regeneration, cancer, neurodegeneration, and inflammation. Despite their immense therapeutic potential, hurdles in the manufacture of clinical-grade exosomes represent significant impediments in realizing that potential. Under this award, the group at MIT will apply mechanistic modeling and process analytical technology to exosome production to better enable the reproducible manufacture of this emerging therapeutic modality.

PERFORMANCE

The Biologics Program's performance measures focus on biological product review, manufacturing diversity and capacity for influenza vaccine production, strengthening detection and surveillance of FDA-regulated products and postmarket inspections to ensure the safety, purity, potency, and effectiveness of biological products, as detailed in the following table.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 +/- FY 2024
233207: Review and act on standard New Molecular Entity (NME) New Drug Application (NDA) and original BLA submissions within 10 months of the 60 day filing date. (Output)	FY 2022: 100% Target 90% (Target Exceeded)	90%	90%	Maintain
233208: Review and act on priority NME NDA and original BLA submissions within 6 months of the 60 day filing date. (Output)	FY 2022: 90% Target 90% (Target Met)	90%	90%	Maintain
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. (Output)	FY 2022: 83% Target 100% (Target Not Met)	90%	90%	Maintain
233206: Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. (Output)	FY 2022: 99% Target: 90% (Target Exceeded)	90%	90%	Maintain
233211: Review and act on new non-user fee, non-blood product applications within 12 months of receipt. (Output)	FY 2022: 0% Target: 60% (Target Not Met)	60%	60%	Maintain
234101: Increase manufacturing diversity and capacity for influenza vaccine production. (Output)	FY 2023: Continued evaluation of new methods to produce high-yield influenza vaccine reference strains. (Target Met)	Continue evaluation of new methods to produce more stable high-yield influenza vaccine reference strains and improve current manufacturing processes	Continue evaluation of new methods to produce more stable high-yield influenza vaccine reference strains and improve current manufacturing processes	Maintain
231301: Percentage of Lot Distribution Reports that were entered into the Regulatory Management System - Biologics License Applications (RMS-BLA) within 7 Days. (Output)	FY 2023: 95% Target 85% (Target Exceeded)	85%	85%	Maintain
234221: Percentage of Biologics significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 92.3% Target: 70% (Target Exceeded)	70%	70%	Maintain
234222: Percentage of Biologics follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 82.4% Target: 65% (Target Exceeded)	65%	65%	Maintain

Figure 36 - Biologics Performance Table

The following selected items highlight notable results and trends detailed in the performance table.

Blood BLA Submissions

Although CBER completed five out of six applications on time, one new BLA application missed the first action due goal. This application was for a new Source Plasma manufacturer that required several information requests and communications between the firm and CBER resulting in an extended time for approval. Although we missed this goal, CBER plans to keep the targets the same moving forward.

Non-User Fee, Non-Blood Applications

CBER received only one new non-user fee, non-blood product BLA during FY 2022. This application is currently in "Complete Response Letter" status because of inspectional issues, and it took longer than expected to incorporate the findings from the inspection into the review of the application. Although we missed this goal, CBER plans to keep the targets the same moving forward.

Influenza Performance Measure

This performance measure supports the Department's national preparedness efforts in combating seasonal influenza, by increasing manufacturing diversity and capacity for influenza vaccine production. In FY 2023, FDA met the target to continue evaluation of new methods to produce high-yield influenza vaccine reference strains and improve current vaccine manufacturing processes. Activities to meet this target included the following:

- FDA continued efforts to develop new methods for determining influenza vaccine potency, an important component in the evaluation of high-yield influenza vaccine viruses, and for expediting vaccine reagent preparation. New methods using mammalian cell culture expression systems to produce antigen for immunization were evaluated for generating the potency antisera needed for vaccine potency assays.
- An H5N8 candidate vaccine virus for a recently identified H5N8 influenza virus with pandemic potential that was generated in FY
- 2021 was used to purify protein for vaccine potency reagent preparation, which can be used for vaccine antigen standardization. Demonstrated that candidate vaccine viruses for influenza viruses with pandemic potential (e.g., H5N8 and H7N9) do not acquire adaptive mutations when generated in egg substrates.
- Continued efforts to evaluate neuraminidase (NA) in circulating viruses and the impact of including NA in candidate vaccines. Showed that inactivated vaccine viruses engineered for higher NA antigen content elicit robust antibody responses against NA in animal models w lowering vaccine doses necessary for HA and NA protective responses.
- Continued collaborations with the Clinical Studies Unit at LID within the NIH to assist in producing recombinant NAs for a vaccine clinical trial and for measuring NA responses from individuals in clinical trials.
- Continued development of new methods for purifying and quantifying potential NA in vaccine antigens, including soluble NA antigens that can be attached to a viral-like particle to create more immunogenic multivalent presentations.

ORA Field Performance Measures

ORA's performance goals measure topics such as our commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to ORA regulatory impact on violators, and are tracked on a 3-year rolling basis. Due to the nature of regulatory actions and subsequent follow-up conducted by FDA, the duration of these events can vary considerably. After regulatory action, FDA also works to schedule follow-up after a reasonable time has passed to allow the firm to correct for the original violations. A 3-year rolling timeline also ensures tracking of all significant violations that require attention and allows for a more robust analysis.

PROGRAM ACTIVITY DATA

Biologics Program Activity Data (PAD)

CBER Workload and Outputs	FY 2023 Final	FY 2024 CR	FY 2025 PB
Original Biologics License Applications (BLA)			
Workload [1]	25	25	25
Total Decisions [2]	31	31	31
Approved	23	23	23
BLA Efficacy Supplements			
Workload [1]	27	27	27
Total Decisions [2]	28	28	28
Approved	21	21	21
BLA Manufacturing Supplements			
Workload [1]	1,357	1,357	1,357
Total Decisions [2]	1,315	1,315	1,315
Approved	1,216	1,216	1,216
BLA Labeling Supplements			
Workload [1]	84	84	84
Total Decisions [2]	82	82	82
Approved	71	71	71
Original New Drug Application (NDA)			
Workload [1]	0	0	0
Total Decisions [2]	1	1	1
Approved	0	0	0
NDA Efficacy Supplements			
Workload [1]	0	0	0
Total Decisions [2]	0	0	0
Approved	0	0	0
NDA Manufacturing Supplements			
Workload [1]	15	15	15
Total Decisions [2]	45	45	45
Approved	12	12	12
NDA Labeling Supplements			
Workload [1]	0	0	0
Total Decisions [2]	2	2	2
Approved	1	1	1
Original Abbreviated New Drug Application (ANDA)			
Workload [1]	0	0	0
Total Decisions [2]	0	0	0
Approved	0	0	0
ANDA Efficacy Supplements			
Workload [1]	0	0	0
Total Decisions [2]	0	0	0
Approved	0	0	0

Figure 37 - CBER Workload and Outputs 1 / 2

ANDA Manufacturing Supplements			
Workload [1]	4	4	4
Total Decisions [2]	6	6	6
Approved	6	6	6
ANDA Labeling Supplements			
Workload [1]	0	0	0
Total Decisions [2]	1	1	1
Approved	1	1	1
Device 510Ks			
Workload [1]	45	45	45
Total Decisions [2]	46	46	46
Final Decision - SE	34	34	34
Device Premarket Applications (PMA)[6]			
Workload [1]	2	2	2
Total Decisions [2]	6	6	6
Approved	3	3	3
Device Premarket Applications (PMA) Supplements [7]			
Workload [1]	45	45	45
Total Decisions [2]	50	50	50
Approved	16	16	16
Investigational New Drugs (IND)			
Receipts: IND (new)	777	777	777
Receipts: IND Amendments	18,034	18,034	18,034
Total Active IND [3]	3,896	3,896	3,896
Investigational Device Exemptions (IDE)			
Receipts: IDE (new)	24	24	24
Receipts: IDE Amendments	320	320	320
Total Active IDE [3]	103	103	103
Patient Safety			
Adverse Event Reports Received [4]	249,563	500,000	450,000
Biological Deviation Reports Received	16,268	15,800	15,800
Sponsor Assistance Outreach			
Meetings	854	854	854
Final Guidance Documents [5]	54	45	45
Admin/Management Support			
Advisory Committee Meetings Held	10	12	12
FOI Requests Processed	350	500	550

[1] Workload includes applications received and filed.

[2] Total Decisions include approved, denied, withdrawn, approvable, approvable pending inspection, not approvable,

[3] Total Active includes investigational applications received and existing applications for which CBER has received at

[4] Includes MedWatch, Foreign reports and VAERS reports. Does not include Fatality Reports for blood tansfusions or

[5] Includes all FDA final guidances issued by CBER and other FDA centers that pertain to biological products.

[6] Includes PMA original, PMA shell, HDE and de novo original applications.

[7] Includes all PMA and HDE supplements, PMA modules, excluding HDE-Other and 513(g) submission types.

Figure 38 - CBER Workload and Outputs 2 / 2

Biologics Field Program Activity Data may be found within the Office of Regulatory Affairs (ORA) chapter beginning on page 161.

ANIMAL DRUGS AND FOODS

PURPOSE STATEMENT

The Animal Drugs and Foods Program is administered by the Center for Veterinary Medicine (CVM) and the Office of Regulatory Affairs (ORA) to protect and promote the health of humans and animals by ensuring:

- The safety of the American food supply
- The safety of animal food and devices
- The safety and effectiveness of animal drugs

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Public Health Service Act (42 U.S.C. 201, et seq.); Animal Drug Amendments (1968) (21 U.S.C. 360b); Generic Animal Drug and Patent Term Restoration Act (1988); Animal Medicinal Drug Use Clarification Act of 1994; Animal Drug Availability Act of 1996; FDA Export Reform and Enhancement Act of 1996; Food and Drug Administration Modernization Act of 1997; Antimicrobial Regulation Technical Corrections Act of 1998; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Animal Drug User Fee Act of 2003 (21 U.S.C. 379j-11 - 379j-12); Minor Use and Minor Species Animal Health Act of 2004; Sanitary Food Transportation Act of 2005; Food and Drug Administration Amendment Act of 2007; Animal Drug User Fee Amendments of 2008 (P.L. 110-316); Animal Generic Drug User Fee Act of 2008 (P.L. 110-316); Patient Protection and Affordable Care Act; FDA Food Safety Modernization Act (P.L. 111-353); FDA Safety and Innovation Act (P.L. 112-144); Animal Drug User Fee Reauthorization Act of 2023 (H.R. 5860); Animal Generic Drug User Fee Reauthorization Act of 2023 (H.R. 5860).

Allocation Methods: Competitive grant; Contract; Direct Federal/intramural.

BUDGET REQUEST

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
Animal Drugs and Foods	**238,847**	**253,877**	**288,353**	**285,299**	**297,312**	**8,959**
Budget Authority	***192,352***	***202,538***	***230,093***	***229,362***	***240,253***	***10,160***
User Fees	***46,495***	***51,339***	***58,260***	***55,937***	***57,059***	***-1,201***
Center	169,707	181,072	204,730	203,111	212,160	7,430
Budget Authority	123,599	130,142	148,141	148,484	156,438	8,297
User Fees	46,108	50,930	56,589	54,627	55,722	-867
Field	69,140	72,805	83,623	82,188	85,152	1,529
Budget Authority	68,753	72,396	81,952	80,878	83,815	1,863
User Fees	387	409	1,671	1,310	1,337	-334
FTE	**1,061**	**1,048**	**1,066**	**1,057**	**1,087**	**21**

Figure 39 - Animal Drugs and Foods Funding History Table

The FY 2025 President's Budget for the Animal Drugs and Foods Program is $297,312,000 of which $240,253,000 is budget authority and $57,059,000 is user fees. The budget authority increase by $10,160,000 compared to the FY 2023 Final Level. User fees decrease by $1,201,000. The Center for Veterinary Medicine (CVM) amount in the request is $212,160,000. The Office of Regulatory Affairs (ORA) amount is $85,152,000.

CVM protects and promotes the health of humans and animals by employing a One Health approach to help ensure the safety of the American food supply, the safety of animal food and

devices, and the safety and effectiveness of animal drugs. This supports the health of food-producing and companion animals, including minor species, and enhances the availability and diversity of approved products. CVM's responsibilities include:

- Ensuring safety and effectiveness of animal drugs
- Ensuring safety and effectiveness of novel technologies, like intentional genomic alterations (IGAs) in animals and animal cell- and tissue-based products (ACTPs)
- Reviewing animal food additives for safety and utility
- Ensuring animal food is safe, made under sanitary conditions, and properly labeled.

CVM's performance measure dashboards highlight accomplishments towards protecting human and animal health. There are dashboards covering the Center's work on animal food safety; compounded animal drugs; emerging technologies; pre-market drug review; and post-market drug safety, effectiveness, and quality; and antimicrobial stewardship in veterinary settings, as well as the Center's performance on animal drug review timelines agreed upon in the Animal Drug and Animal Generic Drug User Fee Amendments of 2023.

These activities and the initiatives requested in the FY 2025 Budget Request support mission critical activities, and Presidential, HHS, and FDA human and animal health priorities.

BUDGET AUTHORITY

FY 2025 President's Budget:
Animal Drugs and Foods
Budget Authority - Dollars in Thousands

	Center	Field	Total
FY 2023 Final	**148,141**	**81,952**	**230,093**
FY 2025 Budget Authority Changes	**8,297**	**1,863**	**10,160**
Requested Increases	**7,859**	**2,891**	**10,750**
Public Health Employee Pay Costs	6,179	2,721	8,900
Enterprise Transformation	67	34	101
IT Stabilization & Modernization	264	136	400
Shortages and Supply Chain-Agency-wide	1,349	-	1,349
Other Adjustments	**438**	**(1,028)**	**(590)**
ORA Transfer to HQ/OGPS	-	(1,452)	(1,452)
FY 2024 Comparability Adjustment	343	378	721
FY 2025 Comparability Adjustment	95	46	141
FY 2025 Budget Net Total: Animal Drugs and Foods	**156,438**	**83,815**	**240,253**

Figure 40 - Animal Drugs and Foods Budget Authority

Total Requested Increases: +$10.7 million / 4 FTE

Public Health Employee Pay Costs: +$8.9 million

Center: +$6.2 million

Field: +$2.7 million

The FY 2025 President's Budget includes $114.8 million in new budget authority to fund approximately 72 percent of the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 and FY 2025 Cost of Living Adjustments (COLA). For FY 2025 this assumes a 2.0 percent for Civilian and 4.5 percent Military pay increase for FTE funded through budget authority. Within the Animal Drugs and Foods program, $8.9 million is provided for pay costs, including $6.2 million for CVM and $2.7 million for ORA.

Enterprise Transformation: +$101,000

Center: +$67,000

Field: +$34,000

The FY 2025 President's Budget provides $2.0 million for Enterprise of Transformation, which includes $101,000 for the Animal Drugs and Foods Program to coordinate and lead several crosscutting agency-wide projects to analyze and implement common business processes and data optimization. Benefits of this funding will include improved communication and data sharing across the life cycle of an inspection, increased access to relevant data to facilitate risk-based decision-making, and introduction of more modern mobile technology for field work to improve the user experience. The office also seeks to standardize the FOIA business processes across the Agency and create effective governance to enable successful process and technology changes.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

IT Stabilization & Modernization: +$400,000

Center: +$264,000

Field: +$136,000

The FY 2025 President's Budget provides $8.3 million for IT Stabilization & Modernization, including $400,000 for the Animal Drugs and Foods Program to further build FDA's centralized enterprise data modernization capabilities and to strengthen FDA's common data infrastructure, data exchange, and IT analytic services, talent, and tools. With these resources, FDA will continue to improve data exchange and underlying technology platforms in support of FDA's programs and mission-critical responsibilities – to better meet the challenges of emerging threats, support needs for real-time evaluation, and more continuously access, analyze, and aggregate multiple sources of information, such as for recalls, adverse events, outbreaks, and pandemics.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

Shortages and Supply Chain: +$1.3 million / 4 FTE

Center: +$1.3 million / 4 FTE

The FY 2025 President's Budget request provides $12.3 million for Shortages and Supply Chain, including $1.3 million for the Animal Drugs and Foods Program to advance FDA's capabilities to help prepare for, build resilience to, and respond to shortages that are supply-driven and/or demand-driven through improved analytics to identify shortage threats and vulnerabilities as well as regulatory approaches to address disruptions and shortages.

USER FEES

Current Law User Fees (-$1.2 million)

Center: -$871,000

Field: -$369,000

The Animal Drugs and Foods Program request includes a decrease of $1.2 million for user fees, compared to FY 2023 Final Level.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

CVM protects and promotes the health of animals including food-producing and companion animals in the United States and supports a $560 billion animal health industry. Households in the United States have approximately 88 million dogs and 61 million cats,[68] and U.S. farmers raise approximately 9.6 billion chickens, 216 million turkeys, 77 million pigs, and 93 million cattle every year.[69] CVM's responsibilities include:

- Ensuring safety and effectiveness of animal drugs
- Ensuring safety and effectiveness of novel technologies, like intentional genomic alterations (IGAs) in animals and animal cell- and tissue-based products (ACTPs)
- Reviewing animal food additives for safety and utility
- Ensuring animal food is safe, made under sanitary conditions, and properly labeled.

CVM also recognizes the importance of the availability of animal foods and drugs. This includes facilitating market entry for new products, as well as monitoring and responding to supply shortages to ensure there is a robust and varied drug supply that veterinarians and animal owners can use to support the health of their animals – which supports the livelihood of animal producers, supports the animal health industries, and helps pets lead healthy lives. CVM partners with FDA's Office of Chief Scientist to support stakeholder driven innovation, invests in research with the goal of enabling products to come to market more easily, and works to address gaps in regulatory science and policy specific to new technologies and emerging health threats.

Additionally, CVM regulated industries are utilizing enhanced technologies and innovative approaches to develop new products for animals. To keep pace, the Agency needs investments to bolster its capacity to protect human and animal health in this changing environment. As such, CVM performed a comprehensive evaluation of how it conducts business with stakeholders in the digital world and has begun re-engineering its mission-critical business processes and corresponding Information Technology (IT) systems to evolve its digital footprint. CVM is partnering with FDA's Office of Digital Transformation (ODT) to implement the recommendations from the IT evaluation. This partnership also helps leverage ODT's expertise in developing new solutions that are cost saving, follow ODT's Technology Modernization Action Plan and Data Modernization Plan, and build on common enterprise infrastructure. These

[68] *AVMA 2022 Pet Ownership and Demographic Sourcebook. See:* https://ebusiness.avma.org/files/ProductDownloads/eco-pet-demographic-report-22-low-res.pdf

[69] USDA. National Agricultural Statistics Service. Agricultural Statistics. US Government Printing Office, Washington DC 20402. See: http://www.nass.usda.gov/

IT enhancements bolster CVM's efforts to protect human and animal health and to quickly respond to natural disasters and emerging threats.

CVM utilizes One Health approaches to help achieve our mission more completely, effectively, and innovatively. CVM brings unique animal and veterinary expertise to cross disciplinary collaborations with other FDA centers, other Federal agencies, States, Territories, Tribes, and international partners, to help solve complex public health problems that cross human, animal, and environmental health. CVM, as a leader in One Health at FDA and within the USG, works with our partners to recognize the interdependence of our work and ensuring more seamless coordination activities, including through the congressionally directed National One Health Framework to Address Zoonotic Diseases and Advance Public Health Preparedness in the United States. CVM's One Health approach also provides more robust approach to opportunities such as innovative technologies like gene-editing as well as challenges such as antimicrobial resistance and supply chain threats.

CVM leads efforts to combat antimicrobial resistance, a major national and world-wide public health threat, as 3,000,000 people in the U.S. are infected with antibiotic resistance bacteria each year and nearly 35,000 people die as a result.[70] The Center is committed to advancing antimicrobial stewardship in veterinary settings, reducing misuse of antimicrobial drugs, and slowing the rising threat of resistance, while enhancing monitoring for the presence of resistant bacteria in retail meats and other commodities through the National Antimicrobial Resistance Monitoring System (NARMS). CVM leverages NARMS data and other sources to estimate the overall risk of antimicrobial resistance when determining whether to approve a new animal antimicrobial drug for a proposed use.

CVM conducts pre-market evaluations of new animal drugs and determines whether these products are safe and effective for their intended use, manufactured to meet current good manufacturing practice requirements, and properly labeled. CVM's research supports new animal drug evaluations by conducting method trials and developing alternative approaches to replace, reduce, or refine the need for animal testing. Pharmacovigilance is also critical oversight tool for the post-market phase of the animal drug lifecycle, as knowledge about the safety profile of an animal drug evolves as it is used on larger populations of animals. CVM monitors the safety of drugs used in animals, the safety of humans exposed to animal drugs, and the effectiveness of animal drugs through a pharmacovigilance system.

Animals generally eat a very limited and defined diet as their sole ration for their entire lifetime, therefore, getting diet formulations correct and controlling contaminants in animal food is critical. When food is contaminated or nutritionally imbalanced, it can have an outsized impact on animal health. CVM's review of new animal food ingredients provides livestock producers access to safe nutritional ingredients to help keep animals healthy, while also ensuring that the meat, milk, and eggs from those animals are safe for people to eat. CVM also monitors the post-market safety phase of the animal food lifecycle by identifying, analyzing, and mitigating serious issues that may result in harm to humans or animals.

Comprehensive risk-based oversight of the animal food supply is vital to protecting the health of both humans and animals. CVM continues prevention-focused efforts under the Food Safety

[70] CDC. National Infection and Death Estimates for Antimicrobial Resistance: https://www.cdc.gov/drugresistance/national-estimates.html

Modernization Act (FSMA) by working to modernize FDA's science- and risk-based animal food safety systems through the establishment of preventive control standards and monitoring industry's compliance with these standards. The Center works extensively with state regulatory and public health partners to continue building an integrated food safety system that supports animal food standards, response efforts, and enhanced surveillance systems.

CVM's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) is a program comprised of 48 state and university veterinary diagnostic laboratories that investigate potential problems with CVM-regulated products and perform diagnostic testing of animal specimens in response to consumer complaints. These laboratories generate pivotal data that may inform regulatory actions and decision making and can potentially lead to manufacturer product recalls. Vet-LIRN is a critical piece of FDA's response capabilities, in part because it is adaptive and flexible in instances where additional capacity is required by demand spikes due to events such as the COVID-19 pandemic and other outbreak situations.

Fostering Animal and Veterinary Innovation

In September 2023, CVM released its Animal and Veterinary Innovation Agenda (AVIA) to foster product development and implement smart, risk-based approaches to regulating modern animal and veterinary products. These actions will further position the agency for continued scientific and technological evolution while helping to bring safe and effective products to the market. It also aims to encourage the development of products for unmet human and animal needs, particularly to address the lack of targeted therapeutics designed and approved for use in animals. CVM wants to spur our regulated industries to grow, become more robust, and to deliver more innovations and approved products to veterinarians, animal and pet owners, and agricultural producers. Having more approved products across all CVM's regulated industries will bolster animal health and human health alike. The new agenda applies to a variety of products, including:

- Animal drugs that address unmet veterinary needs or intended for minor uses or minor species
- Novel food ingredients that work solely in the animal's gut to increase nutritional efficiency and production
- Animal biotechnology products, such as ACTPs and IGAs in animals
- Cell-cultured animal food ingredients

CVM will consider how to modernize our regulatory frameworks to adopt smart approaches that ensure products meet FDA's trusted standards yet are maximally agile and spur innovations to come to market. CVM hopes to work with Congress on areas where modernized authorities may be helpful in spurring and speeding innovations to market. CVM will also be applying a One Health approach to standing up this innovation, and ensuring the Agency is prioritizing innovation that can address important needs across both human and animal health.

As part of the AVIA, CVM will be expanding the Veterinary Innovation Program (VIP), which currently offers technical assistance to developers; creates greater regulatory predictability; reduces overall time to approval; and enables early, extensive consultations. As of October 31, 2023, there are 57 products enrolled in the current program. The expanded program, VIP Plus, will include new tools for developers of ACTPs and IGAs and will improve the efficiency of the FDA's review process by tailoring data requirements to answer risk-based questions specific to

the product. The agency will also provide advanced computational tools that allow reviewers and developers to analyze complex genomic data.

In FY 2023, CVM funded and is working collaboratively on a project with the National Institute of Science and Technology (NIST) that aims to provide an important new resource for researchers and companies creating innovative products by using genome editing to alter the genome of animals. One goal of the product is to generate standardized measurements for characterizing IGAs in cattle and swine that are developed using genome editing. These methods and materials will improve regulators' confidence in developers' evaluations, potentially reducing product review time. These resources will also support the molecular characterization of genome-edited animals, which can apply to animals for uses other than food production, such as organs for transplantation into humans.

Preparedness and Response

In the fight against the opioid epidemic, in FY 2023, CVM partnered with offices across FDA, the Department of Health and Human Services, the Drug Enforcement Administration (DEA) and U.S. Customs Border Protection to address the illicit use of the chemical xylazine in humans. Xylazine is an active pharmaceutical ingredient used in a sedative approved for use in animals. It is not approved for use in people. Xylazine is increasingly found mixed with illicit drugs like fentanyl and heroin. This combination can increase the risks of overdose and is associated with chronic wounds in users that can lead to infection and limb amputation. As a first step in identifying sources of xylazine entering the illicit drug supply, CVM worked with ORA to post an import alert for xylazine entering the U.S. through commercial channels. CVM contributed to the White House Office of National Drug Control Policy National Response Plan to address this dangerous threat head-on.

Additionally, CVM's Vet-LIRN led a proficiency test among 32 veterinary diagnostic laboratories to ensure that their tests for the COVID-19 virus, SARS-CoV-2 are reliable for use in animals. Samples included the omicron variant to verify that laboratories continue to detect emerging variants with their routine testing methods. In addition to testing animals, these laboratories have conducted millions of tests for SARS-CoV-2 in humans. Many laboratories use the same methods for both human and animal testing, so ensuring that these laboratories have sensitive and specific methods to detect SARS-CoV-2, including emerging variants, is critically important for both human and animal health.

Increasing Availability of Safe and Effective Animal Drugs

In September 2023, Animal Drug and Animal Generic Drug User Fee Amendments of 2023 were signed into law, reauthorizing the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA). 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 for food-producing and companion animals.

In the 2018 reauthorization of the ADUFA program, Congress expanded the conditional approval pathway to certain new animal drugs that fill treatment gaps for serious or life threatening- diseases or conditions in major species. In September 2023, CVM conditionally approved Fidoquel-CA1 (phenobarbital tablets) for control of seizures associated with idiopathic epilepsy in dogs. Since this new expanded authority was granted, FDA has used it to conditionally approve four other new animal drugs to treat epilepsy, heart failure, acute

pancreatitis, and anemia associated with chronic kidney disease. FDA has also conditionally approved three drugs to treat certain cancers or cancer-related conditions in dogs during this period under the Minor Use Minor Species conditional approval authority.

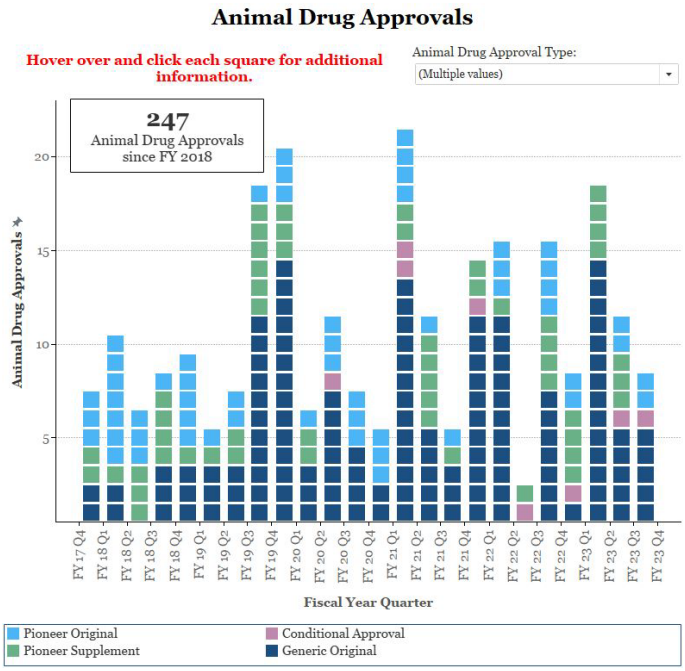

Figure 41 - Animal Drug Approvals

CVM met or exceeded its ADUFA performance commitments and AGDUFA performance commitments in the current reporting year. Some of the notable products that CVM evaluated and approved in FY 2023 include several first --kind therapies. Bexagliflozin is the first sodium-glucose cotransporter 2 inhibitor new animal drug approved by CVM in any species. It is also the first oral new animal drug to improve glycemic control in otherwise healthy cats with diabetes mellitus not previously treated with insulin. CVM also approved the first monoclonal antibody new animal drugs, frunevetmab and bedinvetmab, for the control of pain associated with osteoarthritis in cats and dogs. CVM approved multiple first generics, including flumethasone for treatment of certain diseases that cause inflammation in horses, dogs and cats; moxidectin, for treatment and control of internal and external parasites in cattle; and cyclosporine, for the control of certain skin conditions resulting from a disease called feline allergic dermatitis. Generic animal drugs provide more options for veterinarians and animal owners and may help lower the cost of treatment.

CVM provides additional pathways to legal marketing status and incentives to support drug development for use in minor animal species and for minor uses in major species (horses, dogs, cats, pigs, turkeys, and chickens). Incentives are needed since the small size of these markets does not provide sufficient return on investment for sponsors seeking FDA approval. Since 2009, CVM has provided funding for 69 studies conducted in support of approvals for drugs intended for use in minor species and for minor uses in major species. These drug approvals included:

- Antiparasitic drugs for sheep, goats, and fish
- Drugs to treat various cancers in dogs
- A drug to prevent heartworm disease in ferrets

CVM also administers an alternative to the approval process for non-food minor species called the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index). The Index was designed to provide a different path to legal marketing for drugs for use in animals such as pet birds, ornamental fish, zoo and laboratory animals, and pocket pets. So far, 16 products have been authorized for legal marketing for these underserved populations, including the first analgesic drug formulated and marketed specifically for laboratory rodents and

ferrets. The number of drugs entering the indexing process has increased by 40 percent over the past fiscal year and CVM anticipates this increase to continue.

Mutual recognition agreements with international partners can accelerate the availability of animal drugs in the U.S. In May 2023, CVM and the European Union (EU) announced their decision to expand the scope of the Mutual Recognition Agreement (MRA) Sectoral Annex for Pharmaceutical Good Manufacturing Practices to include inspections of animal drugs. This important step helps ensure the safety and quality of animal drug products, produces greater efficiencies for both regulatory systems by avoiding duplication of animal drug inspections, and enables regulators to devote more resources to areas where there may be greater risk.

Preventing and Responding to Animal Drug Shortages

CVM developed the Animal Drug and Manufacturing System (ADMS) to assess the impact of emerging diseases and natural disasters by leveraging data on animal drug products, active pharmaceutical ingredients, and manufacturing sites. CVM relies on voluntary reporting of disruptions or discontinuances from industry and launched ADMS in 2022 to help animal drug manufacturers to provide more complete facility information. ADMS has been critical in identifying animal drug manufacturing facilities impacted by the current conflict in Israel and evaluating subsequent shortages. When notified of a shortage, CVM conducts targeted outreach to animal drug manufacturers and FDA partners to decrease the duration of the shortage and mitigate harm to humans or animals. In FY 2023, CVM averted the shortage of four approved new animal drugs:

- Factrel, used to treat ovarian follicular cysts in dairy cows, beef cows, and replacement dairy and beef heifers
- Norocillin, used to treat bacterial pneumonia in cattle and sheep, erysipelas (bacterial skin infection) in swine, and strangles (upper respiratory bacterial infection) in horses
- BetaVet, used to control pain and inflammation associated with osteoarthritis in horses
- Diruban, used to treat stabilized heartworm disease in dogs

Monitoring Postmarket Drug Safety

The public depends on CVM to actively monitor animal drug products marketed in the United States for potential safety issues, and to quickly identify, analyze, and mitigate any serious issues that may result in harm to humans or animals. CVM receives approximately 100,000 adverse event reports each year. In FY 2023, CVM reviewed 25 percent of the postmarket safety information it received for all approved actively marketed animal drug products. The Center also monitors the safety of animal drugs, human user safety, and the effectiveness of approved animal drugs by leveraging the largest animal drug adverse event database in the world, with adverse events affecting more than 95,500,000 food animals, and approximately 1,134,000 companion animals. CVM also utilizes adverse event signal detection (data mining) and management strategies to improve how the Center identifies, monitors, and learns from problems experienced with approved and unapproved animal drugs.

Veterinarians in the United States sometimes rely on animal drugs compounded from bulk drug substances to treat animals when no FDA-approved or indexed drug is available. However, FDA has not reviewed the compounded animal drugs for evidence that they are safe, effective, properly manufactured, accurately labeled, and adequately packaged. These unapproved drugs

can be an animal health hazard. Further, compounded animal drugs create an increasing disincentive for drug sponsors to pursue FDA-approved drug development. The global animal drug compounding industry is valued at approximately $1.3 billion, and it is expected to see significant growth in the coming years. In FY 2023, CVM and ORA began implementing final guidance on "Compounding Animal Drugs from Bulk Drug Substances." This implementation included:

- Identifying compounders who produce animal drugs
- Assessing the priority of each inventoried firm relative to FDA's policy objectives
- Conducting a limited number of inspections
- Engaging with key stakeholder groups, including compounding pharmacies and associations for states, pharmacists, and veterinarians

Supporting Antimicrobial Stewardship

CVM is helping to preserve the effectiveness of antimicrobial drugs and slow the development of antimicrobial resistance by working closely with stakeholders to ensure antimicrobial drugs are used in animals only under the oversight of a licensed veterinarian and only when necessary to treat, control, or prevent disease. In September 2023, CVM released its plan for "Supporting Antimicrobial Stewardship in Veterinary Settings, Goals for Fiscal Years 2024-2028," providing stakeholders with a transparent roadmap to advance FDA's three main stewardship goals:

- Align antimicrobial drug product use with principles of antimicrobial stewardship
- Foster stewardship of antimicrobials in veterinary settings
- Enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals

As CVM develops and implements strategies to address individual actions in the plan, it will solicit public feedback on certain key initiatives. Stakeholders and the public can see what has been accomplished thus far and follow progress via FDA-TRACK: Progress on FDA's Support of Antimicrobial Stewardship in Veterinary Settings.

In November 2023, CVM began considering public comments it received on a report, prepared for the FDA by the Reagan-Udall Foundation, outlining a potential framework for establishing a public-private partnership to collect and analyze antimicrobial use data from food-producing animals. Antimicrobial use data can help foster antimicrobial stewardship and slow the development of antimicrobial resistance, because it provides insights into what drugs are being used, how much of the drugs are being used, and how they are being used. FDA has been exploring, with the Foundation's assistance, whether a public-private partnership could balance the need for public health information with practical concerns of the veterinary professionals and producers who would voluntarily contribute to the data repository. CVM expects to make future announcements on this framework's progress within the next calendar year and any future iterations of the framework will be shared for public comment before being finalized.

Also, in May 2023, the public comment period closed for draft update to guidance on "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern. " Over 9,200 comments were received for consideration in the final guidance. The guidance is a tool for assessing the risk that a new animal drug for use in food-producing animals will contribute to the development of antimicrobial resistant bacterial infections in people. It is being updated to reflect:

- Revisions to the risk assessment framework
- Updates to the ranking criteria for determining the degree of medical importance of antimicrobial drug classes
- A revised ranking of antimicrobial drug classes as critically important, highly important, or important based on the newly updated ranking criteria (Appendix A)

The National Antimicrobial Resistance Monitoring System (NARMS)

The National Antimicrobial Resistance Monitoring System (NARMS) monitors antimicrobial resistance in enteric (intestinal) foodborne bacteria in retail meats (via CVM data), ill people (via CDC data) and food animals (via USDA data). NARMS data and other sources inform CVM's evaluation of the overall risk of antimicrobial resistance of a proposed new use of an antimicrobial drug. Limiting a drug's conditions of use based on this risk estimation can mitigate the risk of antimicrobial resistance development.

NARMS is partnering with the Environmental Protection Agency (EPA) to implement a portion of the NARMS Strategic Plan: 2021 – 2025, which emphasizes taking a One Health approach to monitoring antimicrobial resistance in animal pathogens and the environment. In FY 2023, NARMS initiated an interagency agreement with EPA to evaluate environmental surface water samples from Ohio's East Fork Miami Watershed and from the National Rivers and Stream Assessment. CVM will utilize a novel DNA sequencing approach developed in FY 2022 for profiling and analyzing antimicrobial resistance in water samples collected by EPA. Findings from this work will provide a baseline of antimicrobial resistance in surface water.

In August 2023, NARMS released the 2020 Integrated Summary, combining antimicrobial resistance data in bacteria isolated from humans, raw retail meats, and animals at slaughter to examine trends in resistance to the most important antimicrobial agents. NARMS Integrated Summaries are published when both whole genome sequencing and antimicrobial susceptibility testing are completed. Since generating and publishing a summary can be time- and resource-intensive, NARMS makes the most recent data available online through the NARMS Now: Integrated Data tool.

Reviewing Animal Food Ingredients

CVM reviews new animal food ingredients to provide livestock producers access to safe nutritional ingredients to help keep animals healthy, while also ensuring that the meat, milk, and eggs from those animals are safe for people to eat. CVM improved timeliness of pre-market review of multifaceted and innovative new animal food ingredients via Food Additive Petitions (FAPs). From FY 2019 to FY 2023, CVM went from 44 percent of food ingredient reviews on time to 90 percent on time, while moving more reviews through the system. Animals

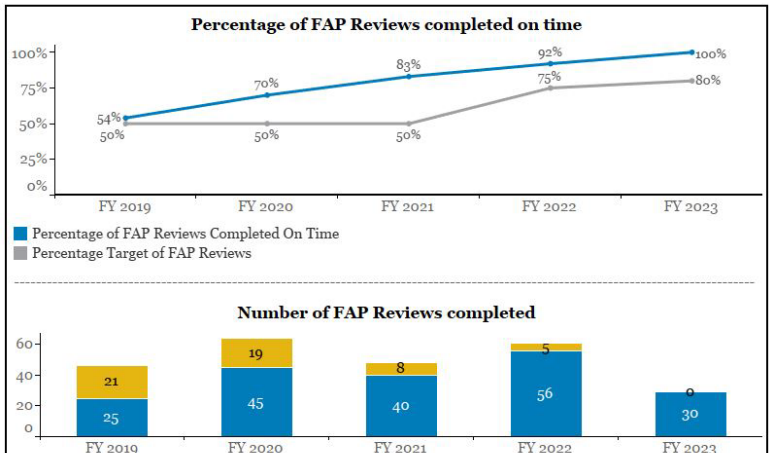

Figure 42 - Percentage of FAP Reviews Completed on Time

generally eat a very limited and defined diet as their sole ration for their entire lifetime, so correct diet formulations and control of contaminants in animal food is critical. Pet owners can also be sure that CVM experts in manufacturing, nutrition, and food safety have evaluated new ingredients added to their pets' food.

The animal food ingredient industry is rapidly evolving. Submissions of innovative new animal food ingredients have become more complex and contain more scientific data for CVM to analyze. For example, CVM approved a food additive petition for an enzyme for use in animal food, fumonisin esterase, breaks down the mycotoxin fumonisin into safe substances. Hot and dry weather, followed by high humidity can lead to growth of the mold that makes fumonisin in corn and other grains. When contaminated grains are fed to animals, the toxin negatively impacts animal health and growth and can pass through into human foods. Fumonisin esterase is produced by a genetically engineered microorganism, and the review of this extremely complex data package required the expertise of molecular biologists, chemists, toxicologists, veterinarians, and animal scientists.

CVM is reviewing its Policy and Procedures Manual, Regulating Animal Foods with Drug Claims, in part to keep pace with innovative uses of substances in food for animals. In October 2022, the Center held a virtual public listening session to gather stakeholder input on how the existing policy could be updated to reflect the evolving scientific knowledge and promote innovation. At this point, the Center believes it will be making changes in policy to allow more uses of ingredients to make food claims, including those that benefit animal production and the environment. In addition, CVM has been working with Congress on new legislative authority that will introduce new approval pathways for novel food ingredients that function in the gut of the animal to affect qualities like feed efficiency, reduced waste output, or reduced pathogens in food products made from animals. CVM is reassessing the way it regulates substances used in animal diets that positively impact animal agriculture to ensure safety, effectiveness, and provide timely access to innovative products to animal producers.

Strengthening Animal Food Safety Oversight

CVM's animal food inspection program was modernized to include a more comprehensive inspection model and a risk-ranked animal food inventory. Intentional and unintentional exposure to improperly formulated, contaminated, mislabeled, or adulterated animal foods can cause illness or death in animals. Each facility receives a comprehensive animal food inspection helping to ensure a holistic, risk-based, and prevention-oriented approach to inspections that better utilizes resources of the Center, ORA, and state inspection partners while ensuring greater inspectional oversight of the animal food industry. This flexible system utilizes additional real-time data from complaints, recalls, and sampling to prioritize facility inspections throughout the year. A risk-based approach prioritizes the safety of humans who consume meat, milk, and eggs from food-producing animals or who handle contaminated animal food, such as pet food, that can result in either the pet or the pet's owner spreading pathogens to humans.

CVM is also continuing to develop policy, including guidance documents, that can help the animal food industry meet regulatory requirements and produce and distribute safe animal food. In FY 2023, CVM published five guidance documents to support domestic and foreign food supplier verification efforts, laboratory accreditation for analysis of foods, and practices to prevent unsafe contamination of animal feed from drug carryover.

Strengthening Domestic Mutual Reliance

FDA continues to support states to evaluate and build animal food inspection infrastructure, while updating inspection and enforcement programs. These investments and ongoing cooperation continuously strengthening the overall safety of the U.S. animal food supply. CVM and ORA continue to support implementation of the FSMA Preventive Controls for Animal Food (PCAF) regulation. In FY 2023, FDA provided funding to 25 states enrolled in the Animal Food Regulatory Program Standards (AFRPS) cooperative agreement, with an additional 15 states electing to use FDA-provided funds to build programs to support implementation of the PCAF in their states. AFRPS provides the tools and resources to enable state regulatory programs to build strong animal food safety infrastructures and systems that complement national standards and promote an integrated food safety system. In June 2023, a revised version of AFRPS was published through a collaboration between FDA, state regulatory partners, and the Association of American Feed Control Officials.

There is an untapped world of state data that could be utilized to influence and impact the national risk profile of animal food facilities and assist in meeting the inspection frequency mandate through mechanisms outside of traditional inspection contract models. CVM and ORA are working with state regulatory partners on a pilot program to enhance methods for data exchange on firm inventory, inspection results, and facility risk-ranking to strengthen the integrated food safety system.

PERFORMANCE

The Animal Drugs and Foods Program's performance measures focus on premarket animal drug application review, significant inspection violations, follow-up inspections conducted, warning letter review, and in-depth case investigations for detection and response, as detailed in the following table.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 +/- FY 2024
243231: Complete review and action on Non-administrative original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year within 180 days. (Output)	FY 2022: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
243232: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year within 240 days. (Output)	FY 2022: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
244204: Complete review and action on warning letters within 25 working days to better safeguard U.S. consumers by alerting firms to identified deviations in order to become compliant. (Output)	FY 2023: 71% Target: 50% (Target Exceeded)	50%	50%	Maintain

Figure 43 - Animal Drugs and Foods Performance Table 1/2

244302: Respond to consumer complaints by initiating in-depth Vet-LIRN investigations. within 30 days of receipt. (Output)	FY 2023: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
214221: Percentage of Human and Animal Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 98.9% Target: 80% (Target Exceeded)	80%	80%	Maintain
224221: Percentage of Human and Animal Drug significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 85.5% Target: 80% (Target Exceeded)	80%	80%	Maintain
214222: Percentage of Human and Animal Food follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 76.0% Target: 65% (Target Exceeded)	65%	65%	Maintain
224222: Percentage of Human and Animal Drug follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 45.7% Target: 55% (Target Not Met)	55%	55%	Maintain

Figure 44 -Animal Drugs and Foods Performance Table 2/2

The following selected items highlight notable results and trends detailed in the performance table.

New Animal Drug Application Review

In FY 2022, CVM exceeded its ADUFA and AGDUFA performance commitments by completing review and action on 100 percent of both non-administrative original NADAs and reactivations, and of non-administrative original ANADAs and reactivations, within the timeframes specified.

Warning Letters

In FY 2023, CVM exceeded the performance target for completing Center recommendations for 50 percent of warning letter package reviews for tissue residue and unapproved drug cases within 25 days. FDA monitors marketed animal drugs to assure their safety and effectiveness as well as food additives and veterinary devices to assure their safety. Warning Letters are issued when firms are found to be in violation of the FD&C Act. Violators are encouraged to take prompt action to correct violations; otherwise, FDA may take additional regulatory action without further notice, including seizure of products and/or injunction.

Vet-LIRN

The Veterinary Laboratory Investigation and Response Network (Vet-LIRN) rapidly responds to consumer complaints related to animal food and drug safety issues. The Network has 48 state

and university veterinary diagnostic laboratories that investigate potential problems with CVM-regulated products and perform diagnostic testing of animal specimens in response to consumer complaints. These laboratories provided pivotal data that led to either manufacturer recalls of contaminated products, or data that helped FDA avoid major expenses for regulatory actions because the investigation results demonstrated that certain products were unlikely to have caused the illnesses.

ORA Field Performance Measures

ORA's performance goals measure topics such as our commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to ORA regulatory impact on violators, and are tracked on a 3-year rolling basis. Due to the nature of regulatory actions and subsequent follow-up conducted by FDA, the duration of these events can vary considerably. After regulatory action, FDA also works to schedule follow-up after a reasonable time has passed to allow the firm to correct for the original violations. A 3-year rolling timeline also ensures tracking of all significant violations that require attention and allows for a more robust analysis.

ORA missed one of its eleven measures, associated with follow-up inspections of Human and Animal Drug firms. This measure is an outcome goal, which depends on the corrective actions made by the firms to bring themselves into compliance, for which ORA has no role or control. Center components may work with firms to provide them guidance and evaluate corrective actions to help enable the firm to achieve compliance. Many violations found at a firm may take significant time and action before compliance can be reached. In some instances, firms do not come into compliance or other issues arise leading to another OAI finding upon re-inspection. While ORA believes this is an important outcome measure to encourage and measure firms' corrective actions, and expects to meet the targets going forward, it is important to recognize that ORA has limited ability to drive compliance, and the ultimate responsibility to comply rests with the firm itself.

Performance Activity Data

Animal Drugs & Foods Program Activity Data (PAD)

CVM Workload and Outputs	FY 2023 Final	FY 2024 CR	FY 2025 PB
New Animal Drug Applications (NADAs) [1]			
Received	9	12	12
Completed	9	11	11
Approved	9	11	11
Pending [2]	13	14	15
New Animal Drug Application Supplements [1,3]			
Received	736	600	600
Completed	711	600	600
Approved	572	525	525
Pending [2]	226	226	226
Abbreviated New Animal Drug Applications (ANADAs) [1]			
Received	24	23	23
Completed	26	23	23
Approved	25	21	21
Pending [2]	0	0	0
Abbreviated New Animal Drug Application Supplements [1,3]			
Received	461	450	450
Completed	474	450	450
Approved	415	375	375
Pending [2]	234	234	234
Investigational New Animal Drug (INAD) Files [4]			
Received	3,053	2,900	2,900
Completed	3,020	2,900	2,900
Pending [2]	350	350	350
Generic Investigational New Animal Drug (JINAD) Files [4]			
Received	809	850	850
Completed	787	850	850
Pending [2]	133	133	133
Food (Animal) Additive Petition Reviews [5] Completed	30	60	70
Investigational Food Additive File Reviews Completed	105	80	90
Adverse Drug Event (ADE) [6]			
ADE Reports Received	92,469	98,000	98,000
Post-Approval ADE Data Reviews	170	180	180

[1] Includes original applications and reactivations. If the application is not approvable, the sponsor

[2] Reflects submissions received during the fiscal year that still require review.

[3] A supplemental application is a sponsor request to change the conditions of the existing approval.

[4] An INAD or JINAD file is established at the request of the sponsor to archive all sponsor

[5] Non-drug substances added to animal feed are considered Food Additive Petitions and require

[6] This measure tracks the number of "Post-approval ADE data reviews" completed each fiscal year.

Figure 45 - Animal Drugs and Foods PAD Table

DEVICES AND RADIOLOGICAL HEALTH

PURPOSE STATEMENT

The modern Devices Program began in 1976, when President Gerald Ford signed the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act to outline a risk-based classification system for devices. The program operates with appropriations and user fees to protect and promote the public health by assuring that U.S. patients and providers have timely and continued access to safe, effective, and high-quality medical devices, including safe radiation-emitting products. This provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products it oversees and helps support the development of new and innovative products to continue to come to market and meet patient needs. The Devices Program facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and provides the assurances patients in the U.S. depend upon.

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Radiation Control for Health & Safety Act (21 U.S.C. 360hh-360ss); Medical Device Amendments of 1976; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Safe Medical Devices Act of 1990; Mammography Quality Standards Act of 1992 (42 U.S.C. 263b); Medical Device Amendments of 1992; Food and Drug Administration Modernization Act of 1997 (FDAMA); Medical Device User Fee and Modernization Act of 2002 (MDUFMA); Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3); Medical Device User Fee Stabilization Act of 2005; Patient Protection and Affordable Care Act of 2010; FDA Amendments Act of 2007 (FDAAA); FDA Safety and Innovation Act of 2012 (FDASIA); FDA Reauthorization Act of 2017 (FDARA) (P.L. 115-52). FDA User Fee Reauthorization Act of 2022 (FDAUFRA) (P.L. 117-180); Consolidated Appropriations Act, 2023 (P.L. 117-328); 21st Century Cures Act (CURES Act) (P.L. 114-255).

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
Devices and Radiological Health	**642,791**	**734,814**	**746,249**	**790,375**	**818,659**	**72,410**
Budget Authority	***408,108***	***419,496***	***449,597***	***444,534***	***465,778***	***16,181***
User Fees	***234,683***	***315,318***	***296,652***	***345,841***	***352,881***	***56,229***
Center	542,939	630,627	637,759	683,710	704,452	66,693
Budget Authority	323,103	331,951	356,362	352,697	366,695	10,333
User Fees	219,836	298,676	281,397	331,013	337,757	56,360
Field	99,852	104,187	108,490	106,665	114,207	5,717
Budget Authority	85,005	87,545	93,235	91,837	99,083	5,848
User Fees	14,847	16,642	15,255	14,828	15,124	-131
FTE	**2,437**	**2,457**	**2,517**	**2,555**	**2,586**	**69**

Figure 46 - Devices Funding History Table

The FY 2025 President's Budget for the Devices Program is $818,659,000 of which $465,778,000 is budget authority and $352,881,000 is user fees. The budget authority increases by $16,181,000 compared to the FY 2023 Final Level; user fees increase by $56,229,000. The Center for Devices and Radiological Health (CDRH) amount in the request is $704,452,000. The Office of Regulatory Affairs amount is $114,207,000.

FDA's focus on both safety and innovation stems from FDA's historic mission to both protect and promote public health by assuring timely patient access to devices that are high-quality, safe, and effective. Innovation in health tech does not simply mean new or novel. It must provide value to patients and consumers. FDA is committed to advancing medical device innovation that can address unmet medical needs to reduce or prevent the adverse health effects from disease, while maintaining FDA's standards. FDA is equally committed to detecting and addressing safety risks earlier, to protect patients from harm and ensure that the Agency remains consistently first among the world's regulatory agencies to identify and act upon safety signals related to medical devices. Both objectives are essential to meeting FDA's public health mission, resulting in more lives saved and improved quality of life.

The FY 2025 Budget enables the Devices Program to continue to make advances in patient safety and in the diagnosing, monitoring, and treatment provided by new devices that patients need, while enhancing safeguards at the same time. This means patients in the U.S. have access to the safe, new, high-quality devices they need to improve and extend their lives, which helps to improve the health care system in the U.S. overall.

The Devices Program continues to see an increasing number of companies choosing to market their devices in the United States first, and FDA continues to see more first in the world approvals here in the United States than in the past. The Devices Program has worked for years to improve the predictability, efficiency, and transparency of FDA regulatory systems so requirements to bring devices to the U.S. market are clear and understood. This ensures that patients ultimately benefit from more safe and effective devices on the market because more companies can understand and meet the FDA's standard. Changes in the Devices Program policies and processes have resulted in an improved medical device pipeline and innovative, safe, and effective technologies.

FDA's success in providing patients with new treatments and diagnostics, and more options for effective health care are due in part to FDA efforts to strengthen the clinical trial enterprise and leverage real world data. The devices program has taken actions to make evidence generation more timely, efficient, and robust. In some cases, FDA is receiving clinical evidence that is more informative and efficiently answering postmarket questions FDA would not have been able to address in the past.

The FY 2025 Budget enables the Devices Program to continue to support such critical advances for patients. By fully and consistently implementing its priorities, along with continuing efforts to transform review and oversight, the Devices Program can realize its vision of U.S. patients having access to high-quality, safe, and effective medical devices of public health importance that meet FDA's standards first in the world.

BUDGET AUTHORITY

FY 2025 President's Budget: Devices and Radiological Health *Budget Authority - Dollars in Thousands*			
	Center	**Field**	**Total**
FY 2023 Final	**356,362**	**93,235**	**449,597**
FY 2025 Budget Authority Changes	**10,333**	**5,848**	**16,181**
Requested Increases	**13,746**	**7,173**	**20,919**
Public Health Employee Pay Costs	12,514	5,008	17,522
Enterprise Transformation	194	55	249
IT Stabilization & Modernization	782	218	1,000
Shortages and Supply Chain-Agency-wide	256	1,892	2,148
Other Adjustments	**(3,413)**	**(1,325)**	**(4,738)**
ORA Transfer to HQ/OGPS	-	(1,936)	(1,936)
FDARA Sec. 905 BA Shift	(5,320)	(63)	(5,383)
FY 2024 Comparability Adjustment	1,655	601	2,256
FY 2025 Comparability Adjustment	252	73	325
FY 2025 Budget Net Total: Devices and Radiological H	**366,695**	**99,083**	**465,778**

Figure 47 - Devices Budget Authority

Total Requested Increases: $20.9 million / 9 FTE

Public Health Employee Pay Costs: +$17.5 million

Center: +$12.5 million

Field: +$5.0 million

The FY 2025 President's Budget includes $114.8 million in new budget authority to fund approximately 72 percent of the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 and FY 2025 Cost of Living Adjustments (COLA). For FY 2025 this assumes a 2.0 percent for Civilian and 4.5 percent Military pay increase for FTE funded through budget authority. Within the Devices program, $17.5 million is provided for pay costs, including $12.5 million for CDRH and $5.0 million for ORA.

Enterprise Transformation: +$249,000 / 2 FTE

Center: +$194,000 / 2 FTE

Field: +$55,000

The FY 2025 President's Budget provides $2.0 million for Enterprise Transformation, which includes $249,000 for the Devices Program to coordinate and lead several crosscutting agency-wide projects to analyze and implement common business processes and data optimization. Benefits of this funding will include improved communication and data sharing across the life cycle of an inspection, increased access to relevant data to facilitate risk-based decision-making, and introduction of more modern mobile technology for field work to improve the user experience. The office also seeks to standardize the FOIA business processes across the Agency and create effective governance to enable successful process and technology changes.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

IT Stabilization & Modernization: +$1.0 million

Center: +$782,000

Field: +$218,000

The FY 2025 President's Budget provides $8.3 million for IT Stabilization & Modernization, including $1.0 million for the Devices Program to further build FDA's centralized enterprise data modernization capabilities and to strengthen FDA's common data infrastructure, data exchange, and IT analytic services, talent, and tools. With these resources, FDA will continue to improve data exchange and underlying technology platforms in support of FDA's programs and mission-critical responsibilities – to better meet the challenges of emerging threats, support needs for real-time evaluation, and more continuously access, analyze, and aggregate multiple sources of information, such as for recalls, adverse events, outbreaks, and pandemics.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

Shortages and Supply Chain: +$2.1 million / 7 FTE

Center: +$256,000

Field: +$1.9 million / 7 FTE

The FY 2025 President's Budget provides $12.3 million for Shortages and Supply Chain, including $2.1 million for the Devices Program to advance FDA's capabilities to help prepare for, build resilience to, and respond to shortages that are supply-driven and/or demand-driven through improved analytics to identify shortage threats and vulnerabilities as well as regulatory approaches to address disruptions and shortages.

USER FEES

Current Law User Fees: +$55.5 million

Center: +$56.1 million

Field: -$613,000

The Devices Program request includes an increase of $55.5 million for user fees, compared to the FY 2023 Final Level, which will allow FDA to fulfil its mission of promoting and protecting the public health by ensuring safety and efficacy of FDA-regulated products.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Devices Program oversees development of new devices that make less-invasive treatments and diagnoses possible and provide new options to patients whose conditions would have been considered untreatable in the past— all while providing the assurances patients depend upon and meeting FDA's standards. The foundation of this program is medical device safety.[71]

[71] *The FDA's standard for product review strives to maximize benefits and minimize risks and significant uncertainties in meeting our principal obligation to make sure that new products are safe and effective.*

There are 255,000 different types of medical devices on the U.S. market, manufactured in more than 27,000 facilities worldwide. FDA's Center for Devices and Radiological Health (CDRH) handles over 20,000 submissions each year, including meeting requests, and it also reviews medical device reports identifying adverse events and device corrections and removals. The Center approves or clears, on average, 13 new or modified devices every business day, authorizes and clears thousands of products for entry into the U.S. market, supports Agency efforts to assess industry compliance with applicable regulation and conducts inspections of domestic and foreign manufacturers. This is all while promoting access, enhancing safety, and advancing innovation. These efforts are critical for the U.S. supply chain, as well as the U.S. health care system as a whole.

The Devices Program is responsible for the regulation and oversight of a wide range of devices that patients and health care providers use every day. These devices range from simple tongue depressors to complex instruments that help save and sustain life, such as heart valves, artificial pancreas, programmable pacemakers with micro-chip technology, MedTech alternatives to opioids, laser surgical devices, and artificial intelligence/machine learning technologies that help with earlier detection of diseases and conditions, among others. Devices also include in vitro diagnostic products, such as next generation sequencing tests, tests for emergent diseases like COVID-19, and complex multivariate assays that help diagnose conditions and help determine which treatments patients should pursue based on their individual genetic makeup. In addition, the Devices Program regulates radiation-emitting electronic products such as X-ray equipment, medical ultrasounds, and MRI machines, as well as monitors mammography facilities to make sure the equipment is safe and properly operated. The Devices Program tailors its oversight of devices according to the degree of risk presented, so it can focus its resources on those products that pose the most risks to patients and assure timely access to devices for U.S. patients.

The Devices Program works with federal partners, health care providers, and regulated industry to mitigate cybersecurity threats from medical devices by encouraging an approach of vigilance, responsiveness, resilience, and recovery. FDA has also been a world leader in harmonizing review and oversight practices to spur development of higher quality devices all over the world. The Agency engages heavily with international counterparts to share information about potential safety concerns with medical devices, and to identify and take action to protect patients and the public health where possible.

Figure 48 - Devices Program Mission & Vision

Vision

The vision of the Devices Program is that patients in the United States have access to high-quality, safe, and effective medical devices of public health importance first in the world. First in the world is not about a competition between countries, but rather a measure of timely patient access.

To achieve this vision, the Devices Program advances innovation of safe, effective, and high-quality medical devices to meet patient needs, and consistently works to protect patients and enhance safety. We are equally committed to advancing safe and effective devices that can address unmet medical needs to reduce the health effects from disease. Both objectives are essential to meeting our public health mission, resulting in more lives saved and improved quality of life.

The Devices Program's recent accomplishments demonstrate this ongoing commitment to improving the safety and quality of life for patients:

- Our commitment to fostering innovation in the medical device industry remained strong in 2023, as we continued to see high numbers of novel medical device authorizations. In fact, this was a banner year for the Center, authorizing 84 novel devices— the second highest- number of devices on record in CDRH's 40-year history.
- CDRH's Breakthrough Devices Program continued to help increase access to innovative, high-quality medical devices, granting Breakthrough Device designation to over 140 devices and granting marketing authorization to 28 Breakthrough Devices in FY 2023. Since the launch of the Breakthrough Devices Program, the agency has granted Breakthrough status to over 865 devices, including devices originally designated under the Expedited Access Pathway program that started in 2015.
- The Center reduced the median time it takes to approve an Investigational Device Exemption (IDE) application by more than 1 year, from 442 days in FY 2011 to 30 days in FY 2015 and has remained at 30 days each subsequent year to date.
- The Early Feasibility Studies Program, in which devices are evaluated early in development, continues to be used across device areas, with 41 studies approved in FY 2022 which represents a doubling in growth since the program began.
- Conducted timely review of more than 3 million medical device adverse event reports received in FY 2023 and completed other pivotal work activities such as addressing supply chain shortages and counterfeit devices related to COVID-19.

The Device Program's success provides patients with new options for effective healthcare. In some cases, we receive clinical data quicker and more efficiently. By strengthening our clinical trial enterprise and leveraging real world data, we can answer post-market questions we would have been unable to address easily in the past.

As evidence of FDA's continued efforts to make the requirements for meeting U.S. marketing standards clearer, devices are being introduced to the market more quickly. An increasing number of companies are bringing their technologies to the U.S. to market first before they do so in other countries, and more products that go through the Devices Program's premarket process are being approved, cleared, and authorized for marketing. The increase in cleared, approved, and authorized medical devices that meet FDA's high standards provides patients more options

to improve and extend their lives than they have had in the past. This work has helped to reduce the time and cost of the total product life cycle of medical devices that meet FDA's standard. Ultimately, CDRH's efforts better serve the needs of patients, who are at the heart of everything the Devices Program does.

Breakthrough Devices Program

FDA's Breakthrough Devices Program has delivered important advancements for patients since its establishment in 2016 by the 21st Century Cures Act. This program is intended to provide patients and health care providers with timely access to medical devices by speeding up development, assessment, and review for premarket approval, 510(k) clearance, and De Novo marketing authorization. Breakthrough Devices must meet the FDA's standards for device safety and effectiveness to be authorized for marketing. The Breakthrough Devices Program reflects our commitment to device innovation and protecting the public health.

In FY 2023, FDA has granted over 140 Breakthrough Device designations bringing the total to over 865 designated Breakthrough Devices since the launch of the program. Importantly, more than 50 percent of companies receiving Breakthrough Device designations are either small or start-up companies (i.e., less than $1M in annual sales). Sponsors of designated Breakthrough Devices continue to benefit from the features of the program, including the ability to receive feedback from FDA more quickly and collaboratively. This can help them to move forward with device development decisions sooner while having more confidence in the data they plan to collect. Devices coming through the Breakthrough Devices Program represent a pipeline of innovations that will improve and extend patient lives in the years to come.

Additionally, in FY 2023, FDA cleared a software that analyzes echocardiograms using a fully automated machine-learning algorithm to estimate the likelihood that the patient has heart failure with preserved ejection fraction. FDA also approved a first-of-a-kind dual chamber leadless pacemaker that enables wireless implant-to-implant communication and synchronization between the atrial and ventricular leadless pacemakers.

Cybersecurity

The Devices Program's goal for medical device cybersecurity is to encourage a coordinated approach of vigilance, responsiveness, resilience, and recovery that fits FDA's culture of continuous quality improvement. This means taking a total product lifecycle approach, starting at the product design phase, where manufacturers are now required by law to demonstrate reasonable assurance of cybersecurity for certain types of devices and their related systems ("cyber devices"), as well as part of general safety and effectiveness for other devices, as part of premarket submissions. This demonstration includes building in security to help mitigate potential risks, followed by having a plan in place for managing any risks that might emerge, and planning for how to reduce the likelihood of future risks.

FDA was granted explicit cybersecurity regulatory authorities for certain types of medical devices as part of the Consolidated Appropriations Act of 2023, which the agency is working to implement. The medical device cybersecurity program also received $5.0M in funding from Congress in FY 2023, which is critical to FDA's ongoing work to support the resiliency of medical devices in the U.S. health care system, including support for the broader USG, which depends on FDA's review of devices for safety and effectiveness.

FDA has published guidance documents that contain recommendations for comprehensive management of medical device cybersecurity risks throughout the total product life cycle. This includes closely monitoring devices already on the market for cybersecurity issues. To enable more expedient actions, the Devices Program's overall approach incentivizes industry to make changes to marketed and distributed medical devices to reduce risk.

FDA is taking steps to help build on the work that the Devices Program and FDA stakeholders have already achieved that include:

- Implementing the explicit cybersecurity regulatory authorities granted by the Consolidated Appropriations Act of 2023, including through FAQs, industry engagements, and a planned guidance.
- Updating the premarket guidance on medical device cybersecurity to better protect against moderate risks, such as ransomware campaigns that could disrupt clinical operations and delay patient care, and major risks such as exploiting a vulnerability that enables a remote, multi-patient, catastrophic incident. The guidance was finalized on September 27, 2023.
- Developing sector resources related to legacy risk management and software bill of materials data normalization via a contractor. The legacy risk management resource will be published in November 2023.
- Develop a sector resource related to threat modeling for remote care delivery via medical devices, via a contractor.
- Co-leading multiple task groups within the recognized healthcare public-private partnership, the Health Sector Coordinating Council, related to device cybersecurity best practices, managing legacy cyber risk, vulnerability communications, manufacturing cybersecurity, and the sector's five-year plan.
- Providing subject matter expertise to the Cybersecurity and Infrastructure Security Agency (CISA) on various efforts, including baseline cybersecurity performance goals for critical infrastructure, newly passed mandatory cybersecurity incident critical infrastructure reporting requirements, and individual medical device cybersecurity vulnerabilities.

Exploitation of medical device cybersecurity vulnerabilities can lead to adverse impacts on patient care and patient safety. Cybersecurity incidents also have the potential to cause domestic supply chain disruptions, which could be particularly devastating in the case of a natural disaster or public health emergency when supplies are limited. The FDA plays an important role in ensuring the safety and effectiveness (including cybersecurity) of medical devices in the face of potential cyber threats and working closely with our U.S. government partners and the entire ecosystem – industry, patients and health care providers and facilities – to mitigate cybersecurity risks.

Digital Health Center of Excellence

The Digital Health Center of Excellence (DHCoE) provides centralized expertise and serves as a resource for digital health technologies and policy for digital health innovators, the public, and FDA staff. The DHCoE is primarily focused on helping both internal and external stakeholders achieve their goals of getting high quality digital health technologies to patients by providing technological advice, coordinating and supporting work being done across the FDA, advancing best practices, and reimagining digital health device oversight. In 2023, the DHCoE responded to

more than 900 inquiries. It also aids developers through CDRH's pre-submission program and its device determination program.

Following the authorization of Food and Drug Omnibus Reform Act of 2022 (FDORA), which granted new authorities for the review of predetermined change control plans for devices, the DHCoE issued draft guidance on Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions in April 2023. In addition, in June 2023, the DHCoE completed a public commitment to issue final guidance on the Content of Premarket Submissions for Device Software Functions. The DHCoE also collaborated across the agency on the discussion paper, "Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products."

The DHCoE is focused in multiple areas including artificial intelligence (AI) and machine learning (ML). Artificial intelligence and machine learning technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. The DHCoE partnered with international regulators to issue "Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles" with our partners from Health Canada and the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA), which draws upon existing guiding principles around Good Machine Learning Practices. In addition, the DHCoE updated a list of FDA-authorized AI/ML-enabled medical devices, which includes nearly 700 authorized devices, as well as a list of FDA-authorized devices that incorporate Augmented Reality/Virtual Reality (AR/VR). These lists serve as resources to the public about these devices and the FDA's work in this area. The DHCoE also released two new AR/VR Infographics to help patients better understand and discuss with their provider the use of medical extended reality (XR), including AR and VR technology, and to assist clinicians decide whether to use medical XR in their practice or outside non-clinical settings such as at home.

The DHCoE continues to develop training for internal and external stakeholders including partnering with the Patient Science and Engagement program in clarifying device pathways for digital health stakeholders. Externally, the DHCoE is a member of multiple collaborative communities focused on AI/ML and wearable technology and involved in multiple MDIC work streams related to MXR and software. The DHCoE is engaged in multiple regulatory science research projects related to AI/ML transparency and bias, real world performance of DHTs, and AR/VR.

Patient Science & Engagement

The Patient Science and Engagement Program for medical devices is committed to engaging with patients, understanding their experiences, and proactively integrating patient perspectives into medical device decisions and regulatory activities where appropriate. FDA has created forward-leaning mechanisms to facilitate patient involvement in regulatory activities as well as fostered innovative approaches to supporting the science of patient input. By collaborating with patients, the research community, and industry, the Devices Program has fostered the creation of well-defined outcome measures and assessments of patient preference information that directly impact medical device decisions.

The Devices Program is at the forefront in describing ways that structured collection of patient preference information can be used as scientific evidence in the evaluation of medical products.

In FY 2023, there were three Medical Devices Advisory Committee Meetings which include patient preference information. On April 6, 2023, FDA posted a web notice seeking early feedback on a list of questions FDA is considering to add and address in the future revision of the Patient Preference Information – Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Device Labeling guidance. In addition, patient-reported outcomes have been included in more than 50 percent of medical device submissions with clinical studies. To facilitate greater inclusion of patient experience data in medical device submissions, FDA issued draft guidance on incorporating assessments to obtain such data. This guidance is the fourth in a series of four methodological guidance documents that describe how stakeholders (patients, caregivers, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making.

The Devices Program launched the Patient Science Topic Area within the Center's Focal Point Program in June 2023, an internal program to support quality and consistency of regulatory review of patient perspective information. Additionally, on September 13, 2023, CDRH held a patient engagement town hall on At-Home Use of Medical Technologies by the Rare Disease Community to provide insight to more than 300 CDRH staff on the role home use devices play in helping patients and caregivers manage their conditions outside of a professional health care facility.

The Devices Program established the first advisory committee comprised solely of patient and family caregiver representatives – the Patient Engagement Advisory Committee (PEAC) – to inform FDA actions. On September 6, 2023, the Committee discussed and made recommendations on the topic of "Advancing Health Equity in Medical Devices."

In FY 2023, CDRH held several co-sponsored, high-profile, public workshops that incorporated patients' perspectives, including two workshops on Medical Devices for Opioid Use, one on Expediting Innovation of Bioelectronic Implant for Vision Restoration, and one on Patient-Reported Outcomes and Vision Related Quality of Life Questionnaire.

The Devices Program is also active in collaborative projects to advance patient science. In FY 2023, CDRH published work directed at exploring opportunities to improve a patient reported outcome measure used in the evaluation of medical devices that would treat symptomatic heart failure and support the advancement of health equity. In addition, scientific articles were published related to CDRH supported patient preference information studies that may inform several high-impact medical device areas, including artificial intelligence/machine learning devices, devices for the surgical treatment of uterine fibroids, and devices to treat heart failure.

Coronavirus (COVID-19)

FDA's work to support access to devices for the COVID-19 response began in January 2020 and continues today as vast numbers of devices marketed under emergency use or various COVID-19 enforcement policies are transitioning to post pandemic status, including full marketing authorization through traditional pathways.

Since 2020, FDA has issued EUAs or granted full marketing authorization to more than 3,200 medical devices for COVID-19 related uses. The FDA rigorously monitored safety signals and medical device reports using the information to publish 21 letters to health care providers and 7

safety communications, and FDA completed other pivotal work activities such as addressing supply chain shortages and counterfeit products related to COVID-19.

The Devices Program continues to prioritize supporting development of at-home tests, balancing speed with safety to ensure they are appropriately accurate and reliable as supported by valid scientific evidence. The Devices Program has authorized 41 over-the-counter (OTC) at-home tests, resulting in hundreds of millions of additional OTC tests available monthly to American consumers.

The Devices Program published two final guidance documents[72] on March 27, 2023, and held a public webinar.[73] The Devices Program also held a public webinar in April 2023, to help device manufacturers of EUA-authorized devices or devices marketed under enforcement policies during the COVID-19 pandemic. These guidance documents provided clarification and guidance on the disposition of these devices after the pandemic and EUA declaration ends and how these devices can obtain full marketing authorization through FDA's traditional pathways. As of October 2023, 41 devices have transitioned to traditional marketing authorization including 15 tests. The Devices Program works closely with these manufacturers, some of whom are not familiar with these marketing pathways or US regulatory processes in general as their first experience was the EUA.

Resilient Supply Chain Program

The Devices Program is working within its resources and limited authorities to develop a proactive approach to promoting medical device supply chain resiliency and preventing shortages that most often impact our vulnerable populations. Since the beginning of the COVID-19 PHE, FDA has received over 450 shortage signals encompassing thousands of medical devices. The Devices Program subsequently implemented or informed mitigations for approximately 350 of the 455 signals. These actions helped reduce the impacts from shortages and helped promote the availability of safe and effective medical devices for patients and our most vulnerable populations.

In FY 2023, the Devices Program continued to make significant strides towards developing the foundation, processes, and procedures for the Resilient Supply Chain Program (RSCP). In FY 2023, RSCP hired permanent and term employees with the expertise in data science, supply chain, and medical devices. In addition, the RSCP established and implemented a cloud-based supply chain analytics and modeling capability that integrates both internal and external data sources and that supports predictive modeling and supply chain analysis. This capability supports the Centers efforts to predict supply chain disruptions and vulnerabilities thereby enhancing our ability to prevent shortages and promote the availability of safe and effective medical devices. The Center actively leads and participates in inter-governmental working groups to address and strengthen supply chains for medical devices. In addition, we routinely perform extensive outreach with a broad spectrum of medical device stakeholders to include but not limited to patients, healthcare systems, health care providers, distributors, manufacturers, and group purchasing organizations. The RSCP continues to work with stakeholders to explore novel

[72] Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency | FDA

[73] https://www.youtube.com/watch?v=ux3IEMewEzE

vehicles such as a public private partnership for enhancing transparency and communication on medical device supply chains.

Case for Quality

The Devices Program has been advancing manufacturing and product quality through its Voluntary Improvement Program (VIP). The program has resulted in increased production and access to higher quality medical devices for patients, decreases in safety issues, and lower production costs, which increases value to industry, patients, providers, payors, and FDA.

Participating manufacturing sites have also demonstrated product quality improvements in the safety and quality of devices for patients, such as 19 percent reduction in process defects, 76 percent reduction in medical device reports, and 48 percent reduction in recalls and field actions since enrollment in the VIP program. The Device Program offers opportunities for participants in VIP, which include modified formats for certain manufacturing submissions and an accelerated review target. To date, the Devices Program has received more than 1,500 modified submissions for manufacturing changes as part of the program which demonstrate a higher rate of manufacturing improvements, new equipment investment, and process optimizations implemented by participating manufacturing sites. Manufacturing sites participating in the program have reported 60 percent faster FDA review of manufacturing changes, 90 percent faster review of manufacturing site transfers, and an 80 percent reduction in paperwork using the streamlined submission templates. Program participants have also shared that at least 15 percent of the submissions have significant cost-savings or direct value that were realized sooner through the accelerated reviews of the program.

On September 15, 2023, FDA published final guidance, "Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program," detailing the Devices Program's policy for participation in the VIP.

On May 2, 2023, the Devices Program, in collaboration with the Medical Device Innovation Consortium (MDIC) published the final white paper on the Corrective and Preventive Action (CAPA) Process Improvement pilot. The MDIC framework showed marked improvements in associated quality management system processes such as trending and risk management, as well as a significant increase in early issue identification and resolution which prevents potential quality or safety defects in the field. Participants implementing the framework reported significant resource savings, were allocate their engineering resources to more impactful and proactive efforts.

Advanced Manufacturing Clearinghouse

The Devices Program has developed an Advanced Manufacturing Clearinghouse (AMCH),[74] which will provide a collaborative and independent third party that identifies and evaluates promising advanced manufacturing technologies used in the medical device or other industries. The clearinghouse will provide non-confidential information about these technologies and strategies for successful implementation. It will also publish assessments of the technology to industry and government to promote and facilitate adoption of more effective and efficient means of manufacturing. Over time, this would enable the adoption of advanced methods and

[74] Advanced Manufacturing Clearing House - MDIC

technologies in U.S. manufacturing to increase production capacity, improve quality, and reduce costs.

The AMCH was launched on May 18, 2023, with a live webinar[75] and an online portal[76] for the intake and evaluation of industry proposals for evaluation. The AMCH has selected and initiated technology implementation which includes deep learning artificial intelligence, digitally integrated control of critical manufacturing processes between the manufacturer and key supplier, establish a digital regulatory portal, and implementation of a connected digital data model and technology for more effective risk management and new product development.

The Devices Program has established an ongoing collaboration with the FDA's Office of Counterterrorism and Emerging Threats (OCET) to establish the Smart Design and Manufacturing Pilot[77] as part of the Innovative Technologies and Advanced Manufacturing Hub (I-TEAM Hub).[78] The pilot uses the ventilator digital twin work and simulated use cases developed by the Devices Program as the foundation to demonstrate the use of digital design, digital manufacturing, and digital management can improve medical device quality, manufacturing, and responsiveness to public health emergencies.

Mammography Quality Standards Act Program

FDA's mammography program—authorized by the Mammography Quality Standards Act (MQSA)—helps to ensure that all women in the United States have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. The program also ensures that patients receive their mammogram results within 30 days and in plain language that they can understand. In July 2023, there are 8,790 MQSA-certified facilities, helping to provide over 39 million mammography procedures for U.S. patients. As part of the mammography program, FDA and its State partners annually inspect certified mammography facilities in the U.S. to ensure compliance with national quality standards for mammography. To support the annual inspections, an additional 18 inspectors from 16 states were trained in FY 2023. In the current inspection cycle, 86.7 percent of mammography facilities had no serious violations and less than one percent of facilities were cited with the most serious violations.

In FY 2023, FDA published updates to the mammography regulations to, among other things, require mammography facilities to notify patients about the density of their breasts, strengthen the FDA's oversight and enforcement of facilities, and help interpreting physicians better categorize and assess mammograms. An extensive outreach effort is ongoing to familiarize facilities and patients with the amended regulations in advance of their implementation at the end of FY 2024.

[75] MDIC Live with MDIC's Advanced Manufacturing Initiative - YouTube

[76] MDIC (Medical Device Innovation Consortium) - (secure-platform.com)

[77] Smart Design and Manufacturing Pilot | FDA

[78] Innovative Technologies and Advanced Manufacturing Hub (I-TEAM Hub) | FDA

Radiological Health Program

The Radiological Health Program protects public health and safety by monitoring industry's compliance with regulatory performance standards to minimize the emissions of and the exposure of people to unnecessary electronic product radiation.

In FY 2023, FDA finalized and implemented amendments to its regulations to better align its medical device and radiological health programs by reducing overlapping requirements. Concurrently, FDA modernized its field compliance framework by updating Compliance Program Guide Manuals for Inspection and Field Testing of Radiation-Emitting Electronic Products and for Compliance Testing of Electronic Products at FDA laboratories. In FY 2023, the program took actions to stop the sale of unsafe Ultraviolet-C germicidal wands that were found to emit hazardous levels of radiation through undercover purchasing of product, conducting laboratory analysis, and pursuing regulatory action against manufacturers along with issuing public safety messaging advising consumers to not use the unsafe products.

The Devices Program, in collaboration with the Radiological Health Program, also continues to collaborate with the medical imaging industry and radiological professional societies to address the safety of all diagnostic imaging modalities. The programs actively seek to address safety issues and incorporate internationally accepted performance requirements and testing methods to enhance product safety through standards. The programs actively collaborate with stakeholders to promote best practices for the clinical selection and use of advanced imaging technologies. For example, in FY 2023, the National Council on Radiation Protection and Measurements, with FDA participation, published: "Commentary No. 33 -- Recommendations for Stratification of Equipment Use and Radiation Safety Training for Fluoroscopy," which provides recommendations for appropriate equipment selection and staff training for different types of fluoroscopy procedures. FDA actively engages with the Conference of Radiation Control Program Directors in a unique federal-state partnership on a number of training and outreach activities to assure that radiation exposure to individuals is kept to the lowest practical level, while not restricting its beneficial uses.

PERFORMANCE

The Devices Program's performance measures focus on premarket device review, postmarket safety, compliance, regulatory science, and Mammography Quality Standards activities which assure the safety and effectiveness of medical devices and radiological products marketed in the United States, as detailed in the following table.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 +/- FY 2024
253233: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 days. (Outcome)	FY 2021: 73.9% Target: 90% (Target Not Met)	90%	90%	Maintain
253234: Percentage of 180-day PMA supplements reviewed and decided upon within 180 days. (Outcome)	FY 2020: 97.0% Target: 95% (Target Exceeded)	95%	95%	Maintain
253235: Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 days. (Outcome)	FY 2020: 95.4% Target: 95% (Target Exceeded)	95%	95%	Maintain
253208: Percentage of De Novo requests (petitions to classify novel devices of low to moderate risk) reviewed and classified within 150 days. (Output)	FY 2020: 62.5% Target: 60% (Target Exceeded)	70%	70%	Maintain
253221: Percentage of Bioresearch Monitoring (BIMO) follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 100.0% Target: 65% (Target Exceeded)	65%	65%	Maintain

Figure 49 - Devices and Radiological Health Performance Table 1/2

252223: Percent of total received High Priority MDRs (Code Blue and Death adverse events) reviewed within 10 days during the year. (Output)	FY 2022: 81.4% Target: 82% (Target Not Met)	88%	90%	2.00%
254203: Percentage of time CDRH meets the targeted deadlines for on-time recall classification (Output)	FY 2023: 98% Target: 85% (Target Exceeded)	85%	85%	Maintain
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. (Output)	FY 2023: 2,150 Target: 2,000 (Target Exceeded)	1,500	1,500	Maintain
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (Outcome)	FY 2023: 98.9% Target: 97% (Target Exceeded)	97%	97%	Maintain
254221: Percentage of Medical Device and Radiological Health significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 87.3% Target: 80% (Target Exceeded)	80%	80%	Maintain
254222: Percentage of Medical Device and Radiological Health follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 73.3% Target: 65% (Target Exceeded)	65%	65%	Maintain

Figure 50 - Devices and Radiological Health Performance Table 2/2

The following selected items highlight notable results and trends detailed in the performance table.

Premarket Device Review

FDA is committed to protecting and promoting public health by providing timely access to safe and effective medical devices. The unprecedented COVID-19 public health emergency from FY 2020 through FY 2022 has impacted CDRH's ability to meet the FY 2021 PMA Original and Panel Track Supplement goal. Throughout FY 2020 to FY 2022, FDA prioritized its COVID-19 related work to address the ongoing public health need for safe and effective medical devices. In FY 2021, the primary circumstance contributing to submissions missing a MDUFA goal was the continued shift in priorities to prioritize the review of EUAs and other activities to respond to the COVID-19 pandemic. This shifting of resources to address the unprecedented volume of EUA submissions and other aspects of the response to COVID-19 significantly impacted FDA's ability to meet MDUFA review goals. At this time, FDA's focus shifted to completion of overdue MDUFA IV submissions as well as a focus on meeting MDUFA V goals. FDA has

reduced the volume of overdue MDUFA IV submissions by over 50 percent. Meeting all MDUFA commitments remains our goal and we are taking critical steps to improve performance, where possible, relative to the FY 2021 cohort.

The number of technical reviews of new applications and data supporting requests for premarket approvals target has been reduced by 25 percent from FY 2023 targets in FY 2024 and FY 2025 based on increased efficiency in the premarket review processes including, for example, the focal point program which reduces unnecessary reviews.

High Priority MDR Review

This goal previously only included Code Blue MDR reports, which represent the most serious adverse events received. Starting in FY 2023, we are also including death adverse events in this goal since those are critical/high priority reports as well and reviewed with the same priority as Code Blues. The Agency plans to review at least 88 percent of all high priority MDRs within 10 calendar days of receipt in FY 2024 and will increase to 90 percent in FY 2025.

For FY 2022, this performance was measured at 81.4 percent, just shy of the 82 percent expected goal. For FY 2022, CDRH was transitioning to this new High Priority performance goal, from Code Blue MDRs only. This transitioned to all HP MDRs, which included additional MDRs into this performance measure. Additionally, with this new expectation for staff, process and system enhancements were created, accompanied by training, to support staff's new expectation. With these process and system enhancements to support this expectation, CDRH expects this goal to be met for FY 2023 and beyond.

ORA Field Performance Measures

ORA's performance goals measure topics such as our commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to ORA regulatory impact on violators, and are tracked on a 3-year rolling basis. Due to the nature of regulatory actions and subsequent follow-up conducted by FDA, the duration of these events can vary considerably. After regulatory action, FDA also works to schedule follow-up after a reasonable time has passed to allow the firm to correct for the original violations. A 3-year rolling timeline also ensures tracking of all significant violations that require attention and allows for a more robust analysis.

PROGRAM ACTIVITY DATA

Devices and Radiological Health Program Activity Data (PAD)			
CDRH Workload and Outputs	**FY 2023 Final**	**FY 2024 CR**	**FY 2025 PB**
Original PMAs and Panel-Track Supplements (without Advisory Committee input)			
Workload [1]	74	64	64
Total Decisions [2]	68	60	60
Approved [3]	38	40	39
Original PMAs and Panel-Track Supplements (with Advisory Committee input)			
Workload	5	4	4
Total Decisions [2]	-	2	2
Approved	-	2	2
Modular PMAs			
Workload	83	82	82
Actions [4]	99	85	85
180-day PMA Supplements			
Workload	172	171	171
Total Decisions [5]	165	157	157
Approved	143	142	142
Real Time PMA Supplements			
Workload	243	265	265
Total Decisions [6]	246	272	272
Approved	236	261	261
510(k) Premarket Notifications			
Workload	4,564	4,541	4,541
Total Decisions [7] (SE & NSE)	3,974	3,998	3,998
Cleared [9] (SE)	3,763	3,776	3,776
Humanitarian Device Exemptions (HDE)			
Workload	4	4	4
Total Decisions [2]	4	3	3
Approved	2	2	2

Figure 51 - CDRH Workload and Outputs 1/2

Investigational Device Exemptions (IDE)			
Workload	367	369	369
Total Decisions [8]	358	361	361
Approved	203	206	206
Investigational Device Exemption Supplements			
Workload	1,919	1,920	1,920
Closures [10]	1,845	1,847	1,847
Pre-Submissions			
Workload	3,910	4,367	4,587
Closures [11]	3,839	4,306	4,516
De Novo			
Workload	97	92	92
Total Decisions [14]	112	122	122
Granted	44	48	48
Standards			
Total Standards Recognized for Application Review	1,494	1,510	1,530
Medical Device Reports (MDRs) [12]			
Reports Received	3,345,683	3,880,992	4,501,951
Analysis Consults [13]	566	577	577

[1] Workload' includes applications received and filed. (Receipt Cohort)

[2] Total Decisions' include approval, approvable, approvable pending GMP inspection, not approvable, withdrawal, and denial - regardless of the fiscal year received. (Decision Cohort)

[3] Approved' includes applications approved regardless of the fiscal year received. (Decision Cohort)

[4] Actions' include accepting the module, request for additional information, receipt of the PMA, and withdrawal of the module. (Decision Cohort)

[5] Total Decisions' include approval, approvable, approvable pending GMP inspection, and not approvable.

[6] Total Decisions' include approval, approvable, and not approvable. (Decision Cohort)

[7] Total Decisions' include substantially equivalent (SE) or not substantially equivalent (NSE). (Decision Cohort)

[8] Total Decisions' include approval, approval with conditions, disapproved, withdrawal, or other decisions. (Decision Cohort)

[9] Cleared' includes substantially equivalent decisions (SE). (Decision Cohort)

[10] Closures' include approval, approval with conditions, disapproved, acknowledge, withdrawal, or other decisions. (Decision Cohort)

[11] Closures' include a meeting with Industry, deficiency, or other. (Decision Cohort)

[12] MDRs' include initial and supplemental individual and summary Medical Device Reports.

[13] Analysis Consults' include analysis of individual and summary Medical Device Reports (analyzing trends and

[14] Total Decisions include granted, declined, and withdrawal – regardless of the fiscal year received. (Decision Cohort)

Figure 52 - CDRH Workload and Outputs 2/2

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

PURPOSE STATEMENT

The National Center for Toxicological Research (NCTR) was established in 1971. As a national scientific resource, NCTR conducts peer-reviewed research to support FDA's strategic priorities to advance regulatory science and engage globally to encourage the implementation of science-based standards. In support of FDA, NCTR enhances FDA's basis for science-based regulatory decision making by conducting collaborative research to:

- Expedite the translation of laboratory findings to clinical and regulatory applications.
- Assess novel toxicological testing strategies to assist the FDA in expediting the regulatory decision-making process, minimizing the need for animal studies.
- Provide strategies to reduce and rapidly detect contaminants in FDA-regulated products.
- Identify adverse effects earlier in product development.

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b) (1)); Food and Drug Administration Modernization Act; Food and Drug Administration Amendments Act of 2007; FDA Food Safety Modernization Act (P.L. 111-353); Modernization of Cosmetics Regulation Act of 2022

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
National Center for Toxicological Research (Budget Authority)	66,634	70,482	76,919	77,505	80,590	3,671
FTE	308	305	286	286	286	---

Figure 53 - NCTR Funding History Table

The FY 2025 President's Budget for the National Center for Toxicological Research (NCTR) is $80,590,000 of which is all budget authority. The budget authority increases by $3,671,000 compared to the FY 2023 Final Level. The FY 2025 Budget will allow NCTR to continue research to support emerging technologies and toxicology assessments required by FDA and maintain the scope of NCTR's collaborative research in support of FDA product centers. Specifically, NCTR will continue to:

- Accelerate FDA's capability to manage and analyze research and regulatory data using bioinformatics and artificial intelligence (AI).
- Minimize the need for animal studies by validating and advancing the use of alternative models by assessing emerging toxicological testing strategies.
- Support the FDA Predictive Toxicology Roadmap (FDA PTR) and Advancing Alternative Methods.
- Showcase One Health through antimicrobial resistance (AMR) research.
- Support the Center for Drug Evaluation and Research (CDER) in evaluating drug compounding procedures to ensure safe and effective compounded drug products.
- Provide the FDA product centers with the timely and definitive toxicity assessments required for informed public-health decisions on substances such as cannabis-derived products, including cannabidiol (CBD), and opioids.
- Address the unmet needs of minority and at-risk populations.

- Provide data surrounding understudied populations such as minorities, pregnant women, neonates, and children.

This research performed at NCTR is collaborative with scientists from around the world in government, academia, and industry so that partners can exchange views on how to develop, apply, and implement innovative methodologies relative to regulatory assessments. Investments in these areas in recent years have enhanced the capabilities and expertise within the FDA that enable the capitalization of global scientific advancements and expansion of FDA's regulatory-science capacity, ultimately benefiting the American public. These funds will allow such efforts to continue and provide programs and associated projects the opportunity to develop.

BUDGET AUTHORITY

FY 2025 President's Budget: NCTR *Budget Authority - Dollars in Thousands*	
	Total
FY 2023 Final	**76,919**
FY 2025 Budget Authority Changes	**3,671**
Requested Increases	**3,132**
Public Health Employee Pay Costs	2,891
Enterprise Transformation	39
IT Stabilization & Modernization	150
Shortages and Supply Chain-Agency-wide	52
Other Adjustments	**539**
FY 2024 Comparability Adjustment	586
FY 2025 Comparability Adjustment	(47)
FY 2025 Budget Net Total: NCTR	**80,590**

Figure 54 - NCTR Budget Authority

Total Requested Increases: $3.1 million

Public Health Employee Pay Costs: +$2.9 million

Center: +$2.9 million

The FY 2025 President's Budget includes $114.8 million in new budget authority to fund approximately 72 percent of the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 and FY 2025 Cost of Living Adjustments (COLA). For FY 2025 this assumes a 2.0 percent for Civilian and 4.5 percent Military pay increase for FTE funded through budget authority. Within the NCTR program, $2.9 million is provided for pay costs.

Enterprise Transformation: +$39,000

Center: +$39,000

The FY 2025 President's Budget provides $2.0 million for Enterprise of Transformation, which includes $39,000 for NCTR to coordinate and lead several crosscutting agency-wide projects to analyze and implement common business processes and data optimization. Benefits of this funding will include improved communication and data sharing across the life cycle of an

inspection, increased access to relevant data to facilitate risk-based decision-making, and introduction of more modern mobile technology for field work to improve the user experience. The office also seeks to standardize the FOIA business processes across the Agency and create effective governance to enable successful process and technology changes.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

IT Stabilization & Modernization: +$150,000

Center: +$150,000

The FY 2025 President's Budget provides $8.3 million for IT Stabilization & Modernization, including $150,000 for NCTR to further build FDA's centralized enterprise data modernization capabilities and to strengthen FDA's common data infrastructure, data exchange, and IT analytic services, talent, and tools. With these resources, FDA will continue to improve data exchange and underlying technology platforms in support of FDA's programs and mission-critical responsibilities – to better meet the challenges of emerging threats, support needs for real-time evaluation, and more continuously access, analyze, and aggregate multiple sources of information, such as for recalls, adverse events, outbreaks, and pandemics.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

Shortages and Supply Chain: +$52,000

Center: +$52,000

The FY 2025 President's Budget provides $12.3 million for Shortages and Supply Chain, including $52,000 for NCTR to advance FDA's capabilities to help prepare for, build resilience to, and respond to shortages that are either supply-driven, demand-driven, or both through improved analytics to identify shortage threats and vulnerabilities as well as regulatory approaches to address disruptions and shortages.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The accomplishments and planned research in the following narrative exemplify NCTR's support of the emerging priorities of the FDA Product Centers, particularly the Focus Areas of Regulatory Science.[79] NCTR, within FDA's Office of the Chief Scientist, generates research data to help FDA make better-informed regulatory decisions by ensuring the safety and efficacy of FDA-regulated products, thus promoting public health. At the beginning of FY 2024, 69 percent of NCTR's ongoing protocols were collaborative in nature. The remaining 31 percent are NCTR-led projects that support the agency's regulatory mission. The adjacent figure represents the percentage of NCTR's collaborative work that is attributed to specific research entities. This figure highlights the supportive role NCTR provides to FDA and other federal agencies. The following paragraphs represent only a small subset of completed and upcoming regulatory science research at NCTR. The section headers below indicate NCTR research focus areas and other areas of interest to the American public and FDA.

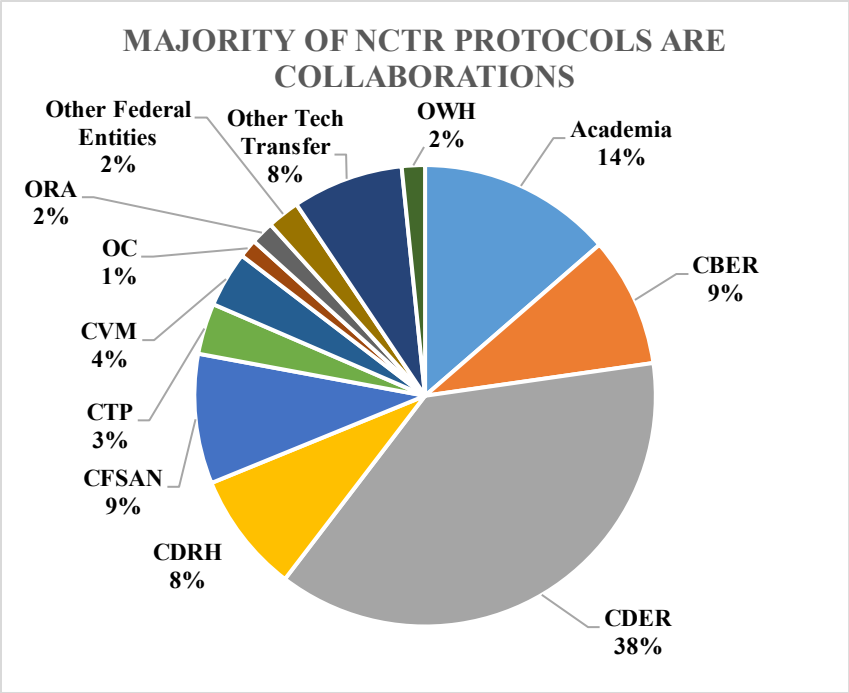

Figure 55 - Majority of NCTR Protocols are Collaborations

Opioids

According to the Center for Disease Control and Prevention (CDC) data analyzed by the National Institutes of Health, more than 106,000 persons in the U.S. died from drug-involved overdose in 2021, with 68 percent of those deaths attributed to synthetic opioids.[80] Deaths involving synthetic opioids (largely illicitly made fentanyl) and stimulants (such as cocaine and methamphetamine) have increased in recent years. In addition, overdose deaths accelerated during the COVID-19 pandemic.[81] FDA's efforts to reduce the misuse and abuse of opioids are

[79] *For more information, please visit:* Focus Areas of Regulatory Science Report | FDA

[80] *For more information, please visit:* Drug Overdose Death Rates | National Institute on Drug Abuse (NIDA) (nih.gov)

[81] For more information, please visit: Understanding Drug Overdoses and Deaths | Drug Overdose | CDC Injury Center

outlined in various guidance.[82] Support for opioid-related research can also be found in the Focus Areas of Regulatory Science: Substance Use Disorders. In support of these efforts, NCTR is conducting research related to opioid addiction and toxicity potential.

Use of prescription opioids in women leads to greater risk for cardiovascular disease (CVD) when compared with men and nonusers.[83] The U.S. Department of Health and Human Services (HHS) Office of Women's Health (OWH) has developed a white paper to initiate research on examining prevention, treatment, and recovery issues for women who misuse opioids, have opioid use disorders, and/or overdose on opioids.[84] Currently, systematic knowledge is lacking for risk factors associated with the increased cardiotoxicity of prescription opioid use (POU) in women. An ongoing study at NCTR in collaboration with the Center for Drug Evaluation and Research (CDER) is utilizing big data analysis and AI-related tools to identify sex differences in POU-associated CVD using multi-data sources to promote the evaluation of the post-market safety of opioid products. The novel analytical tools available in FDA databases, i.e. the FDA Adverse Events Reporting System (FAERS) Real-Time Application for Portable Interactive Devices (RAPID) and Sentinel, along with other electronic health record sources provide the possibility for systematic tracking and detection of previously unrecognized sex-differentiated POU-associated CVD risk factors. The results of this study may provide information to help FDA drug reviewers and physicians become aware of sex differences to certain opioid drugs and combinations with other prescription drugs, therefore, preventing or reducing risk of the POU drug-induced CVD in women.

Babies born to mothers who used opioids during pregnancy may have brain damage and respiratory problems. Replacing illicit opioid use during pregnancy with methadone or buprenorphine, called medication-assisted treatment (MAT), is considered best practice for both the mother and the baby. These drugs decrease withdrawal symptoms during pregnancy and often lead to better health outcomes for the infants, but they still carry risks for the developing fetus. Anticipating a large population of adolescents with a history of perinatal exposure to methadone or buprenorphine, there is an unmet need to understand the long-term effects of perinatal exposure to MAT. Therefore, NCTR has recently initiated a Perinatal Health Center of Excellence (PHCE) funded, two-phase, nonclinical research study on potential long-term neurobehavioral effects that may occur due to MAT exposure during vulnerable periods of development. The project will optimize a nonclinical model of MAT exposure that will simulate newborns that are weaned off opioids. NCTR will then conduct a full study of the long-term developmental effects which will include an assessment of the contributions related to maternal care. The project is expected to last into FY 2025.

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[82] *For more information, please visit:* FDA's Efforts to Address the Misuse and Abuse of Opioids | FDA and FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use | FDA

[83] Khodneva Y, Muntner P, Kertesz S, Kissela B, Safford MM: Prescription Opioid Use and Risk of Coronary Heart Disease, Stroke, and Cardiovascular Death Among Adults from a Prospective Cohort (REGARDS Study). *Pain Med* 2016, 17(3):444-455.

[84] *For more information, please visit: OWH News: Opioids and Women Final Report Released | Office on Women's Health (*womenshealth.gov*)*

Another closely related PHCE-funded NCTR opioid study will assess the effects of methadone or buprenorphine and their combined use with cannabinoids on neural stem cells. This study will investigate the molecular and cellular changes caused by each drug and their combinations during early stages of brain development. This is important because opioids are often used in combination with cannabis and cannabis-derived products. Understanding if these different drugs interact is crucial for interpreting the results obtained from safety studies. It will also support the development of strategies to guide the safe use of methadone and buprenorphine during pregnancy.

A recent publication from NCTR provides insight into opioid receptor binding activity to create potentially safer opioid-like compounds. According to this publication, in 1999 there were 6,984 opioid-related deaths, while in 2020, the number of fatalities significantly increased by approximately 14-fold to 94,371. These statistics highlight the ever-increasing safety concern of opioid pain medications and show the need for drug makers to develop safer alternatives. This publication is part of a larger research project, in collaboration with FDA's CDER and the National Center for Advancing Translational Sciences (NCATS), to create an Opioid Agonists/Antagonists Knowledgebase (OAK) to assist review and development of analgesic products for pain management and opioid use disorder treatment.

Showcasing One Health at NCTR with a focus on Antimicrobial Resistance (AMR) Research

Antibiotics play a crucial role in promoting human and animal health. According to the Center for Disease Control (CDC), more than 2.8 million antimicrobial-resistant infections occur in the U.S. each year, and more than 35,000 people die as a result.[85] Thus, antimicrobial resistance (AMR) is included as a Focus Areas of Regulatory Science: Antimicrobial Resistance for FDA. The FDA's One Health Mission is to provide "Optimal public health outcomes for humans and animals in their shared environment."[86] Below are a few examples of NCTR efforts to help combat AMR with a focus on utilizing One Health principles.

A potential source for antimicrobial-resistant pathogens is through the food supply, as such FDA Center for Veterinary Medicine (CVM) has led the National Antimicrobial Resistance Monitoring System (NARMS) in conjunction with CDC and the U.S. Department of Agriculture. Foodborne pathogens that cause more severe disease are those that require antimicrobial therapy, thus NCTR, in collaboration with CVM, is leading efforts to better understand factors that contribute to increased pathogenicity in NARMS-monitored pathogens and whether novel approaches can be used to limit their disease-causing ability and the need for antimicrobials across the One Health continuum.

To standardize the methodology for detecting, annotating, and/or reporting AMR in regulated products, a NCTR project in collaboration with CVM, the Office of Regulatory Affairs, the Center for Food Safety and Applied Nutrition (CFSAN), and the Center for Devices and Radiological Health (CDRH) will create standard operating procedures for sample collection and bioinformatic description of AMR from water used for food and agriculture. These methods can eventually be expanded to describe AMR across all commodities, matrices, and products under

[85] For more information, please visit: *2019 Antibiotic Resistance Threats Report | CDC*

[86] *For more information, please visit: Cross-cutting Topics: One Health Initiative | FDA*

FDA purview for which the assessment of AMR is critical. Synchronized methods across agencies will expand the capacity for highly coordinated surveillance and stewardship. A portion of this research was supported via a grant from the Office of the Chief Scientist.

In collaboration with CVM and the University of Arkansas at Pine Bluff, NCTR researchers are also developing tools to efficiently assess the role of plasmids (genetic structures outside of the bacterial chromosome that often carry genes encoding AMR and/or virulence traits) that can be spread among pathogens. These efforts target the understanding of factors that increase the ability of resistance plasmids to be transmitted among bacteria spreading AMR. Recent NCTR publications describing this and similar work can be found in *Microorganisms* and *Frontiers in Microbiology*.

Another One Health-related project deals with 6-PPD-quinone, a product of environmental oxidation of the tire rubber stabilizer 6-PPD, that has been identified as a very potent toxin for certain species of salmonids and has been implicated in the death of large numbers of coho salmon in the Pacific Northwest following urban stormwater runoff into river streams. NCTR, in coordination with several other federal agencies including the U.S. Environmental Protection Agency, United States Geological Survey, and the National Institute of Environmental Health Sciences, has initiated research that aims to characterize the toxicological properties of 6-PPD-quinone to enable the development of a holistic understanding of the potential environmental and human toxicological liabilities of this compound. These One Health efforts have capitalized on the tools that NCTR has deployed as part of its Rapid Response Program described below.

Artificial Intelligence (AI)

NCTR recognizes the variety of regulatory science applications that could benefit from AI, as well as its predictive potential. Using advanced AI technologies, NCTR's bioinformatic scientists have the expertise to both compile unique FDA datasets and design software applications specific to each product center's needs. These capabilities may serve to improve public health and expedite FDA review.

A recent NCTR-led publication in *Regulatory Toxicology and Pharmacology* is entitled "Artificial intelligence and real-world data for drug and food safety – A regulatory science perspective." This publication highlights discussions and debates of the eleventh annual Global Summit on Regulatory Science (GSR21) which focused on "Regulatory Sciences for Food/Drug Safety with Real-World Data (RWD) and Artificial Intelligence (AI)." The conference provided a platform for discussion and collaboration across global regulatory agencies in advancing regulatory science.

NCTR created AI4TOX an FDA program that aims to apply AI methods to develop new tools such as:

- **AnimalGAN** aims to predict animal-toxicology data for untested chemicals through learning models that leverage existing animal data. We are exploring an AI-based generative adversarial network (GAN) architecture to learn from existing animal studies to generate animal-relevant toxicological data without conducting additional animal experiments. In FY 2024 and FY 2025, NCTR will conduct research to extract more interpretable information from the AnimalGAN models and ascertain their value to assist

the regulatory decision-making process. A recent FY 2023 publication describing aspects of this research can be found in *Chemical Research in Toxicology*.

- **SafetAI** was developed using novel deep-learning methods for toxicological endpoints that are critical to the safety review of drug candidates before entering clinical trials in humans. The objective of SafetAI is to develop AI models for toxicological endpoints that are critical to assess drug safety and may add value to the review of drug candidates prior to human testing. This collaboration with CDER is aimed at supporting the Investigational New Drug (IND) review process.
- **BERTox** was developed using the most advanced AI-powered natural language processing tools to better analyze FDA documents and publicly available data sources for improved efficiency and accuracy of information retrieval and toxicity assessment. BERT (Bidirectional Encoder Representations from Transformers) is an open-source machine learning framework for natural language processing. The concerns about the fairness and bias of AI models are ever-increasing. Using inappropriate or inadequate data to train AI models may reinforce biased patterns and lead to biased predictions or decisions. In support of and in collaboration with CDER, NCTR will evaluate the biases of different AI language models that could be adopted by the FDA for toxicity assessments. Scientists will then develop a strategy to mitigate bias that will influence the model application. Recent NCTR collaborative publications can be found in *Frontiers in Artificial Intelligence* and the *International Journal of Environmental Research and Public Health*.
- **PathologAI** is an AI framework for animal-pathology data which could facilitate the identification of lesion type, location, and severity in histology slides. Preclinical pathology is a central component in toxicity evaluation and regulatory assessment with animal studies, however, it is a laborious process and requires extensive training. Nevertheless, discrepancies among pathologists still exist. Meanwhile, the rapid advancement in image analysis with AI has been extensively evaluated in clinical application with encouraging results.

Supporting the FDA Predictive Toxicology Roadmap (FDA PTR) and Advancing Alternative Methods – Biomarkers and Organ-On-A-Chip Technology

The FDA PTR describes a framework where the Agency decision-making process is progressively informed by novel methods that support the 3Rs principle (replacement, reduction, and refinement of animals used in research, testing, and teaching).[87] These methods have the potential to reduce animal use and provide faster and more human-relevant data than that generated by whole animal-based methods. To ensure that novel methods can be relied upon for both product development and regulatory decision-making, NCTR is conducting comprehensive assessments of specific emerging in vitro technologies, such as organ-on-a-chip, in close collaboration with the product centers. This type of research will inform and empower regulators, thus protecting public health. The use of biomarkers and emerging in vitro technology are specific examples of how NCTR is supporting the PTR and contributing to Advancing Alternative Methods at FDA.

[87] For more information, please visit: *https://www.fda.gov/science-research/about-science-research-fda/fdas-predictive-toxicology-roadmap*

Supporting FDA PTR - Biomarkers

Often, biomarkers can serve a dual role as indicators of disease and toxicity. FDA has identified biomarkers as a Focus Area of Regulatory Science. NCTR scientists are supporting PTR by evaluating biomarkers to detect brain damage, at an earlier stage. For example, NCTR investigated the possibility of detecting biomarkers of neurotoxicity using Magnetic Resonance Imaging (MRI), which could result in earlier, non-invasive detection of neurological disorders, safety assessments of regulated products, and provide a better understanding of drug-induced brain damage and possible prevention. Using MRI imaging in this way could also reduce the number of animals needed in the preclinical setting. Non-invasive imaging technologies such as MRI have great potential to improve the quality and precision of neurotoxicity testing, especially if they can be utilized in a systematic manner to potentially inform qualified biomarkers as either a detection surrogate or supplement and a guide to existing methods. The goal of this project was to further the development of MRI biomarkers of neurotoxicity to improve its quality and performance (sensitivity and specificity) characteristics. This project reached a major milestone in FY 2023 with the submission of a Letter of Intent for biomarker qualification. Biomarker research is also underway for drug-induced liver injury (DILI), cardiotoxicity, and Alzheimer's disease as examined briefly below.

Supporting FDA PTR – New Alternative Methods

Novel non-animal and human-specific technologies, like organ-on-a-chip technology for disease modeling, are a priority for research organizations across government, academia, and industry. One such technology currently being assessed at NCTR is a brain-on-a-chip. Successfully implementing a translational, valid, in vitro model of the brain could be of great value to the Agency when assessing regulated products for the treatment of neurological disorders such as Alzheimer's disease (AD). A chip model format for AD may allow FDA to detect regulated products that interact with neurodegenerative diseases and promote disease progression in a vulnerable population. Moreover, this model would provide a screening platform to assess the potential neurotoxic effects to a "healthy" brain for new products under consideration by the Agency. Initial experiments show that brain-chips can be constructed using five different cell types from the brain, differentiated from patient-derived stem cells. Moreover, endpoints related to brain function and the development of AD pathology have been standardized. Future experiments will compare those endpoints between control and AD brain-chips. This project will continue into FY 2025.

Another chip technology currently under evaluation at NCTR is liver-on-a-chip, with the intent to investigate the changes of both conventional and investigational DILI biomarkers. The data may also be useful for FDA to better assess the liver-chip platform's ability to predict idiosyncratic DILI— a treatment-related rare disease. DILI accounts for half of the U.S. acute liver-failure cases and represents a significant public health issue, partially because the currently used DILI biomarkers have limitations. The new biomarkers identified during this alternative-model study are expected to complement existing DILI biomarkers to help improve drug safety and promote public health. A paper describing issues related to assessment of biomarkers in this format was recently published. A new protocol has been developed to assess major commercial liver-on-a-chip platforms using cells from multiple species focusing on the extrapolations between in vivo and in vitro DILI endpoints and species differences in DILI responses. Each of these studies are designed to facilitate translation between the use of new

alternative models and traditional animal toxicology studies for making risk assessment determinations.

Research Addressing the Unmet Needs of Minority and At-Risk Populations

NCTR conducts research in support of FDA's efforts to generate data focused on underserved populations such as ethnic minorities, women, and those with rare diseases. The FDA has specifically identified these research efforts in the Focus Area of Regulatory Science Report. The report identifies cross-cutting areas for Minority Health and Health Equity, Women's Health, and Rare Diseases.

A recently initiated project, in collaboration with FDA's Office of Minority Health and Health Equity (OMHHE), uses AI to examine racial disparities in the treatment of patients with heart failure. There is significant concern that current medical practices, like the American Heart Association Get with the Guidelines–Heart Failure Risk Score, tend to steer ethnic minority patients away from critical care such as specialized cardiology services and cardiac surgery. This study is projected to be finalized in FY 2025 and will use AI methods to evaluate electronic health record data and investigate racial/ethnic disparities in critical care given to heart failure patients. Another OMHHE project seeking to address health disparities focuses on developing a Charlson comorbidity index for the American Indian community using cardiovascular, prescription medication, and social determinants variables amassed by the Strong Heart Study. The project will continue into FY 2024.

An OWH funded women's health-related project at NCTR is investigating novel predictive biomarkers of doxorubicin-induced cardiotoxicity in breast cancer patients. The overall goal is to develop new clinical plasma biomarkers to predict cardiotoxicity prior to the occurrence of cardiac tissue damage for the prevention of permanent damage as well as identify patients at highest risk for cardiac damage. This research addresses an unmet need in women's health within the OWH by developing new biomarkers to assess cardiotoxicity of chemotherapies in female cancer patients thus helping OWH achieve the goals of advancing drug safety in women's health, particularly in cardiovascular health. The biomarkers would serve as the basis for a rigorous validation effort. Fully qualified biomarkers could facilitate FDA's regulation of drugs, provide important information for drug labels, and provide sponsors with methods to improve drug safety, which aligns with FDA research priorities in biomarkers and personalized medicine.

In collaboration with CDER and the Center for Biologics Evaluation and Research (CBER), NCTR is also investigating rare diseases like myelodysplastic syndromes, which are a rare group of blood cancers resulting from altered development of blood cells within bone marrow. The focus of this work is on developing a targeted, error-corrected next generation sequencing panel to quantify myeloid neoplasm-associated genetic mutations. This work will continue into FY 2024.

Rapid Response Program

In FY 2023, NCTR received funding from Congress to support the New Era of Smarter Food Safety initiative. The intent of this initiative is to leverage technology and other tools and approaches to create a safer, more digital, and traceable food system. NCTR funded various research to support the initiative and sought to establish a Rapid Response Program at NCTR to assist CFSAN in quickly responding to foodborne illness. One example of this effort at NCTR was in response to a food product that was recently recalled due to gastrointestinal distress and

liver toxicity in consumers. NCTR was able to quickly design and execute a series of studies to help clarify the toxicity associated with the recalled product.

Although the Rapid Response Program was originally established to increase NCTR's capacity to quickly respond to foodborne illness, NCTR has expanded this capability to other FDA-regulated products such as drugs and dietary supplements. As an example, NCTR recently deployed fast response protocols which streamline in vitro assessments of toxicity in in vitro liver and heart models to assist in determining what experimental models can best represent how humans metabolize toxicants. These approaches are expected to not only enable a faster Agency response to protect public health, but also enact a regulatory process that is increasingly grounded in the 3Rs principle.

Drug Compounding

Compounded drugs are another focus area of great concern to FDA because they are not reviewed for safety or efficacy prior to public consumption. Compounding is generally performed by a licensed pharmacist, a licensed healthcare professional, or— in the case of an outsourcing facility —a person under the supervision of a licensed pharmacist. This person combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. The growing concern for public health resulted in the enactment of the Drug Quality and Security Act (DQSA, Public Law 113-54) and the recent establishment of the Compounding Quality Center of Excellence which serves to support outsourcing facilities in their efforts to provide high quality compounded drugs. FDA's concerns are summarized online at Focus Area: Quality of Compounded Drugs | FDA and here Human Drug Compounding. NCTR is conducting research to support the safety of compounded drugs in direct collaboration with CDER.

Serious health problems and significant medical costs can be the consequence of inappropriate application of sporicidal agents (chemicals that destroy bacterial and fungal spores when used in sufficient concentration for a specified contact time) at compounding pharmacies. While pharmaceutical manufacturers are required to comply with current good manufacturing practice (CGMP) and validate the effectiveness of disinfectants at their facilities, compounding pharmacies are exempt from CGMP. In addition, outsourcing facilities can follow the labeling on the disinfectants and do not need to validate the effectiveness of disinfectants in their facilities. An ongoing NCTR study, in collaboration with CDER, aims to establish a sporicidal efficacy database with standardized methodology, improving CDER's ability to accurately assess the sporicidal efficacy of disinfectants used at compounding pharmacies and outsourcing facilities. A recent publication related to this research can be found in the *Journal of Industrial Microbiology and Biotechnology*. This study is expected to continue into FY 2024.

Another compounding-related study at NCTR, in collaboration with CDER, seeks to characterize the cellular toxicity of compounded triamcinolone-moxifloxacin (Tri-Moxi), a common anti-inflammatory drug used after cataract surgery. A FDA investigation was required in 2017 as a result of poor compounding practices of Tri-Moxi. The results of this ongoing study will provide the FDA with a toxicity profile of compounded Tri-Moxi and assess the impact of compounding procedures. These data may enable the Agency to identify potential safety gaps related to compounding and address problems identified in relevant adverse event reports. For some medications, compounding pharmacies devise their own compounding methodology and formulations. CDER became aware of compounding formulas that use relatively novel excipients

(an inactive substance that serves as the vehicle or medium for a drug or other active substance) or excipients at considerably higher levels than those found in an approved drug product. To address these issues, an ongoing study is assessing safe dose levels of all compounded substances in Tri-Moxi (triamcinolone acetonide, moxifloxacin, poloxamer 407, methylparaben, and propylparaben), the impact of the compounding procedure, and potential relevant synergistic effects. This study is expected to continue into FY 2024.

Cannabis-Derived Products such as Cannabidiol (CBD)

FDA recognizes the opportunities that cannabis or cannabis-derived compounds have for widespread consumer consumption and potential therapeutic use. However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug, and Cosmetic Act[88] and that may put the health and safety of consumers at risk.[89] Since 2015, FDA has sent over 100 warning letters to various companies selling unapproved or unlawful cannabis-derived products,[90] with 30 warning letters issued in 2022. In 2018, FDA approved the cannabis-derived drug, Epidiolex — a CBD oral solution that treats tuberous sclerosis complex and seizures associated with two rare and severe forms of epilepsy in patients one year of age and older.[91] Despite that approval, much is still unknown about the potential toxicities related to the thousands of cannabis-derived products marketed as foods, beverages, cosmetics, dietary supplements, and products for animals. NCTR is working with the FDA product centers to answer questions about the science, safety, and quality of products containing CBD, including the efforts listed below.

Significant concern was raised during the FDA review of Epidiolex that the potential toxicity of the major CBD metabolite in humans was not adequately modelled in the submitted pre-clinical studies because there were considerable differences in the biotransformation of CBD between experimental animals and humans. In order to enable the conduct of studies that can clarify important regulatory concerns such as the potential male reproductive toxicity of CBD, NCTR is conducting studies that aim to identify which specific models may be able to appropriately recapitulate the human metabolism of CBD.

While there is significant consumer interest and increased use of topical CBD-containing products in the U.S., including skin-care products and other cosmetics, important data gaps remain regarding their safety. The limited data available on the dermal absorption of CBD does not allow the FDA to predict whether CBD at levels present in cosmetic products can enter the bloodstream and affect distal organs. In collaboration with CFSAN, NCTR scientists are evaluating the pharmacokinetics (movement of a substance within the body and its metabolism) of dermal CBD exposure. The findings from this study are expected to assist CFSAN in

[88] *For more information, please visit: www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act*

[89] *For more information, please visit: www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd*

[90] *For more information, please visit: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters*

[91] *For more information, please visit: www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms*

assessing the safety of CBD and hemp-derived cosmetics for human use. This work will continue into FY 2024, with data reported via publication(s) in FY 2025.

Perinatal Health Center of Excellence (PHCE), Pediatric Medicine, and Maternal Medicine

The research conducted through the FDA's PHCE, which is managed by NCTR, focuses on the perinatal period (the time period including maternal, premature, neonatal, and pediatric periods, as well as development throughout childhood) which is vastly understudied. PHCE funds Agency research with broad regulatory impact to fill knowledge gaps in safety, efficacy, or potential toxicity that currently exist for the perinatal period, with the goal to strengthen the scientific basis of decision-making for FDA-regulated products used during the perinatal period. Numerous findings from PHCE funded studies were published in scientific journals in FY 2023, with topics ranging from:

- Improving computerized tomography (CT) imaging techniques for pediatric patients
- AI-enabled devices for pediatric use
- Oncology drugs during pregnancy
- Neonatal outcomes and consequences following maternal SARS-CoV-2 infection in pregnancy

A full list of publications related to PHCE-funded research can be found here.

In FY 2023, 13 new PHCE projects were selected to be awarded. Including the 4 ongoing second-year projects, the PHCE funded 17 projects in FY 2023. These PHCE projects were led by primary investigators from CBER, CDER, CDRH, and NCTR. Topics for these new projects include, but are not limited to:

- Non-Immune biomarkers for Zika virus
- Simulation tools to reform the dosing strategy of therapeutic antibodies in pregnancy and young pediatric patient population
- Perinatal CBD central nervous system (CNS) activity and toxicity
- Immunogenicity of mRNA vaccines in early age
- Impact of emerging SARS-CoV-2 variants on placental functions and neonatal outcomes
- Advancing the application of lactation physiologically-based pharmacokinetic models
- Predictive toxicology models of drug placental permeability using 3D-fingerprints and AI
- New alternative models of folliculogenesis (maturation of fertilizable egg) for assessing drug/chemical toxicity

The FY 2023 first-year projects will extend into their second year in FY 2024, with three new first-year projects awarded funding in FY 2024.

PERFORMANCE

NCTR's performance measures focus on research to advance the safety of FDA-regulated products.in order to protect and improve the health of the American public as represented by the following table:

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target
263103: Conduct translational and regulatory research to advance the safety of products that FDA regulates. (Output)	FY 2023: In collaboration with CDER, NCTR identified potential safety gaps related to drug compounding procedures and addressed problems identified in relevant adverse event reports. (Target Met) FY 2023: CBER and NCTR scientists developed a human microphysiological placental barrier model and demonstrated that it can be used to effectively predict pharmacokinetic (PK) parameters. A manuscript highlighting study findings was submitted to *Reproductive Toxicology* in August 2023. (Target Met)	Provide preliminary results on the effects of methadone or buprenorphine (used during opioid detox) and their combined use with cannabinoids. Provide preliminary results on the value of microbiome assessments to improve the safety evaluation of FDA-regulated products.	In collaboration with CDER, provide data to address scientific knowledge gaps regarding potential neuropsychiatric risks to patients chronically taking montelukast. In collaboration with CDER and OWH, identify early signs of sex difference in adverse events during drug development using bioinformatics.
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies. (Output)	FY 2023: In collaboration with CBER, NCTR developed a testicular organoid microphysiological system (MPS) capable of supporting Zika virus infection and viral replication. A manuscript was submitted for publication in FY2023. (Target Met)	Develop explainable AI models to facilitate FDA application of AI and improve regulatory guidance to evaluate AI-centric products. Utilize AI to improve utilization of FDA labeling documents, predictive modeling, drug repurposing and/or improve databases for regulatory use to improve safety evaluations.	In collaboration with CDER, provide data to assist FDA in developing Guidance for Industry for the use of liver microphysiological system in drug safety evaluation.
262401: Develop biomarkers to assist in characterizing an individual's genetic profile in order to minimize adverse events and maximize	FY 2023: NCTR worked towards improving MRI biomarkers by developing and implementing an automated MRI image processing and analysis tool. A related publication can be found in Neurotoxicology and Teratology. (Target Met) FY 2023: NCTR characterized the development of an Alzheimer's Disease brain-chip for comparison to healthy brain-chips. (Target Met)	Provide preliminary results on a method that aims to detect chemicals capable of producing cancer by a mechanism not related to gene damage. Initiate the development of biomarkers associated with a susceptibility to Non-Alcoholic Fatty Liver Disease (NAFLD) and NAFLD-related liver carcinogenesis.	In collaboration with CDER, promote the development of biomarkers and elucidate pathways that may support the development of more effective therapies for Alzheimer's Disease.

Figure 57 - NCTR Performance Table 1/2

264101: Develop risk assessment methods and build biological dose-response models in support of food protection. (Output)	FY 2023: Preliminary findings of the study to evaluate the virulence potential of pathogens such as Salmonella enterica using a 3D-structured tissue culture system were presented to the NCTR Science Advisory Board in 2023. Initial studies are promising; however, the system still requires further optimization and refinement. (Target Met)	Generate an E. coli virulence gene data set for use in the development of the E. coli virulence gene database.	In collaboration with CVM, characterize potential targets for anti-virulence drugs in food-producing animals.
263104: Use new omics technologies to develop approaches that assess risk and assure the safety of products that FDA regulates. (Output)	FY 2023: In collaboration with Elsevier (via CRADA), NCTR scientists developed a preliminary predictive model to improve Drug Induced Liver Injury (DILI) assessment. The preliminary model utilizes in silico (computer-based) methods including, Artificial Intelligence (AI), as an alternative to animal methods. (Target Met)	Provide preliminary results on the development of a method to analyze genetic material to detect specific microorganisms from non-sterile pharmaceutical products.	In collaboration with CDER, develop a preliminary human liver 3D cell model and use this model for assessing drug-induced liver toxicity.
263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products. (Output)	FY 2023: In collaboration with Elsevier (via CRADA), NCTR scientists developed a preliminary predictive model to improve Drug Induced Liver Injury (DILI) assessment. The preliminary model utilizes in silico (computer-based) methods including, Artificial Intelligence (AI), as an alternative to animal methods. (Target Met)	Apply publicly available language models (e.g., BERT and BioBERT) to FDA drug labeling documents to provide a scientific basis to support FDALabel and the CDER review process.	In collaboration with CDRH, develop a preliminary database of extractable/leachable chemicals from medical devices.

Figure 58 - NCTR Performance Table 2/2

PROGRAM ACTIVITY DATA

National Center for Toxicological Research Program Activity Data (PAD)

Program Workload and Outputs	FY 2023 Final	FY 2024 CR	FY 2025 PB
Research Outputs			
Research Publications	129	140	145
Research Presentations	119	130	135
Patents (Industry)	14	14	15
Leveraged Research			
Federal Agencies (Interagency Agreements)	5	5	5
Nongovernmental Organizations	56	56	56

Figure 59 – NCTR Program Workload and Outputs

OFFICE OF REGULATORY AFFAIRS - FIELD ACTIVITIES

PURPOSE STATEMENT

FDA is responsible for the regulatory oversight of food, medical, and tobacco products purchased and consumed by Americans. FDA-regulated products account for about 20 cents of every dollar spent in the United States. The Office of Regulatory Affairs (ORA) advances FDA's mission by conducting field operational activities for FDA-regulated products to ensure their safety, effectiveness, and quality. As FDA's lead office for all agency regulatory field activities, ORA is responsible for a wide range of mission-critical activities including:

- inspections and investigations (including criminal investigations),
- sample collection and analyses,
- examination of FDA-regulated products offered for import into the United States,
- oversight of recalls and execution of enforcement actions,
- response to consumer complaints and emergencies
- development and promotion of partnerships and information sharing with federal, state, local, and international regulatory partners including mutual reliance partners

Authorizing Legislation: Filled Milk Act (21 U.S.C. §§ 61-63); Federal Meat Inspection Act (21 U.S.C. § 679(b)); Federal Import Milk Act (21 U.S.C. § 141, et seq.); Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, et seq.); The Office of Criminal Investigations (OCI) of ORA conducts criminal investigations and executes search warrants as permitted by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372), the Public Health Service Act (42 U.S.C. 262) and the Federal Anti-Tampering Act (18 U.S.C. 1365); Poultry Products Inspection Act (21 U.S.C. § 467f(b)); Small Business Act (15 U.S.C. § 638); The Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.); Executive Order 11490, § 1103; Comprehensive Drug Abuse Prevention and Control Act of 1970 (84 Stat. 1241); Controlled Substances Act (21 U.S.C. § 801, et seq.); Lead-Based Paint Poisoning Prevention Act (42 U.S.C. § 4831(a)); Federal Advisory Committee Act (5 U.S.C. Appx. 2); Federal Caustic Poison Act (44 Stat. 1406); Egg Products Inspection Act (21 U.S.C. § 1031, et seq.); Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. § 3701, et seq.) and Executive Order 12591; Equal Access to Justice Act (5 U.S.C. § 504); Consumer-Patient Radiation Health and Safety Act of 1981 (42 U.S.C. §§ 10007 and 10008); Patent Term Extension (35 U.S.C. § 156); Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. §§ 1401-1403); Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. §138a); Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration (FDA), and Related Agencies Appropriations Act of 1997 (Public Law 104-180); Best Pharmaceuticals for Children Act (Public Law 107-108), as amended by Pediatric Research Equity Act of 2003 (Section 3(b)(2) of Public Law 108-155); Drug Quality and Security Act of 2013; Food and Drug Administration Reauthorization Act of 2017 (FDARA) (P.L. 115-52).

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
Office of Regulatory Affairs	1,224,098	1,262,073	1,354,061	1,335,621	1,390,896	36,835
Budget Authority	*1,130,376*	*1,157,329*	*1,227,968*	*1,207,102*	*1,260,238*	*32,270*
User Fees	*93,722*	*104,744*	*126,093*	*128,519*	*130,658*	*4,565*
FTE	5,205	5,086	5,121	5,084	5,093	-28

Figure 60 - ORA Funding History Table

The FY 2025 President's Budget for the Office of Regulatory Affairs Program is $1,390,896,000 of which $1,260,238,000 is budget authority and $130,658,000 is user fees. The budget authority increases by $32,270,000 compared to the FY 2023 Final Level. User fees increase by $4,565,000.

BUDGET AUTHORITY

FY 2025 President's Budget: ORA *Budget Authority - Dollars in Thousands*	Field Foods	Field Human Drugs	Field Biologics	Field Animal Drugs & Foods	Field Devices	Field Total
FY 2023 Final	**794,230**	**210,501**	**48,050**	**81,952**	**93,235**	**1,227,968**
FY 2025 Budget Authority Changes	**17,955**	**4,176**	**2,428**	**1,863**	**5,848**	**32,270**
Requested Increases	**30,619**	**8,634**	**3,142**	**2,891**	**7,173**	**52,459**
Microbioligical and Nutrition	1,300	-	-	-	-	1,300
Public Health Employee Pay Costs	28,000	8,125	2,211	2,721	5,008	46,065
Enterprise Transformation	298	84	25	34	55	496
IT Stabilization & Modernization	1,021	425	92	136	218	1,892
Shortages and Supply Chain-Agency-wide	-	-	814	-	1,892	2,706
Other Adjustments	**(12,664)**	**(4,458)**	**(714)**	**(1,028)**	**(1,325)**	**(20,189)**
ORA Transfer to HQ/OGPS	(16,214)	(3,630)	(968)	(1,452)	(1,936)	(24,200)
FDARA Sec. 905 BA Shift	-	(2,002)	(55)	-	(63)	(2,120)
FY 2024 Comparability Adjustment	3,167	1,033	275	378	601	5,454
FY 2025 Comparability Adjustment	383	141	34	46	73	677
FY 2025 Budget Net Total: ORA	**812,185**	**214,677**	**50,478**	**83,815**	**99,083**	**1,260,238**

Figure 61 - ORA Budget Authority

Total Requested Increases: +$52.4 million / 14 FTE

Public Health Employee Pay Costs: +$46 million

Field Foods: +$28.0 million

Field Human Drugs: +$8.1 million

Field Biologics: +$2.2 million

Field Animal Drugs and Foods: +$2.7 million

Field Devices: +$5.0 million

The FY 2025 President's Budget includes $114.8 million in new budget authority to fund approximately 72 percent of the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 and FY 2025 Cost of Living Adjustments (COLA). For FY 2025

this assumes a 2.0 percent for Civilian and 4.5 percent Military pay increase for FTE funded through budget authority. Within the Office of Regulatory Affairs, $46 million is provided for pay costs.

Enterprise Transformation: +$496,000/ 2 FTE

Field Foods: +$298,000/ 2 FTE

Field Human Drugs: +$84,000

Field Biologics: +$25,000

Field Animal Drugs and Foods: +$34,000

Field Devices: +$55,000

The FY 2025 President's Budget provides $2.0 million for Enterprise of Transformation, which includes $496,000 for the Office of Regulatory Affairs (ORA) to coordinate and lead several crosscutting agency-wide projects to analyze and implement common business processes and data optimization. Benefits of this funding will include improved communication and data sharing across the life cycle of an inspection, increased access to relevant data to facilitate risk-based decision-making, and introduction of more modern mobile technology for field work to improve the user experience. The office also seeks to standardize the FOIA business processes across the Agency and create effective governance to enable successful process and technology changes.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

Human Foods Program Transformation: +$1.3 million / 2 FTE

Field Foods: +$1.3 million / 2 FTE

The FY 2025 President's Budget provides $15.0 million for Microbiological and Nutrition, including $13.7 million to CFSAN and $1.3 million to ORA.

ORA will utilize these funds for hiring consumer safety officers to support implementation of the rule as well as participate in outreach engagements, enhance IT systems, and training needed for this rule. The FDA final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) establishes additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List. The proposed requirements would help the FDA rapidly and effectively identify recipients of those foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death.

IT Stabilization & Modernization: +$1.9 million

Field Foods: +$1.0 million

Field Human Drugs: +$425,000

Field Biologics: +$92,000

Field Animal Drugs and Foods: +$136,000

Field Devices: +$218,000

The FY 2025 President's Budget provides $8.3 million for IT Stabilization & Modernization, including $1.9 million for the Office of Regulatory Affairs (ORA) to further build FDA's centralized enterprise data modernization capabilities and to strengthen FDA's common data infrastructure, data exchange, and IT analytic services, talent, and tools. With these resources, FDA will continue to improve data exchange and underlying technology platforms in support of FDA's programs and mission-critical responsibilities – to better meet the challenges of emerging threats, support needs for real-time evaluation, and more continuously access, analyze, and aggregate multiple sources of information, such as for recalls, adverse events, outbreaks, and pandemics.

Additional information on this request may be found within the FDA Headquarters chapter on page 205.

Shortages and Supply Chain: +$2.7 million / 10 FTE

Field Biologics: +$814,000 / 3 FTE

Field Devices: +$1.9 million / 7 FTE

The FY 2025 President's Budget provides $12.3 million for Shortages and Supply Chain, including $2.7 million for ORA to advance FDA's capabilities to help prepare for, build resilience to, and respond to shortages that are supply-driven and/or demand-driven through improved analytics to identify shortage threats and vulnerabilities as well as regulatory approaches to assess disruptions and shortages. ORA will use the $2.7 million towards additional resources to keep pace with the volume of manufacturers across the global medical device and biologics industry to enable stronger supply chains and reduce the risk of shortages in the future. These funds will be used to hire investigators to expand our global approach to perform inspections and investigations that will enable more robust regulatory oversight of the drug, device, and biologics industry. This will enable greater accessibility and improve the stability of the device and biological product supply chain to help avoid shortages of critical medical products, and further support of the CARES Act which was enacted in March 2020.

USER FEES

Current Law User Fees: +$3.5 million

Field Human Drugs: +$4.0 million

Field Biologics: +$320,000

Field Animal Drugs and Foods: -$369,000

Field Devices: -$613,000

Field Center for Tobacco: +$203,000

The Office of Regulatory Affairs Program request includes an increase of $3.5 million for current law user fees authorized.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

Overview

The FDA's Office of Regulatory Affairs (ORA) is the lead office for all field activities. ORA inspects and investigates manufacturers and facilities across all regulated commodities, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States. ORA also works with state, local, tribal, territorial (SLTT) and foreign counterparts to fulfill FDA's mission and extend oversight reach. ORA is responsible for a wide range of activities critical to FDA's public health mission, including:

- inspections and investigations, (including criminal investigations)
- sample collection and analyses
- examination of FDA regulated products offered for import into the United States,
- oversight of recalls and execution of enforcement actions
- response to consumer complaints and emergencies
- development of regulation, guidance and policy pertaining to field activities,
- development, maintenance, and promotion of federal, state, and local partnerships
- information sharing with domestic and international regulatory and mutual reliance partners

ORA is working to improve its capabilities to predict, prepare for, and respond to public health emergencies and threats in the nation and across the globe by strengthening its network of regulatory partners and applying shared data and knowledge in the application of surveillance and enforcement activities. By targeting the products that pose the greatest risk, American patients and consumers can have added confidence in and timely access to safe foods and medical products.

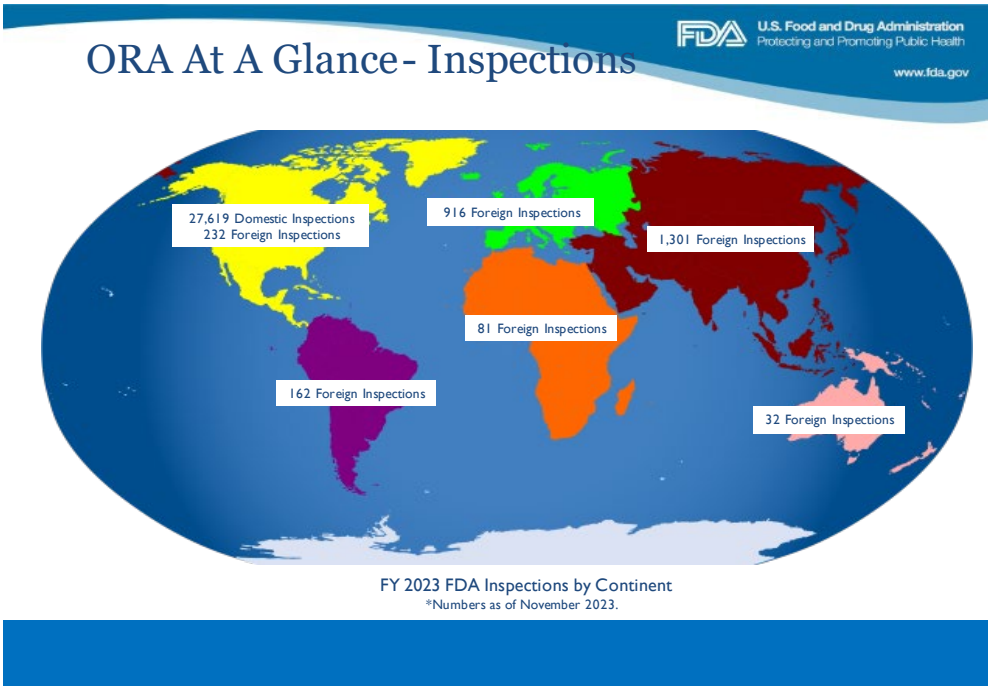

Figure 62 - FY 2023 FDA Inspections by Continent

Recent Accomplishments

Three of ORA's most significant accomplishments from the past year are highlighted here and described in more detail below.

Supporting the Opioid Initiative
ORA continues to address the opioid public health crisis as a top priority. ORA is fully implementing the new authorities included in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act), signed into law on October 24, 2018. Additionally, ORA has also prioritized efforts to increase personnel, improve workspace, enhance analytical detection tools, and improve information technology (IT) infrastructure at the eight international mail facilities (IMF).

Expanding FDA Medical Product Safety
ORA continues to advance key initiatives in medical product safety including the Foreign Unannounced Inspection Pilot (FUIP), Advanced Medical Product Manufacturing, and Regulatory Harmonization to Advance Medical Device Quality and Access.

Initiating a New Era of Smarter Food Safety
The New Era of Smarter Food Safety leverages technology and other tools to create a safer and more digital, traceable food system. Working with partners in the public and private sectors, ORA continues to advance goals in each of the four priority areas to enhance traceability, improve predictive analytics, respond more rapidly to outbreaks, address new business models, reduce contamination of food, and foster the development of stronger food safety cultures.

Field Accomplishments - Medical Products
Supporting the Opioid Initiative

ORA's IMF staff work diligently to examine and document suspicious mail parcels. However, ORA investigators are only able to inspect a fraction of the incoming international mail packages due to the volume of products entering the United States. In FY 2023, ORA has reviewed more than 86,000 products coming through IMFS. ORA estimates that staff at IMFs physically inspect less than 0.05 percent of all inbound international mail packages. Recognizing these hurdles, ORA is increasing existing resources and efficiencies, and is identifying innovative ways to expand its impact. ORA also continues to evaluate ways to streamline IMF processes, increase workspace, and make IT improvements that expand parcel review.

To further collaboration, information sharing, and enforcement, FDA and CBP agreed on a joint National Operational Strategy (NOS). The resulting operation "Operation Opioid and Other Drugs" (OOOD) began in early FY 2022, specifically targeting unapproved drugs and illegal opioids at the IMFs and courier hubs. These joint efforts began with data sharing between agencies to inform location and product targeting for joint operations. Based on the data analysis, FDA and CBP partnered at eight IMFs and five Express Courier Hubs (ECH) to identify products of interest. OOOD also made use of FDA's rapid screening technologies to aid in identifying misbranded drugs. During FY 2022 OOOD operations, over 3,500 parcels were examined which resulted in approximately 395,000 tablets/capsules/pieces consisting of unapproved drugs and controlled substances being refused, destroyed, or referred to CBP for regulatory action. Findings from the FY 2022 OOOD operations also resulted in the addition of

seven APIs to FDA's 801(u) targeting list, which furthers the agency's ability to protect public health by removing drugs posing a significant public health concern from distribution when they are encountered at the IMF. The FY 2022 OOOD operational data and results supported the development of FY 2023 OOOD targeting which consisted of 9 nationally dispersed operations; 5 IMF, 3 land border ports, two express consignment hubs, and 2 dedicated operations focused on imports from Guam. FY 2023 OOOD concluded on June 17, 2023. During FY 2023 OOOD operations, 1,333 lines were examined which resulted in 208,818 tablets/capsules/pieces being removed from the supply chain. These operations also provided sufficient information to make seven recommendations for APIs to be considered for inclusion in the 801(u) list. FY 2024 OOOD operational plans are now under development.

In May 2023, scientists and their senior leaders from ORA's Office of Regulatory Science, the Drug Enforcement Administration, and Customs and Border Protection, met at the El Paso Intelligence Center (EPIC) to establish a joint federal science laboratory, INTREPID (Intelligence National Threat Response El Paso Illicit Drug) Laboratory. By sharing laboratory space at EPIC and leveraging the vast technical knowledge and intelligence from three diverse perspectives, INTREPID scientists use their combined expertise and state-of-the-art analytical methodologies to provide research, scientific support and actionable intelligence on the nature and source of rapidly evolving illicit drug threats. The data derived from INTREPID offers the law enforcement community in depth analysis of seized materials to provide trafficking linkages and geo sourcing of illicit drugs and precursor materials. Current efforts are focused on attribution associated with counterfeit opioid tablets and bulk powders in seized drugs also found to contain xylazine.

ORA's criminal investigators are working to tackle the serious crime of health care professionals tampering with opioids intended for patient use. In one example, ORA was involved in a case where a nurse working at a hospital, was sentenced to four years in prison in May 2023 after pleading guilty to tampering with vials and syringes of the painkiller hydromorphone, which she knew were intended to be administered to patients in the critical care unit of the hospital. She removed the hydromorphone from the vials and syringes, replaced the hydromorphone with saline solution, and returned the adulterated containers. In total, she stole 116 vials and syringes of hydromorphone.

ORA continues to monitor the marketplace for products marketed to prevent, treat, mitigate, or cure opioid addiction and withdrawal. In June 2022, FDA issued five warning letters to firms marketing kratom products with claims that the products were therapeutic for opioid cessation and withdrawal. ORA conducted investigations into more than two dozen firms marketing products with these claims.

ORA also protects consumers by working to prevent illegal online sales of opioids. The Cybercrime Investigation Unit targets illegal online marketplaces and manufacturers that sell counterfeit opioids. For example, in June 2023 OCI, with assistance from the FBI, the DEA, and the Colombian National Police, dismantled the "Undertaker45" criminal organization which distributed counterfeit Adderall containing methamphetamine, counterfeit oxycodone containing fentanyl, and counterfeit Xanax containing alprazolam derivatives. The Undertaker45 organization operated on the dark web and utilized both the mobile chat application Telegram and encrypted email service Protonmail for communication. This law enforcement action resulted in the arrest of 3 individuals, including 1 arrest in Colombia, the seizure of 3 kilograms

of counterfeit Adderall, Oxycodone and Xanax and the seizure of approximately $451,000 in illicit proceeds.

Foreign Unannounced Inspection Pilot

In FY 2022 Congress provided ORA with additional funding to continue support for the Foreign Unannounced Inspection Pilot (FUIP), increase unannounced inspections, and hire additional foreign office-based investigators for foreign facility inspections in India. As of the end of FY 2023, FDA has initiated 79 for-cause and surveillance inspections in India as part of the first two or three phases for that country. The inspections. will help FDA better understand trends and where inspection notification type may be impactful after completion of the Phase II control group consisting of pre-announced inspections, which is currently ongoing in India.

Phase I of the FUIP in China launched in July 2023. By the end of FY 2023, FDA conducted 4 for-cause inspections in China as part of the first two of three phases of the FUIP for that country. This phase may be impacted due to issues in obtaining visas for our FDA investigators on time (due to extensive visa application requirements) and two new laws implemented in China on July 1, 2023, National Security Law and Espionage Law have led to concerns over personal safety and have led us to implement more stringent requirements on using Department of State (DoS) contract interpreters. The health and safety of all personnel, including those in the FDA China Office and DoS interpreters, remains a top priority for the pilot.

Advanced Medical Product Manufacturing

In FY 2023, ORA solidified its advanced manufacturing team with the hiring of several staff to support Advanced Medical Products Manufacturing (AMPM) and Medical Countermeasures initiatives. This new AMPM team will ensure ORA inspectional readiness for rapid advancements in medical products manufacturing. The AMPM team engages with agency counterparts to support and facilitate industry's adoption of innovative technologies and to establish a regulatory framework for FDA that aligns with advances to manufacturing in industry. The program leverages recommendations from a needs assessment contract to enhance ORA investigators' advanced manufacturing training through partnerships. Additionally, ORA engages with our foreign regulatory partners to maintain awareness of global industry and regulatory advancements and to share best practices with other regulators, including ongoing efforts with EMA's Quality Innovation Group. The projected growth of this program will place additional demands on the Agency and may prompt a discussion of longer-term resource needs.

Regulatory Harmonization to Advance Medical Device Quality and Access

ORA is actively engaged with Center counterparts to update policies and procedures, develop training, create stakeholder communication, and develop a new inspection approach to prepare to implement a regulation that, once finalized, will harmonize FDA's medical device regulations more closely with global standards. The proposed rule, "Medical Devices; Quality System Regulation Amendments," was issued in February 2022, and would incorporate by reference the international standard for quality management systems for medical devices, ISO 13485:2016 into FDA's quality system regulation, 21 CFR Part 820. The agency aims to publish the final rule in December 2023 with a delayed effective date. Once effective, FDA device regulations will be more harmonized with requirements of many countries using ISO 13485 as a foundation for device manufacturing quality requirements. Significant efforts have been underway to enhance our IT systems to support the 820 new requirements and to ensure ORA inspection findings and

citations are available for investigators once the regulation is implemented. ORA has also been working to develop the new inspection paradigm and requirements, online training modules and classroom instructions to roll out in 2025. ORA is using this opportunity to enhance FDA's medical device inspection approach to keep pace with these wide-ranging changes. The projected growth of this program will place additional demands on the Agency and may prompt a discussion of longer-term resource needs.

Premarket and Bioresearch Monitoring Activities

ORA's Bioresearch Monitoring (BIMO) program completes inspections and data audits, which are integral to ensuring the safety and effectiveness of new medicines, medical devices, food and color additives, veterinary products, and oversight of new tobacco products, during the FDA preapproval process. This program provides regulatory oversight of the data offered in support of product applications, to ensure the data is factual and the studies are properly conducted. As of September 30, 2023, the BIMO Program has completed 786 domestic inspections, 230 foreign inspections, and 21 remote regulatory assessments.

Advancing the Availability of Biological Products

The biomanufacturing and biotechnology sectors are experiencing rapid growth and hold great promise for new lifesaving and life-sustaining products. While small in comparison to a growing industry, the Office of Biological Products Operations (OBPO) has exercised an important role in its oversight of manufacturers of biological products, most of which are lifesaving and life sustaining, including blood products, plasma derivatives, recombinant plasma therapeutics, vaccines, and cell gene therapies by focusing resources on the highest risk manufacturers. FDA completes surveillance and enforcement activities throughout the distribution chain and allocates inspectional resources based on risk estimates associated with specific domestic and foreign firms. Using a preventive model to prioritize resources, ORA can efficiently focus inspection efforts, in conjunction with FDA centers as well as applicable SLTT regulatory partners. As a result, ORA completed 1,052 post-market surveillance activities in FY 2023, helping to ensure access to safe and effective biological products.

Field Accomplishments - Food Safety

New Business Models and Retail Modernization Action Plan

ORA engaged in the three-day New Business Model Summit in October 2022, collaborating on food safety with other FDA components and a broad array of stakeholders including industry, consumers, academia, and regulatory partners. This ongoing collaboration will establish and enhance business models to ensure the safety of food and modernize retail food safety approaches. FDA evaluated feedback from the docket and the summit to inform the New Business Models and Retail Modernization Action Plan. Goals in FY 2023 include clarifying FDA's regulatory scope, ensuring adequate oversight of food sold through e-commerce and enhancing food safety education across the e-commerce food sector, from industry to consumers. This will take extensive outreach and collaboration by the Food Program with states, retail regulatory associations, other federal agencies, and industry.

Food Safety Culture Class

To improve ORA's ability to enhance inspectional training as part of the New Era of Smarter Food Safety initiative, ORA, and key stakeholders, including academia, developed a Food Safety Culture Class delivered by North Carolina State University (NCSU) Safer Plates program. More

than 1,000 FDA Food Program staff have been trained, along with 100 staff from regulatory partners. Course material was shared with competent authorities of foreign governments and is available to industry via the NCSU website. This course socializes the importance of food safety behaviors and advances FDA's food safety mission in educating regulated industry and protecting consumers.

Infant Formula

In response to the infant formula recall and shortage crisis, ORA worked closely with state partners on infant formula complaint investigations and sampling. To alleviate some of the supply chain demands, ORA inspected domestic and foreign infant formula and infant formula ingredient manufacturers seeking enforcement discretion. Additionally, ORA worked with CFSAN and foreign manufacturers to expedite the importation process for foreign firms who met the requirements of the "Infant Formula Enforcement Discretion Policy: Guidance for Industry" issued May 2022. Providing certain requirements were met, this allowed needed infant formula into the United States to meet the needs of consumers. In addition, ORA proactively improved the consumer complaint process to include required notification of senior officials of complaints that have potential for significant public health impact and added disposition targets to the complaint process. In January 2023, ORA worked with CFSAN subject matter experts to develop and deliver an infant formula workshop that offered modernized training for investigators. Currently ORA is developing a dedicated cadre of staff that will be responsible for leading and working alongside other trained ORA investigators to conduct all domestic and international infant formula inspections. The cadre is expected to be fully stood up in FY 2024.

Promoting an Integrated Food Safety System (IFSS)

ORA provides funding and programmatic support to SLTT regulatory jurisdictions to encourage robust oversight and ensure an IFSS. For example, in FY 2023, ORA awarded 85 contracts ($16.8 million total) to regulatory partners representing 44 states and Puerto Rico to enable approximately 8,600 inspections (including approximately 700 human food preventive controls inspections), and site visits. In addition, the FDA awarded 230 cooperative agreements and/or grants to all 50 states and 13 stakeholder associations ($99.1 million) to enhance program infrastructure, capacity, and capabilities that resulted in establishment of numerous education and outreach programs, inspection of thousands of produce farms by grantees and other oversight enhancements.

The FDA also signed three new Domestic Mutual Reliance Partnership Agreements with state programs in FY 2023, bringing the total to 13. These agreements coordinate efforts between the FDA and a state to advance mutual food safety goals and minimize duplication of effort by leveraging states' non-contract inspections and other activities to support and inform regulatory oversight.

Field Accomplishments - Cross Cutting

Remote Regulatory Assessment

At the onset of the COVID-19 pandemic, the FDA enhanced and expanded the use of a variety of oversight tools and developed new ways to optimize our surveillance and use new approaches to protect and promote public health when conducting inspections was difficult or not possible.

Remote regulatory assessments (RRAs) were developed and include voluntary interactive evaluations (such as remote livestreaming video of operations, teleconferences, and screen sharing) in addition to requests to review records and other information under existing statutory or regulatory authority. The FDA has used these tools, domestically and abroad, throughout the pandemic to provide important information that helps FDA maintain a level of regulatory oversight.

RRAs in support of oversight of drug manufacturing has also led to the issuance of warning letters, import alerts, as well as product application approval decisions; it was expanded to outsourcing facilities under section 503B of the FD&C Act. In FY 2022, ORA completed 179 RRAs for human and animal drug manufacturers. Additionally, ORA received and evaluated surveillance reports for foreign work from mutual recognition agreement partners and PIC/S inspectorates.

In FY 2022 designed a new approach to our oversight of foreign manufacturers that coupled RRAs, product sampling at the border, and importer inspections to provide an additional layer of regulatory oversight that did not previously exist. This program, Alternative Oversight of Foreign Facilities (AOFF), continued in FY 2023. In FY 2023, the agency covered 133 unique foreign suppliers as part of AOFF. Specifically, ORA conducted 57 RRAs, resulting in one voluntary recall, two warning letters issued and two firms added to import alert. Additionally, as part of AOFF we initiated 15 FSVP inspections and collected 211 target samples, 14 import lines being refused, and seven firm product combinations being added to import alert.

Expanding Public Health through Information Sharing

ORA engages with regulatory partners at all levels to share data and information to increase efficiency and public health and safety. This includes developing and maintaining IT systems used across FDA, industry, state, local and other regulatory partners to maximize the use and analysis of data collected during regulatory oversight and enforcement activities.

As a result of steps taken in FY 2020 to expand and implement agreements to share trade secret information with qualified foreign authorities according to section 708(c) of the FD&C Act, ORA responded to 201 requests in FY 2023 related to this authority, out of a total of 489 requests for information. Confidentiality commitments enable this information sharing (limited in scope to drugs only) with the competent authorities for each European Union Member State and United Kingdom.

ORA has expanded the ORA Data Exchange, used by domestic regulatory partners with sharing agreements to submit and review FDA data, to multiple agencies within 49 states. Information submitted by domestic regulatory partners ranges from laboratory analysis to inspections conducted on behalf of FDA to documents related to produce safety partnerships between states and FDA. In FY 2023 the ORA Data Exchange expanded options for submissions by domestic regulatory partners and made available methods for those partners to search FDA firm related information relevant to State activities. ORA is also engaged in a proof-of-concept phase with 20 state partners to expand information sharing using the Information Disclosure Portal (IDP) built

on the Food Shield platform. The platform provides a controlled electronic environment to share non-public information more efficiently than traditional email applications.

ORA continues to expand its Non-Contract Inspection Program under its Foods Program, which allows ORA to obtain state inspection findings from non-contract inspections for those states that voluntarily participate in the program. The information is used to inform inspection planning, improve efficiencies, and expand the agency understanding of regulated industry. In addition, ORA shares inspection findings with the states to expand their datasets and understanding of local regulated industry. FDA currently has long-term information sharing agreements with 380 local and state health departments. In FY 2023, ORA also developed and championed a new long--term information sharing agreement that creates efficiencies in allowing parent state health departments to seamlessly share with their local counterparts, providing a more rapid rate of transmission during times of emergency and outbreak. Several key partner states, including Texas, Wisconsin, and Michigan have expressed interest to sign in FY 2024. To date, ORA has received state inspection findings for more than 1,000 firms and is using the data to increase understanding of the inventory and streamline resource planning within ORA.

On May 31, 2023, FDA and the European Union expanded its MRA to include veterinary pharmaceuticals, allowing FDA to use good member practice inspection data from 16 EU member states who in turn will utilize FDA inspection data for their public health mission. Prior to this expansion, this MRA covered human pharmaceuticals only. It has proved a valuable public health tool, allowing FDA to classify 808 pharmaceutical inspections from our MRA partners to date of which 176 of those were classified in FY 2023. The MRA, and this expansion, allows FDA and our MRA partners to continue focusing on higher risk areas, leading to greater public health and safety.

On January 12, 2023, the FDA signed the Agreement on Mutual Recognition between the Swiss Confederation and the United States of America Relating to Pharmaceutical Good Manufacturing Practice. By signing such an agreement, with the Swiss Confederation (Switzerland), the FDA and the Swiss Agency for Therapeutic Products (Swissmedic) will be able to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities, avoiding the need for duplicate inspections. This memorandum of understanding (MOU) entered into force in July 2023 and allows both regulatory bodies to rely on the factual findings from each other's inspections thus avoiding duplicate inspections and allowing FDA to expand its inspectional reach even further.

Import Operations

Over the last decade, there has been a significant increase in FDA-regulated products introduced for import into the U.S. market (Table 1). While this growth has been difficult to match with available resources, ORA has made several advances in targeting and processing imported products for entry.

Program Area	2019	2020	2021	2022	2023	5 Yr Actual Percent Growth*	2023 Percent of Total Lines	Estimate 2024	Estimate 2025
Foods	17,722,742	16,983,686	18,651,210	19,344,104	18,988,802	1%	37.59%	19,178,690	19,757,886
Cosmetics	2,762,411	2,350,216	3,060,422	3,152,235	3,921,224	8%	7.76%	3,960,436	4,080,041
Human Drugs	838,267	959,585	1,003,661	1,021,775	1,028,742	4%	2.04%	1,039,029	1,070,408
Animal Drugs & Feeds	481,684	493,192	550,811	572,292	537,313	2%	1.06%	542,686	548,113
Biologics	181,328	152,158	177,977	64,884	60,026	-14%	0.12%	60,626	61,845
Medical Devices & Rad Health	22,967,758	22,512,049	25,521,999	25,521,999	25,710,505	2%	50.90%	25,967,610	26,751,832
Tobacco Products	280,901	275,261	263,943	229,389	266,131	-1%	0.53%	268,792	271,480
Total	45,235,091	43,726,147	46,788,819	49,906,678	50,512,743	2%	100.00%	51,017,870	52,541,606

*Percent growth based on a five-year average of actuals from FY 2019 - FY 2023

Figure 63 - Number of Import Lines by Program Area: FY 2019 through FY 2025 (Est.)

ORA oversees food importers through establishment of the remote inspection protocol for Foreign Supplier Verification Programs (FSVP) inspections. In FY 2023 ORA conducted 1,889 FSVP inspections of which 744 were conducted onsite and 1,155 were performed remotely. On January 10, 2023, FDA issued the FSVP final guidance. This guidance provides information to importers of human and animal food about how they can comply with the FSVP regulation. It includes recommendations on the requirements to analyze the potential hazards in food; evaluate a foreign supplier's performance and the risk posed by the food; and determine and conduct appropriate foreign supplier verification activities. The guidance also addresses how importers can meet modified FSVP requirements in a variety of categories, such as requirements for importers of dietary supplements or very small importers. The guidance finalizes a draft guidance issued in 2018. In response to comments received to the draft guidance, changes were made to the final guidance, including providing additional clarification regarding to what food the FSVP regulation applies; what information must be included in the FSVP; and who must develop and perform FSVP activities.

ORA continues implementation of the Voluntary Qualified Importer Program (VQIP). On January 1, 2023, the VQIP application portal became available and remained open to accept completed VQIP applications through May 31, 2023. This year, FDA received eight VQIP applications for FY 2024 benefits, including extensions from all six previously approved applicants from FY 2023. The associated information for all importers who have paid the user fee and have been approved for participation in this program may be found in the FDA Data Dashboard under "Approved VQIP Importers."

The FDA has been partnering with U.S. Customs and Border Protection (CBP) to monitor and target illegitimate imported shipments of xylazine, an animal drug increasingly found in the illicit drug supply, mixed with other drugs like fentanyl and heroin. In addition to collaborating across agencies, in February 2023, FDA published Import Alert 68-20, "Detention Without Physical Examination of Xylazine Active Pharmaceutical Ingredients (API) and Unapproved Finished Drug Products Containing Xylazine." The implementation of this import alert allows FDA to use targeted screening to identify future shipments from foreign suppliers known to have

previously provided unapproved xylazine for importation into the United States. As of August 29, 2023, four firms are listed on this import alert and subject to detention without physical examination.

Leveraging Laboratory Capabilities

FDA laboratories contribute to the Agency's mission through scientific testing on regulated products, applied research, and support of inspectional and compliance operations, as well as criminal investigations. Analyses performed in the laboratories include advanced vibrational spectroscopies, nuclear magnetic resonance, chemical separations, and mass spectrometry to detect and identify unapproved drugs and chemical contaminants in a vast variety of products including human and animal foods, vaping liquids, and drugs. Microbiological testing of foods and sterile medical products and whole genome sequencing (WGS) are also used for epidemiological trace-back based on genetic fingerprinting. ORA laboratories adhere to a strict quality system and regulatory standards framework for testing obligations and are all accredited to ISO 17025:2017 standard. ORA currently operates 15 laboratories at 12 locations across the United States and Puerto Rico and is in the process of expanding a satellite laboratory program at selected ports of entry. Satellite labs provide rapid screening and identification of unapproved, illicit, and counterfeit pharmaceuticals including opioids, and are currently operational in Chicago and Miami, with two additional locations planned to be online in FY 2024.

Data Modernization and Enhanced Technologies

ORA is committed to supporting expanded regulatory authorities, increasing productivity, and maintaining program integrity through its IT systems and initiatives. ORA continues to make progress to enhance and modernize its IT portfolio and expand functionality to encompass and support new regulatory requirements and business initiatives.

ORA continues researching and testing artificial intelligence (AI) machine learning (AI/ML) models to strengthen the ability to target which shipments of imported foods pose the greatest risk of violation and use that information to improve targeted import review resources.

Field Accomplishments – Enforcement

Compliance, Enforcement, and Criminal Investigation Activities

ORA investigates unlawfully marketed products that make claims but have not gone through FDA required processes to establish they prevent, treat, or cure diseases or other health condition. ORA has the primary responsibility for criminal investigations conducted by FDA and for all law enforcement and intelligence issues pertaining to threats against FDA-regulated products and industries. In FY 2023, criminal investigations led to 176 arrests and more than $976 million in forfeitures and seizures.

The COVID-19 pandemic, which has brought with it an illicit market of fraudsters and profiteers seeking to take advantage of the public health crisis, underscores the importance of FDA's criminal investigations. As of September 30, 2023, ORA opened approximately 174 criminal cases involving fraudulent COVID-19 products and obtained indictments in several of these cases. Many cases involve imported medical products, including unapproved drugs that are touted as "cures," bogus test kits, and substandard medical devices.

Enhancing Opioids Enforcement

In compliance with the 2018: SUPPORT for Patients and Communities Act (SUPPORT Act), the U.S. Postal Service (USPS) and FDA signed an MOU in July 2023 to develop and establish a bilateral electronic international mail data exchange service between USPS and FDA for parcels handled at the IMF. The new integration would unify data management and electronically share data between the USPS and FDA systems via a single access point, allowing both agencies to efficiently exchange data in lieu of manual data entry into individual agency IT systems. This will provide transparent real-time automated messaging on parcel tracking and disposition at the IMF and target suspected parcels to better keep noncompliant products away from U.S. consumers while minimizing unnecessary delays.

In October 2020, leadership from FDA, CBP, and the U.S. Immigration and Customs Enforcement, Homeland Security Investigations (ICE-HSI) signed an MOU to stop harmful products that pose a threat to public health and attempt to enter the United States through IMFs. To enhance collaboration and information sharing outlined in this MOU, FDA and CBP agreed upon a National Operational Strategy, which launched in FY 2022. This strategy targeted unapproved drugs and illegal opioids in the IMF and courier hubs. In FY 2022 and 2023, collaborative operations with CBP, successfully prevented more than 603,000 tablets/ capsules/pills of unapproved drugs and controlled substances (including opioids) from entering U.S. commerce.

The SUPPORT Act added section 801(u) to the FD&C Act, giving FDA authority to treat an FDA-regulated article as a drug if it is or contains an active pharmaceutical ingredient (API), if the article is an ingredient that presents significant public health concern. FDA continually updates the API list, to ensure the statutory criteria is met under 801(u) of the FD&C Act. using an established review process. Section 801(u) gave FDA more authority to limit importation, which helps reduce the domestic distribution of violative drugs. This helped lead to an increase in the overall refusal and destruction rate to more than 83 percent of violative refused drug products in FY 2023, an increase from the 48 percent refusal rate in FY 2019.

Enhancing Tobacco Enforcement

The "Deeming Rule," which published May 10, 2016, in the Federal Register, extended FDA's authority to "deem" electronic cigarettes, cigars, hookah, and pipe tobacco and their components and parts, as tobacco products. FDA further expanded its authority on March 15, 2022, by clarifying in the FD&C Act that FDA has jurisdiction over products containing nicotine from any source, including non-tobacco nicotine products. In FY 2023, ORA completed 143 inspections of domestic tobacco product manufacturers, 197 investigations, and three premarket tobacco application (PMTA) records assessments (via an RRA).

In January 2020, FDA published the guidance for industry, "Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization," to describe FDA's intent to prioritize enforcement resources regarding the marketing of certain deemed tobacco products that lack premarket authorization. To reduce availability of youth access to ENDS, ORA and CTP worked together to focus import surveillance activities of tobacco products, on flavored, cartridge-based ENDS products. The

enforcement strategy was further updated to include PMTA requirements for products that had a negative action on March 2021. In FY 2023 FDA examined more than 318 lines (a line is a distinct product, which may include one or more products, within a shipment) of ENDS products, and found 46 percent (or 143 lines) to be violative. However, due to enforcement constraints, such as pending litigation, FDA only refused admission to 21 of these otherwise violative lines. By leveraging FDA's partnership with CBP, the collaborating agencies have prevented violative ENDS products from reaching the U.S. consumer. In July 2023, CBP and FDA worked with other federal and state regulatory stakeholders to pilot a joint operation to leverage regulatory authorities across agencies and prevent entry of violative ENDS products. ORA and CTP expect to expand enforcement of ENDS products lacking market authorization, focusing on flavored products, during the first quarter of FY 2024. This expanded enforcement will allow ORA to verify market authorization for flavored ENDS, not just those receiving a negative action, furthering the FDA's efforts to reduce the availability of imported ENDS lacking market authorization in domestic commerce.

Managing a World-Class Workforce and Promoting a Culture of Excellence

Recruitment and Retention

ORA's ability to advance its mission of protecting and promoting public health relies on the ability to recruit and retain a highly skilled, professional workforce. From successfully filling vacancies to providing a pathway for career advancement, ORA ensures the best management practices are consistently used across the organization and throughout the employees' tenure.

To optimize hiring results, ORA uses consolidated and coordinated cohort hiring, talent acquisition planning, strategic hiring planning at the super-office level, targeted recruitment outreach, standardization of the interview and selection process, all direct hire methods, including Schedule A, veteran hiring, Pathways Internships, Commissioned Corps, and Title 21. ORA has had challenges in hiring since the termination of its direct hire authority for investigators, however managers are working hard to create a pipeline to close hiring gaps and retain a highly skilled workforce. ORA's overall employee count was 4,947 at the end of FY 2021 and 4,719 at the end of FY 2022. ORA's hiring goal for FY 2023 was to hire 100 full-time equivalents (FTEs). ORA met the hiring goal, gaining 331 FTEs by the end of the fiscal year, but did experience difficulties keeping up with attrition. With the expansion of Title 21 to include food and cosmetics positions, ORA has pivoted toward recruiting talent from the private sector via Title 21 and hopes to show gains in FY 2024.

In support of our public health mission, ORA's Office of Training Education and Development (OTED) provides training, education, and development programs to ORA's inspectional and managerial staff. In addition, OTED continues to offer free training to our SLTT regulatory partners – a critical part of developing and maintaining a regulatory workforce across the country. In FY 2023 ORA held 231 courses for 4,781 ORA and SLTT employees, through virtual instructor- led training, classroom, and blended training courses. In FY 2023, the FDA, in collaboration with nine stakeholder associations and the Partnership for Food Protection (PFP), have developed a 5-year strategic plan to design and implement an optimal, sustainable, integrated national regulatory & laboratory training system (RLTS) that supports the goals of an

IFSS. The strategic plan addresses training for FDA and SLTT regulators & laboratorians working in manufactured food, produce, eggs, animal food, retail food, Grade "A" milk, and molluscan shellfish. Having an optimal training system that does not rely solely on FDA to provide training to SLTT partners will increase access and availability to our SLTT partners and address attrition needs while being more efficient with federal monies. The IFSS Strategic Plan will be implemented in FY 2024.

PERFORMANCE

ORA's performance measures focus on import screening activities, laboratory capacity, and domestic and foreign inspections to ensure that food, feed, and medical products available to the American public are safe and effective, as detailed in the following table.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 +/- FY 2024
214221: Percentage of Human and Animal Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 98.9% Target: 80% (Target Exceeded)	80%	80%	Maintain
224221: Percentage of Human and Animal Drug significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 85.5% Target: 80% (Target Exceeded)	80%	80%	Maintain
234221: Percentage of Biologics significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 92.3% Target: 70% (Target Exceeded)	70%	70%	Maintain
254221: Percentage of Medical Device and Radiological Health significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 87.3% Target: 80% (Target Exceeded)	80%	80%	Maintain
214222: Percentage of Human and Animal Food follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 76.0% Target: 65% (Target Exceeded)	65%	65%	Maintain

Figure 64 - ORA Performance Table 1/2

224222: Percentage of Human and Animal Drug follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 45.7% Target: 55% (Target Not Met)	55%	55%	Maintain
234222: Percentage of Biologics follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 82.4% Target: 65% (Target Exceeded)	65%	65%	Maintain
254222: Percentage of Medical Device and Radiological Health follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 73.3% Target: 65% (Target Exceeded)	65%	65%	Maintain
253221: Percentage of Bioresearch Monitoring (BIMO) follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 100.0% Target: 65% (Target Exceeded)	65%	65%	Maintain
214206: Maintain accreditation for ORA labs. (Outcome)	FY 2023: 12 labs Target: 12 labs (Target Met)	12 labs	12 labs	Maintain
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). (Outcome)	FY 2023: 3,200 rad & 2,600 chem Target: 3,200 rad & 2,600 chem (Target Met)	3,200 rad & 2,600 chem	3,200 rad & 2,600 chem	Maintain

Figure 65 - ORA Performance Table 2/2

The following selected items highlight notable results and trends detailed in the performance table.

ORA Field Performance Measures

ORA's performance goals measure topics such as our commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to ORA regulatory impact on violators, and are tracked on a 3-year rolling basis. Due to the nature of regulatory actions and subsequent follow-up conducted by FDA, the duration of these events can vary considerably. After regulatory action, FDA also works to schedule follow-up after a reasonable time has passed to allow the firm to correct for the original violations. A 3-year rolling timeline also ensures tracking of all significant violations that require attention and allows for a more robust analysis.

ORA missed one of its eleven measures, associated with follow-up inspections of Human and Animal Drug firms. This measure is an outcome goal, which depends on the corrective actions made by the firms to bring themselves into compliance, for which ORA has no role or control.

Center components may work with firms to provide them guidance and evaluate corrective actions to help enable the firm to achieve compliance. Many violations found at a firm may take significant time and action before compliance can be reached. In some instances, firms do not come into compliance or other issues arise leading to another OAI finding upon re-inspection. While ORA believes this is an important outcome measure to encourage and measure firms' corrective actions, and expects to meet the targets going forward, it is important to recognize that ORA has limited ability to drive compliance, and the ultimate responsibility to comply rests with the firm itself.

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2023 Final	FY 2024 CR	FY 2025 PB
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,704***	***8,000***	***8,000***
Domestic Food Safety Program Inspections	5083	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.	
Imported and Domestic Cheese Program Inspections	11		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	201		
Domestic Fish & Fishery Products (HACCP) Inspections	497		
Import (Seafood Program Including HACCP) Inspections	111		
Juice HACCP Inspection Program (HACCP)	94		
Interstate Travel Sanitation (ITS) Inspections	585		
Domestic Field Exams/Tests	1,637	2,082	2,082
Domestic Laboratory Samples Analyzed	14,844	15,164	15,164
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS[1]	***1,243***	***1,230***	***1,230***
All Foreign Inspections	1,243	1,230	1,230
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***8,947***	***9,230***	***9,230***
IMPORTS			
Import Field Exams/Tests	89,832	140,673	140,673
Import Laboratory Samples Analyzed	16,843	17,609	17,609
Import Physical Exam Subtotal	**106,675**	**158,282**	**158,282**
Import Line Decisions	18,988,802	19,178,690	19,757,886
Percent of Import Lines Physically Examined	0.56%	0.83%	0.80%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***5,654***	***7,106***	***7,106***
State Contract Food Safety (Non HACCP) Inspections	***4,917***	***6,263***	***6,263***
State Contract Domestic Seafood HACCP Inspections	***507***	***679***	***679***
State Contract Juice HACCP	***34***	***46***	***46***
State Contract LACF/Acidified Food Inspections	***90***	***101***	***101***
State Contract Foods Funding	$13,628,431	$13,764,716	$13,902,363
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***14,601***	***16,336***	***16,336***

[1] The FY 2023 actual unique count of foreign inspections includes 133 OGPS inspections (71 for China, 56 for India, & 6 for Latin America).

Figure 66 – ORA Workload and Outputs 1/7

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2023 Final	FY 2024 CR	FY 2025 PB
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***49***	***65***	***65***
Domestic Inspections	49	65	65
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***1***	***0***	***0***
Foreign Inspections	1	0	0
IMPORTS			
Import Field Exams/Tests	5,378	4,883	4,883
Import Laboratory Samples Analyzed	381	390	390
Import Physical Exam Subtotal	**5,759**	**5,890**	**5,890**
Import Line Decisions	3,921,224	3,960,436	4,080,041
Import Line Decisions	0.15%	0.15%	0.14%
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***50***	***65***	***65***

Figure 67 – ORA Workload and Outputs 2/7

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2023 Final	FY 2024 CR	FY 2025 PB
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,407***	***1,414***	***1,414***
Pre-Approval Inspections (NDA)	64	70	70
Pre-Approval Inspections (ANDA)	51	80	80
Bioresearch Monitoring Program Inspections	503	571	571
Drug Processing (GMP) Program Inspections	379	540	540
Compressed Medical Gas Manufacturers Inspections	16	33	33
Adverse Drug Events Project Inspections	41	66	66
OTC Monograph Project and Health Fraud Project Inspections	4	15	15
Compounding Inspections[1]	40	110	110
Domestic Laboratory Samples Analyzed	741	970	970
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS[2,3]	***864***	***983***	***983***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	***104***	***105***	***105***
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	***197***	***200***	***200***
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	***240***	***245***	***245***
Foreign Drug Processing (GMP) Program Inspections	***410***	***531***	***531***
Foreign Adverse Drug Events Project Inspections	***6***	***8***	***8***
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,911***	***2,397***	***2,397***
IMPORTS			
Import Field Exams/Tests	7,328	7,600	7,600
Import Laboratory Samples Analyzed	1033	885	885
Import Physical Exam Subtotal	**8,361**	**8,025**	**8,025**
Import Line Decisions	1,028,742	1,039,029	1,070,408
Percent of Import Lines Physically Examined	0.81%	0.82%	0.75%
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,911***	***2,397***	***2,397***

[1] The number of compounding inspections includes inspections of compounders that are not registered with FDA as outsourcing facilities.

[2] The FY 2023 actual unique count of foreign inspections includes 86 OGPS inspections (17 for China, 69 for India, and 0 for Latin America).

[3] Count of "Third Party" Foreign Inspections 28 (not included in Overall counts above)

Figure 68 – ORA Workload and Outputs 3/7

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2023 Final	FY 2024 CR	FY 2025 PB
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,306***	***1,682***	***1,682***
Bioresearch Monitoring Program Inspections	158	160	160
Blood Bank Inspections	383	689	689
Source Plasma Inspections	194	206	206
Pre-License, Pre-Market Inspections	108	69	69
GMP Inspections	25	40	40
GMP (Device) Inspections	8	10	10
Human Tissue Inspections	437	517	517
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***79***	***81***	***81***
Bioresearch Monitoring Program Inspections	27	30	30
Foreign Human Tissue Inspections	4	5	5
Blood Bank Inspections	6	7	7
Pre-License, Pre-market Inspections	6	5	5
GMP Inspections (Biologics & Device)	35	33	33
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***1,385***	***1,763***	***1,763***
IMPORTS			
Import Field Exams/Tests	296	300	300
Import Line Decisions	60,026	60,626	61,845
Percent of Import Lines Physically Examined	0.49%	0.49%	0.49%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,385***	***1,763***	***1,763***

Figure 69 – ORA Workload and Outputs 4/7

Field Animal Drugs & Foods Program Activity Data (PAD)									
Field Animal Drugs and Feeds Program Workload and Outputs	**FY 2023 Final**			**FY 2024 CR**			**FY 2025 PB**		
	Total	**Animal Drugs**	**Feeds**	**Total**	**Animal Drugs**	**Feeds**	**Total**	**Animal Drugs**	**Feeds**
FDA WORK									
DOMESTIC INSPECTIONS									
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***1,138***	***80***	***1,058***	***1,371***	***117***	***1,254***	***1,371***	***117***	***1,254***
Pre-Approval /BIMO Inspections	24	24	0	36	36	0	36	36	0
Drug Process and New ADF Program Inspections	52	52	0	75	75	0	75	75	0
BSE Inspections	156	0	156	200	0	200	200	0	200
Feed Contaminant Inspections	0	0	0	2	0	2	2	0	2
Illegal Residue Program Inspections	153	0	153	200	0	200	200	0	200
Feed Manufacturing Program Inspections	203	0	203	205	0	205	205	0	205
Domestic Laboratory Samples Analyzed	810	0	810	981	5	976	981	5	976
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS[1]	***67***	***46***	***21***	***61***	***46***	***15***	***61***	***46***	***15***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	15	15	0	15	15	0	15	15	0
Foreign Drug Processing and New ADF Program Inspections	35	35	0	35	35	0	35	35	0
Foreign Feed Inspections	2	0	2	2	0	2	2	0	2
BSE Inspections	3	0	3	2	0	2	2	0	2

Figure 70 – ORA Workload and Outputs 5/7

TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***1,205***	***126***	***1,079***	***1,432***	***163***	***1,269***	***1,432***	***163***	***1,269***
IMPORTS									
Import Field Exams/Tests	3219	362	2857	3836	711	3125	3836	711	3125
Import Laboratory Samples Analyzed	536	0	536	798	0	798	798	0	798
Import Physical Exam Subtotal	**3755**	**362**	**3393**	**4634**	**711**	**3923**	**4634**	**711**	**3923**
Import Line Decisions	537,313	74,414	462,899	542,686	75,158	467,528	548,113	75,910	472,203
Percent of Import Lines Physically Examined	0.70%	0.49%	0.73%	0.85%	0.95%	0.84%	0.85%	0.94%	0.83%
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***2,055***	***0***	***2,055***	***2,055***	***0***	***2,055***	***2,055***	***0***	***2,055***
State Contract Inspections: BSE	1,389	0	1,389	1,389	0	1,389	1,389	0	1,389
State Contract Inspections: Feed Manufacturers	447	0	447	447	0	447	447	0	447
State Contract Animal Feeds Funding	$2,946,845	0	$2,946,845	$2,976,313	0	$2,976,313	$3,006,076	0	$3,006,076
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***3,260***	***126***	***3,134***	***3,487***	***163***	***3,324***	***3,487***	***163***	***3,324***

[1] The FY 2023 actual unique count of foreign inspections includes 4 OGPS inspections (3 for China and 1 for India).

Figure 71 - ORA Workload and Outputs 6/7

Field Devices and Radiological Health Program Activity Data (PAD)

Field Devices and Radiological Health Program Workload and Outputs	FY 2023 Final	FY 2024 CR	FY 2025 PB
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,010***	***2,297***	***2,297***
Bioresearch Monitoring Program Inspections	208	230	230
Pre-Market Inspections	52	55	55
Post-Market Audit Inspections	3	24	24
GMP Inspections	941	1,143	1,143
Inspections (MQSA) FDA Domestic (non-VHA and VHA)	820	825	825
Domestic Radiological Health Inspections	30	77	77
Domestic Field Exams/Tests	12	27	27
Domestic Laboratory Samples Analyzed	102	125	125
FOREIGN INSPECTIONS	***443***	***466***	***466***
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS[1]			
Foreign Bioresearch Monitoring Inspections	9	12	12
Foreign Pre-Market Inspections	36	40	40
Foreign Post-Market Audit Inspections	22	25	25
Foreign GMP Inspections	369	375	375
Foreign MQSA Inspections	7	11	11
Foreign Radiological Health Inspections	40	45	45
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***2,453***	***2,763***	***2,763***
Import Field Exams/Tests	14,917	22,435	22,435
Import Laboratory Samples Analyzed	223	485	485
Import Physical Exam Subtotal	**15,140**	**22,920**	**22,920**
Import Line Decisions	25,710,505	25,967,610	26,751,832
Percent of Import Lines Physically Examined	0.06%	0.09%	0.09%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***7,557***	***7,504***	***7,504***
Inspections (MQSA) by State Contract	7,533	7,535	7,535
GMP Inspections by State Contract	24	36	36
State Contract Devices Funding	$241,465	$243,879	$246,318
State Contract Mammography Funding	$12,735,457	$12,862,812	$12,991,440
Total State Funding	**$12,976,922**	**$13,106,691**	**$13,237,758**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***10,010***	***10,256***	***10,256***

[1] The FY 2023 actual unique count of foreign inspections includes 15 OGPS inspections (11 China and 4 for India)

Figure 72 – ORA Workload and Outputs 7/7

TOBACCO CONTROL ACT

PURPOSE STATEMENT

The Center for Tobacco Products (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA works to protect the public health of the U.S. population from tobacco-related death and disease by comprehensively regulating the manufacture, distribution, and marketing of tobacco products; educating the public, especially youth, about the dangers of using tobacco products; and promoting and supporting strategies that ensure an equitable chance at living a healthier life for everyone.

FDA executes regulatory and public health responsibilities in program areas that support the following objectives:

- Reducing initiation of tobacco product use
- Encouraging cessation among tobacco product users
- Decreasing the harms of tobacco products

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31); The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333); Public Health Service Act of 1944 (42 U.S.C. 201); Federal Advisory Committee Act of 1972, as amended.

Allocation Methods: Competitive Grants; Contracts; Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
Tobacco	**765,697**	**746,518**	**677,165**	**684,324**	**798,588**	**121,423**
User Fees	***765,697***	***746,518***	***677,165***	***684,324***	***798,588***	***121,423***
Center	746,810	725,178	654,671	661,627	775,891	121,220
Field	18,887	21,340	22,494	22,697	22,697	203
FTE	**1,228**	**1,259**	**1,303**	**1,303**	**1,363**	**60**

Figure 73 - CTP Funding History Table

The FY 2025 President's Budget is $798,588,000, which is all user fees. $775,891,000 is for the Center for Tobacco Products and $22,697,000 for the Office of Regulatory Affairs (ORA). This is an increase of $121,423,000 above the FY 2023 Final Level.

The budget requests user fees in the amount of $114,230,000 above the FY 2025 level authorized in the Tobacco Control Act for a total of $826,230,000, less the amounts for GSA Rent ($9,877,000), FDA Headquarters ($11,365,000), FDA White Oak Campus ($3,176,000) and Other Rent and Rent Related ($4,626,000), which are shown in their own sections of the budget request.

USER FEES

Section 919 of the of the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to assess user fees on tobacco products that fall within six product classes: cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. Currently, the Tobacco Control Act does not provide a means for FDA calculation and collection of user fees for electronic nicotine delivery systems (ENDS) products – which include e-cigarettes – and certain other deemed and

novel products. These products represent an increasing share of FDA's tobacco regulatory activities. The effectiveness of the tobacco program will continue to be diminished as fixed costs rise and the Agency is forced to continue spreading its flat budget of $712 million across all regulated products, including ENDS, both those containing tobacco-derived nicotine and those containing non-tobacco nicotine (NTN), which includes synthetic nicotine. Therefore, FDA requests an additional $114.2 million in user fees. This request includes $100 million and the authority to include manufacturers and importers of all deemed products among the tobacco product classes for which FDA assesses tobacco user fees. This request also includes an increase of $14.2 million to adjust the currently authorized collections of $712 million to inflation. To ensure that resources keep up with all tobacco products, the proposal would also index future collections to inflation. This additional funding will support hiring more staff and help FDA bolster its tobacco product regulatory activities – including those related to application reviews, compliance and enforcement, policy development, and research programs, as it works to reduce tobacco related disease and death.

This proposal would ensure that FDA has the resources to address all regulated tobacco products, including e-cigarettes, which are the most used tobacco product by youth, as well as future novel products.

Strategic Priorities and Strategic Planning

In response to an evaluation by an independent expert panel facilitated by the Reagan-Udall Foundation, CTP initiated the development of a new comprehensive 5-year strategic plan, which was published on December 18, 2023. The plan's development has been a key center priority and was informed by engagement with an array of external stakeholders through a public comment period and listening session.

CTP's Strategic Plan represents a new chapter that builds upon the strong foundation that was established and has been cultivated since the center's inception in 2009. Guided by this plan, CTP aims to reduce the negative health effects caused by tobacco use by ensuring a well--regulated marketplace, preventing people from starting to use tobacco products, encouraging people who use tobacco products to quit, and reducing the harm caused by tobacco product use.

The CTP Strategic Plan defines five goals:

- Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance
- Ensure Timely, Clear, and Consistent Product Application Review
- Strengthen Compliance of Regulated Industry Utilizing All Available Tools, Including Robust Enforcement Actions
- Enhance Knowledge and Understanding of the Risks Associated with Tobacco Product Use
- Advance Operational Excellence

These goals are reinforced by four cross-cutting themes that are emphasized throughout the plan: science, health equity, stakeholder engagement, and transparency. The goals, outcomes, objectives, and cross-cutting themes outlined in this strategic plan will facilitate meaningful advancements in our mission to make tobacco-related disease and death part of America's past, not our future.

Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance

Section 907 of the FD&C Act gives FDA the authority to issue, via notice-and-comment rulemaking, tobacco product standards that are appropriate for the protection of the public health. This authority is one of the most powerful tools that FDA has to regulate tobacco products. FDA has been working toward the issuance of final proposed product standards to prohibit menthol as a characterizing flavor in cigarettes[92] and to prohibit characterizing flavors (other than tobacco) in cigars.[93]

These product standards are based on clear science and evidence establishing the addictiveness and harm of these products. These actions will decrease initiation, experimentation, and progression to regular smoking among nonusers, particularly youth and young adults, and increase the likelihood that current smokers will stop smoking. Additionally, these actions are also expected to substantially decrease tobacco-related health disparities and to advance health equity across population groups. These groups include some racial and ethnic populations, those with lower household income and educational attainment, and individuals who identify as lesbian, gay, bisexual, transgender, queer, intersex, and other sexual and gender minority populations (LGBTQI+), all of whom are particularly burdened by tobacco-related morbidity and mortality.

The Spring 2023 Unified Agenda of Regulatory and Deregulatory actions included FDA's plans to develop a proposed product standard that would establish a maximum nicotine level to reduce the addictiveness of cigarettes and certain other finished tobacco products.[94] The goals of the proposed rule would be to reduce the addictiveness of cigarettes and certain other finished tobacco products, thus giving those who are addicted to smoking a greater ability to quit as well as to help prevent experimenters (mainly youth) from initiating regular use and becoming regular smokers. Each year, 480,000 people die prematurely from a smoking attributed- disease, making tobacco use the leading cause of preventable disease and death in the United States. Additionally, cigarette use alone costs $600 billion a year in direct health care and lost productivity due to morbidity and premature mortality from smoking and secondhand smoke exposure.[95]

Addiction to nicotine in combusted products is the main driver of sustained use of these products. Such a product standard, if proposed and then finalized after a thorough process that would include a public notice and comment period, would render these products minimally addictive or non-addictive. Lowering nicotine levels to minimally addictive or non-addictive levels would decrease the likelihood that future generations of young people become addicted to cigarettes and certain other combusted tobacco products and help more currently addicted smokers to quit.

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[92] https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes

[93] https://www.federalregister.gov/documents/2022/05/04/2022-08993/tobacco-product-standard-for-characterizing-flavors-in-cigars

[94] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0910-AI76

[95] https://www.sciencedirect.com/science/article/pii/S074937972200294X?via%3Dihub

Ensure Timely, Clear, and Consistent Product Application Review

FDA serves as a critical public health gatekeeper between tobacco product manufacturers and consumers by performing scientific review before new tobacco products and modified risk tobacco products (MRTPs) are authorized to be commercially marketed and sold. Manufacturers are required to obtain FDA authorization before marketing new tobacco products[96] or MRTPs.[97]

Foundational rules, such as one that sets forth content and format requirements for premarket tobacco product applications (PMTAs) and requirements for manufacturers to maintain records establishing that their tobacco products are legally marketed have been finalized. Work continues on others, such as a proposed rule that would establish content and format requirements for modified risk tobacco product applications (MRTPAs). In addition to developing rules and guidances, CTP regularly evaluates the application review process to identify areas where process improvements could enhance CTP work efficiencies. CTP is also taking several actions to strengthen the premarket review program, to include hosting public meetings, in response to recommendations from the RUF evaluation. Further, CTP is hiring additional scientific and regulatory staff to review new product applications.

Strengthen Compliance of Regulated Industry Utilizing All Available Tools, Including Robust Enforcement Actions

FDA focuses on the utilization of a national program of inspections, investigations, monitoring, and review of tobacco products, sales, manufacturing, and advertising. FDA's compliance programs ensure that regulated companies and tobacco products comply with the FD&C and related regulations. FDA will continue to take vigorous compliance and enforcement actions aimed at unauthorized tobacco products that remain on the market and ensure that tobacco products are not being marketed and/or sold to underage persons.

Continued planned activities FDA is currently prioritizing include:

- Investigating whether manufacturers may be manufacturing and/or marketing ENDS. products, including those containing NTN, that have not gone through premarket review or received a negative marketing order from the Agency.
- Identifying and enforcing on unauthorized ENDS on the market to best prevent youth use of these products.
- Conducting inspections and investigations at brick-and-mortar retail locations.
- Conducting inspections of tobacco manufacturing facilities and remote regulatory assessments when necessary.
- Inspecting vape shops to ensure that they are in compliance with the requirements of the FD&C Act and regulations.

[96] A "new tobacco product" is any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

[97] A "modified risk tobacco product" is any tobacco product that is sold or distributed for use to reduce harm, or the risk of tobacco-related disease associated with commercially marketed tobacco products.

- Investigating manufacturers' internet storefronts and distribution practices, other online retailers, and taking enforcement actions if violations of the restrictions, including online sales to underage persons, are found.
- Enforcing manufacturing, importation, sales, distribution, marketing, promotion, advertising, and labeling requirements including for products containing NTN, by issuing Import Alerts, Civil Money Penalties (CMPs), No-Tobacco-Sale Orders (NTSOs) or other actions such as injunctions, seizures.
- Referring potential criminal activity to FDA's Office of Criminal Investigations for criminal prosecution.
- Informing small businesses of existing guidances, regulations, and submission pathways through publications and online webinars and answering questions from regulated industry.

CTP is taking several actions to address recommendations in the RUF evaluation, including:

- Continuing to collaborate closely with senior officials from the U.S. Department of Health and Human Services (HHS) Office of General Counsel (including FDA Office of Chief Counsel), FDA Office of the Commissioner, and U.S. Department of Justice (DOJ) on issues related to enforcement.
- Routinely meeting with federal partners – including the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), the Federal Trade Commission (FTC), and U.S. Customs and Border Protection (CBP) – to discuss opportunities for sharing information and leveraging resources to support enforcement actions.
- Improving transparency regarding compliance and enforcement through website updates, including making our website easier to use and understand.

Enhance Knowledge and Understanding of the Risks Associated with Tobacco Product Use

Using a variety of communication methods and platforms, CTP ensures the general public and stakeholders understand tobacco regulations, their importance for public health, and the impacts or consequences that happen if there is non-compliance with regulatory actions.

CTP also maximizes impact on public health by focusing public education campaign efforts on at-risk populations, such as youth who are experimenting with tobacco or are susceptible to use. To address high use rates among youth, CTP will continue to prioritize e-cigarette prevention media campaigns tailored for youth that will be informed by findings from formative research, market intelligence perception and brand surveillance, results of outcome evaluations and real-time monitoring and surveillance efforts, as well as changes in youth tobacco use trends.

FDA will also continue to:

- Ensure the general public understands tobacco regulation and its importance for public health by developing and making accessible plain language communication material using a variety of communication methods and platforms.
- Cultivate relationships with stakeholders to build and augment broad awareness of, and familiarity with, the Center's regulatory priorities and actions.
- Design, implement, and evaluate paid media campaigns, informed by research to effectively educate at-risk populations, especially young people, about the dangers of using tobacco products.

- Develop and disseminate education materials for adults to communicate the benefits of cessation, address misperceptions, and provide cessation resources in partnership with the National Institutes of Health (NIH)'s National Cancer Institute (NCI) and public health organizations.
- Expand the Tobacco Education Resource Library,[98] which provides free youth tobacco prevention and adult cessation resources to partners in public health and local organizations.
- Expand the Vaping Prevention and Education Resource Center by developing new and innovative resources for middle and high school educators and parents. [99]
- Raise tobacco retailers' awareness and understanding of FDA tobacco regulations and requirements to encourage voluntary compliance through the "This is Our Watch" Retailer Education initiative. [100]
- Conduct research to understand consumer and healthcare practitioner perceptions about cessation, nicotine, and relative risk of tobacco products, including studies to ensure that messages have no unintended effects among youth and former smokers.
- Foster tobacco regulatory research through the Tobacco Regulatory Science Program (TRSP), an interagency partnership between the NIH and FDA CTP, by publishing a Notice of Funding Opportunity for "Public Health Communication Messaging about the Continuum of Risk for Tobacco Products" to award a single Research Project Cooperative Agreement which will utilize health communication research to better understand the impact that messaging about the continuum of risk for tobacco products may have on various segments of the population.

CTP is taking several actions to address recommendations in the RUF evaluation, including:

- Continuing to solicit input on our campaigns, including from the general public.
- Updating the public education webpages to share information documenting the importance of, and opportunities to provide input into, CTP's campaign program.
- Routinely sharing the latest center updates with the public, including through published statements, email updates, and posts on social media on topics such as premarket review, compliance and enforcement, and other center news.

Advance Operational Excellence

FDA is committed to continually advancing operational enhancements and fostering initiatives that encourage innovation, collaboration, and knowledge sharing. CTP aims to optimize business processes and service-oriented solutions, focusing on strategic IT development and operational optimization. By facilitating IT development and enhancements that produce integrated IT and data platforms while optimizing IT system efficiency, the center will reduce redundancy and costs and relatedly, ensure data protection and privacy.

[98] https://digitalmedia.hhs.gov/tobacco/

[99] https://digitalmedia.hhs.gov/tobacco/educator_hub

[100] https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/our-watch

FDA is focused on growing our workforce to support our strategic initiatives and continues to invest in the agency's workforce by continually assessing workloads and identifying strategies to help manage work-life balance, strengthening retention, and anticipating future staffing needs. To support these efforts, in October 2023, CTP received Direct Hire Authority from the Office of Personnel Management for eight mission critical series. This authority provides CTP the ability to expedite the hiring process and swiftly fill essential vacancies throughout the Center.

FDA is committed to diversity, equity, inclusion, and accessibility (DEIA) to cultivate an engaged workforce that reflects the country it serves. Among other activities, CTP offers DEIA trainings to staff and prioritizes recruitment of highly qualified diverse candidates.

FDA's request also includes a proposal to extend the hiring authorities in the 21st Century Cures Act (Cures Act) to the Agency's tobacco program to improve its ability to recruit, hire, and retain personnel with the needed skills to effectively meet its public health mandate. This authority would help CTP address a variety of challenges that have delayed the hiring of highly qualified staff, especially for tobacco product premarket review. The RUF evaluation recommended FDA seek this authority.

Additional Support Activities

FDA will continue to:

- Partner with other agencies and centers, including NIH, CDC, and FDA's National Center for Toxicological Research (NCTR) to expand the tobacco regulatory science base and fund priority Tobacco Regulatory Science (TRS) research.
- Fund new research projects through NIH to address FDA time-sensitive research.
- Fund the Population Assessment of Tobacco and Health (PATH) Study analyses and sub studies via NIH to more comprehensively examine new and emerging issues related to tobacco use behavior and health.
- Examine the prevalence of tobacco product use among middle and high school students, including e-cigarettes.
- Collect and analyze PATH Study participant responses and biomarker data to assess tobacco use transitions over time among youth and adults.
- Conduct targeted priority research with contract research organizations.
- Develop and enhance enterprise IT systems to support the tracking, management, and review of product applications and data, along with research and administrative activities to improve management and analysis of scientific and regulatory data.
- Conduct surveillance and evaluation of tobacco products and the use of such products by monitoring data sources such as national surveys and retail sales data, and reviewing adverse events reporting, such as all reports submitted by the public through the Safety Reporting Portal to identify new or concerning trends in an evolving marketplace.

In addition, FDA is continuing efforts with the Nicotine Steering Committee, which includes representatives from CTP, CDER, CDRH, and FDA's Office of the Commissioner. Efforts include:

- Continuing work to develop options for a comprehensive regulatory approach to nicotine containing products.
- Seeking opportunities for cross-agency efforts to promote tobacco cessation.
- Exploring options for expanding pharmacotherapies and other means for treating nicotine addiction and promoting cessation.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

FDA takes a comprehensive approach to reduce the negative health effects of tobacco use by issuing regulations, conducting research, educating Americans on tobacco products, and enforcing the law when violations are found. The Agency also reviews and evaluates applications for new and modified risk tobacco products to determine if those products are allowed on the market.

Some of FDA's authorized activities include:

- Inspecting tobacco product manufacturing establishments and tobacco retailers to ensure compliance with laws and regulations.
- Establishing tobacco product standards to protect public health.
- Issuing regulations on the marketing and advertising of tobacco products.
- Establishing and strengthening health warnings for tobacco products.
- Taking enforcement action for violations of the Tobacco Control Act and implementing regulations.

The following selected accomplishments demonstrate FDA's delivery of its regulatory and public health responsibilities.

Regulation

The Tobacco Control Act gave FDA immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and in 2016 FDA finalized a rule – Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act) – which extended FDA's tobacco authorities to all tobacco products, including cigars, hookah (waterpipe) tobacco, pipe tobacco, nicotine gels, and e-cigarettes.

In April 2022, Congress passed a law clarifying FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine.

On March 8, 2023, FDA proposed new requirements for tobacco product manufacturers regarding the manufacture, design, packing and storage of their products. [101] These proposed requirements would help protect public health by, among other things, minimizing or preventing contamination and limiting additional risks by ensuring product consistency. FDA held a public oral hearing on April 12, 2023, to gather additional comments from stakeholders, including industry, the scientific community, advocacy groups, and the public on the proposed requirements. FDA also held a meeting of the Tobacco Products Scientific Advisory Committee (TPSAC) on May 18, 2023, to seek recommendations from the Agency's outside panel of experts on the requirements laid out in the proposed rule. The proposed rule was also available

[101] https://www.fda.gov/news-events/press-announcements/fda-proposes-new-requirements-tobacco-product-manufacturing-practices

for public comment for 210 days. The agency reviews all comments as part of the rulemaking process.

In FY 2023, FDA continues to work to finalize product standards to prohibit menthol as a characterizing flavor in cigarettes[102] and prohibit all characterizing flavors (other than tobacco) in cigars.[103] The Agency also continues to develop a proposed product standard that would establish a maximum nicotine level to reduce the addictiveness of cigarettes and certain other combusted tobacco products.[104]

Product Review and Evaluation

FDA's authority to regulate tobacco products includes premarket review of new tobacco products and marketing review of modified risk tobacco products (MRTPs) to determine if the applicable statutory standard is met.

New tobacco products are submitted for FDA review under one of these three marketing pathways:

- Premarket tobacco product application (PMTA)
- Report demonstrating substantial equivalence (SE Report) to a valid predicate tobacco product
- Request for exemption from demonstrating substantial equivalence (EX REQ)

MRTPs are submitted for FDA review under the modified risk tobacco product application (MRTPA) pathway.

FDA has made considerable progress in reviewing the unprecedented volume of applications for more than 26 million tobacco products that have been submitted over the last three years — completing acceptance review of 99 percent of submissions to date. FDA posts current data on its Tobacco Product Application Metrics & Reporting webpage.[105]

PMTA, SE, and EX REQ Review

Under the PMTA pathway, manufacturers must demonstrate to FDA that the marketing of the new tobacco product would be appropriate for the protection of the public health (APPH). This standard requires FDA to consider the risks and benefits to the population, including users and non-users of tobacco products. As of September 30, 2023, FDA has authorized the marketing of 45 products through the PMTA pathway, including 23 tobacco-flavored e-cigarette products and devices.[106]

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[102] https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes

[103] https://www.federalregister.gov/documents/2022/05/04/2022-08993/tobacco-product-standard-for-characterizing-flavors-in-cigars

[104] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0910-AI76

[105] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting

[106] https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders

As of September 30, 2023, FDA has issued Marketing Denial Orders (MDOs) to approximately 330 companies, which collectively manufacture and market approximately over 1.2 million products. [107] In addition to these MDOs, FDA has issued Refuse to Accept (RTA) and Refuse to File (RTF) actions for approximately 24.8 million products These products are not legally marketed or distributed in the United States, and retailers who sell these illegal products risk FDA enforcement action.

Under the SE pathway, manufacturers may submit regular or provisional SE Reports to seek FDA authorization to legally market a new tobacco product.[108] FDA has built a science-based process to review these SE Reports to determine whether the new product is substantially equivalent to a valid predicate product. "Regular SE Reports" are those Substantial Equivalence Applications that require a marketing authorization prior to being introduced to the U.S. market. "Provisional SE Reports" are applications for new tobacco products that meet the following criteria: (1) the SE Report was submitted by March 22, 2011; and (2) the products were introduced or delivered for introduction into interstate commerce for commercial distribution in the U.S. after February 15, 2007, and prior to March 22, 2011.

A tobacco product that is substantially equivalent is one that FDA has determined has the same characteristics as a predicate tobacco product or has different characteristics than the predicate tobacco product, but the information submitted by the applicant demonstrates that marketing the product does not raise different questions of public health.[109]

FDA reviews SE Reports to determine if the new tobacco product is substantially equivalent to the predicate tobacco product and is in compliance with the requirements of the FD&C Act. If both criteria are met, FDA issues an order permitting the product to be legally marketed in the United States. As of September 30, 2023, FDA has received over 15,000 product applications and has closed over 58 percent of these.

An EX REQ can be submitted by the original manufacturer for any new tobacco product seeking an exemption order.[110] FDA may issue an exemption order for a new tobacco product if FDA determines that: (1) the new tobacco product is modified by adding or deleting a tobacco additive or increasing or decreasing the quantity of an existing tobacco additive; (2) the proposed modification is minor and to a legally marketed tobacco product; (3) an SE Report is not necessary; and (4) an exemption is otherwise appropriate. An Abbreviated Report must be submitted to FDA after an exemption order is issued and is required to legally market a new tobacco product. As of September 30, 2023, FDA has received over 4,800 product applications and has closed nearly 78 percent of these.

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[107] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Marketing%20Denial

[108] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/substantial-equivalence

[109] A valid predicate tobacco product is one that was commercially marketed in the United States – other than for test marketing – as of February 15, 2007, or a product previously found to be substantially equivalent by FDA.

[110] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/exemption-substantial-equivalence

Modified Risk Tobacco Products

A MRTP is any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Before marketing a MRTP, manufacturers must submit a MRTPA and receive an FDA order authorizing that the product reduces harm or the risk of tobacco-related disease. As of September 30, 2023, FDA has received 65 MRTP applications. FDA issued one Modified Risk Granted Order (MRGO) in FY 2023 for a snuff smokeless tobacco product, which authorizes the product to be marketed with a specific claim related to reduced risk of lung cancer if cigarette smokers switch completely to it.[111] FDA posts publicly available materials from past MRTPAs, and those under review.[112]

Research

FDA invests in research to inform regulatory actions by addressing scientific knowledge gaps, enhancing scientific understanding, and encouraging research that addresses eight Scientific Domains.[113] In FY 2023, FDA invested more than $165 million in scientific research through collaborations with NIH and CDC, and to various research organizations. This research focuses on reducing youth initiation of tobacco use, reducing tobacco product harms to ensure that products on the market are appropriate for the protection of the public health, and encouraging those who already use tobacco products to quit or switch to tobacco products that have received a modified risk order from FDA.

In addition to conducting independent research to support regulatory science, CTP partners with several other FDA Centers including NCTR, Center for Food Safety and Nutrition (CFSAN), and FDA's Southeast Tobacco Laboratory, as well as other governmental agencies, including NIH and CDC. By leveraging the expertise of other federal agencies, FDA brings science-based regulation to the manufacturing, marketing, and distribution of tobacco products.

NIH Tobacco Regulatory Science Program (TRSP)

Through a collaboration with NIH, FDA is able to tap into NIH's well-established infrastructure for the solicitation, review, and management of scientific research. FDA works with TRSP to stimulate tobacco regulatory research and fund projects to study FDA research priority areas. In FY 2023, FDA funded more than 140 research projects via NIH TRSP. These research projects include grants which will address important FDA research priorities.[114]

A key component of the CTP–NIH TRSP collaboration includes funding the Tobacco Centers of Regulatory Science (TCORS). The objective of TCORS is to conduct multidisciplinary research that will inform and assess FDA's prior, ongoing, and potential regulatory activities. TCORS investigators also have the flexibility and capacity to respond to FDA's research needs as issues

[111] https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-granted-orders-promotion/modified-risk-granted-orders

[112] https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products#under-review

[113] https://www.fda.gov/tobacco-products/research/research-priorities

[114] https://prevention.nih.gov/tobacco-regulatory-research

are raised in today's rapidly evolving tobacco marketplace. In FY 2023, FDA awarded the third round of TCORS through NIH TRSP.

On June 1, 2023, FDA announced that CTP and NIH awarded funding for a Center for Rapid Surveillance of Tobacco (CRST). Through rapid surveillance and reporting of information, CRST will enhance CTP and the research community's ability to understand, document, and quantify changes in the tobacco product marketplace and tobacco use patterns. CRST will support time-sensitive data acquisition strategies, data harmonization, data synthesis and analysis, and reporting activities on emerging and current tobacco use.

Population Assessment of Tobacco and Health (PATH) Study

FDA funds the PATH Study via NIH's National Institute on Drug Abuse (NIDA),[115] with NIH contributing co-funding in FY 2024 and both agencies collaborating on the scientific aspects of the study. Additional NIH collaborators were added in FY 2023. The PATH Study is an ongoing nationally representative, longitudinal cohort study of approximately 46,000 users of tobacco products and those at risk for tobacco use with a national sample of U.S. civilian, non-institutionalized persons ages 12 and older.

Research topics in the PATH Study include examining patterns of tobacco use over time, such as switching products and using multiple products, as well as seeking to understand perceptions, knowledge, attitudes, and use of tobacco products. The study also assesses exposures from tobacco use, related biomarkers, and potential health outcomes.

Data are collected in "Waves" and the PATH Study measures are updated each wave to reflect the changing tobacco marketplace and regulatory environment. The questionnaire data and documentation are made available to researchers and the public and biomarker data are made available to researchers.[116] An annual fact sheet with a summary of the Study is available to the public. The PATH Study disseminates findings via online tables, papers, and presentations and provides trainings. Over 700 papers were published by researchers using PATH data, including CTP scientists.

National Surveys

To enhance the evidence base, CTP collaborates with other federal agencies to support national surveys and studies, including the National Health Interview Survey (CDC) and the Tobacco Use Supplement to the Current Population Survey (Census Bureau and NIH). To provide critical data on youth use and perceptions of tobacco products, FDA has collaborated with the Office on Smoking and Health, CDC, to conduct the National Youth Tobacco Survey (NYTS) on an annual basis since 2011. FDA funding expands the scope and increases the frequency of data collection for the NYTS. The NYTS is a large annual survey of a nationally representative sample of middle and high school students that focuses exclusively on tobacco. NYTS allows FDA to monitor youth awareness of, susceptibility to, experimentation with, and use of a wide range of tobacco products. Findings from the 2023 NYTS (conducted March 9 – June 16, 2023) indicated that an estimated 2.8 million U.S. middle and high school students reported currently

[115] https://www.fda.gov/tobacco-products/research/fda-and-nih-study-population-assessment-tobacco-and-health

[116] https://www.icpsr.umich.edu/web/NAHDAP/series/606

using tobacco products in 2023, with e-cigarettes being the most commonly used product (2.1 million students).[117]

Compliance and Enforcement

FDA has a comprehensive compliance and enforcement program to monitor industry compliance with regulatory requirements, and to restrict access and marketing of tobacco products, including e-cigarettes to youth. Among FDA's highest enforcement priorities are ENDS products for which no application is pending, including, for example, those with a MDO and those for which no application was submitted. To increase the Agency's transparency with regard to these efforts, in February 2023, FDA launched a webpage detailing its advisory and enforcement actions for unauthorized tobacco products. From October 1, 2022, through October 31, 2023, and consistent with FDA's policy to prioritize the enforcement of certain e-cigarettes and other deemed products on the market illegally, the Agency has taken many actions, including, for example:

- Refused admission into the U.S. of over 130 shipments of tobacco products, including disposable ENDS, for violations of the FD&C Act.
- Issued more than 140 warning letters to firms for manufacturing, selling, and/or distributing new tobacco products without marketing authorization from FDA.
- In October 2022, the DOJ, on behalf of FDA, filed permanent injunctions against six e-cigarette manufacturers. The injunctions require the defendants to stop manufacturing, selling, and distributing their e-cigarettes and to obtain marketing authorization from FDA before marketing such products, as required by law.
- In February 2023, FDA filed its first civil money penalty (CMP) complaints against four e-cigarette manufacturers. The Agency has filed CMP complaints against 35 e-cigarette manufacturers during this timeframe for violations of the FD&C Act relating to tobacco products, including the failure to obtain the required marketing authorization for new tobacco products.
- Conducted multiple coordinated nationwide retailer inspection efforts that included investigations of hundreds of retailers and distributors and resulted in FDA issuing over 400 warning letters for the illegal sale of unauthorized tobacco products. These products included Puff, Hyde, and Elf Bar brand disposable e-cigarettes—products that come in flavors known to appeal to youth and which were commonly reported brands used by youth e-cigarette users in 2022.

Tobacco Retailer Inspection Program

As of October 31, 2023, FDA has contracts for tobacco retailer compliance check inspections in 56 states and U.S. territories. Compliance check inspections pertain to tobacco marketing, sales, and distribution of tobacco products at retail locations and include ensuring compliance with age and ID verification requirements.

Although many tobacco retailers comply with FDA's tobacco laws and regulations, FDA conducts compliance check inspections and issues advisory and enforcement actions such as Warning Letters, CMPs, and NTSOs when violations are found. Since the inception of the

[117] https://www.cdc.gov/mmwr/volumes/72/wr/mm7244a1.htm?s_cid=mm7244a1_w

Tobacco Program's retailer inspection activities through October 31, 2023, FDA has conducted well over 1.4 million retailer inspections and issued more than 163,000 advisory and enforcement actions resulting in 130,845 Warning Letters and 30,990 CMPs. In FY 2023 alone, the Agency conducted more than 108,000 retailer inspections and over 18,000 advisory and enforcement actions resulting in 14,260 Warning Letters and 3,877 CMPs. FDA, for the first time, issued CMPs seeking the maximum penalty amount of $19,192 for a single violation to 22 retailers for selling unauthorized tobacco products, which is a statutory violation different than the other CMPs issued this fiscal year. A searchable database of all retailer inspections and all enforcement actions that have resulted from those inspections is available at: https://timp-ccid.fda.gov/

Tobacco Manufacturer Inspections

FDA regularly inspects registered establishments that manufacture or process tobacco products to determine compliance with existing laws and regulations through CTP's coordination with Office of Regulatory Affairs (ORA). Please see the ORA Chapter for more information about ORA's tobacco operations. FDA also facilitates inspections at vape shops using contracted inspectors. Since the inception of the Tobacco Program's manufacturer inspection activities through October 31, 2023, CTP has overseen the completion of more than 4,300 inspections of vape shops to verify whether they were engaged in manufacturing activities, and ORA has completed 840 routine biennial inspections of tobacco product manufacturers, a small percentage of which were Remote Regulatory Assessments (RRAs). FDA has initiated post-inspection regulatory action against non-compliant manufacturers and distributors. Since the enactment of the Tobacco Control Act on June 22, 2009, through October 31, 2023, FDA has issued approximately 400 warning letters as a result of post inspectional compliance activities. This includes issuance of over 120 warning letters in FY 2023.

Promotion, Advertising, and Labeling Activities

FDA conducts surveillance of websites, social media, and magazines and other publications that promote and sell tobacco products, including e-cigarettes and other ENDS products, in the U.S. market, and takes enforcement action when violations are found. Since the enactment of the Tobacco Control Act on June 22, 2009, through October 31, 2023, FDA has issued over 1,275 warning letters related to promotion, advertising, and labeling activities, as a result of its internet and publication surveillance activities. This includes issuance of over 100 warning letters in FY 2023. FDA also conducts investigations of events where free samples of tobacco products are distributed and events sponsored by the tobacco industry to ensure compliance with the Tobacco Control Act.

Public Education Campaigns

Public education campaigns are an evidence-based component of comprehensive tobacco control efforts to drive down prevalence rates and improve public health. Under the Tobacco Control Act, FDA has the authority to educate the public about the dangers of using tobacco products. FDA has implemented multiple public education campaigns designed to reduce tobacco initiation, disrupt progression to sustained use and encourage cessation by focusing on key populations who remain at-risk for using tobacco. FDA is conducting a multi-year outcome evaluation with a nationally representative longitudinal cohort design to evaluate the impact of exposure to "The Real Cost" cigarettes and e-cigarettes prevention campaigns on changes in teens' beliefs about the consequences of using these products. In 2024, FDA will also initiate an

implementation evaluation that will survey teens on a monthly basis to assess campaign message awareness, attention, engagement, processing, and receptivity to help hone campaign messaging and media strategy.

The Real Cost – Cigarette Prevention

In February 2014, FDA launched its first national teen smoking prevention campaign under the campaign brand, "The Real Cost." The campaign is designed to prevent teens aged 12-17 who were open to smoking cigarettes from doing so and to reduce the number of teens who moved from experimenting with smoking cigarettes to regular use.

An evaluation found that in the first two years of "The Real Cost" smoking prevention effort, research showed that the campaign prevented up to 587,000 youth ages 11 to 19 from initiating smoking, half of whom might have gone on to become established adult smokers – saving more than $53 billion by reducing smoking-related costs like early loss of life, costly medical care, lost wages, lower productivity, and increased disability. Through the campaign, FDA continues to provide national paid media messages via digital media platforms such as YouTube, while delivering critical cigarette prevention messaging to specific teen audiences that have a higher prevalence and risk of smoking. In January 2023, "The Real Cost" launched two new ads communicating scientific facts about cigarette smoking. One ad, "Auctioneer," focuses on the negative mental health effects of cigarette smoking and withdrawal, a new messaging area for the campaign. The other ad, "Said Every Smoker Ever," introduces youth to the fact that three out of four teens who smoke will continue into adulthood and focuses on the negative consequences of cigarette addiction. FDA plans to launch new advertisements for the campaign in 2024.

The Real Cost – ENDS Prevention

According to published data from the 2023 NYTS, approximately 2.13 million (7.7 percent) U.S. middle and high school students were estimated to be current e-cigarette users. FDA remains committed to educating teens about the harms of e-cigarette use and continues to make advancements to prevent and decrease youth e-cigarette use. "The Real Cost" youth e-cigarette prevention campaign is designed to educate the more than 10.7 million teens and raise awareness about the negative consequences associated with e-cigarette use and discourage them from starting or continuing e-cigarette use. The campaign utilizes various strategies to reach its intended audiences including digital and social media advertisements.

Since launching in 2018, the campaign has shown positive results for effective reach and engagement. Digital metrics indicate the campaign's advertising has reached up to 90 percent of all teens nationwide, has generated over 24 billion ad views, and has achieved high levels of online engagement. Across social media platforms, the campaign has engaged teen audiences resulting in more than 10 million likes, over 570,000 shares, and over 129,000 comments. FDA plans to launch new advertisements for the campaign in 2024.

Based on the most recent outcome evaluation data collected between June and September 2022, results showed that approximately 84 percent of youth were aware of at least one e-cigarette campaign ad and 68 percent of teens were aware of "The Real Cost" brand. In addition, results based on multiple years of data suggest that there are significant associations between exposure to "The Real Cost" ads and increases in agreement with campaign-specific beliefs. These

changes in campaign-specific beliefs have historically been shown to be predictive of behavior change.

FDA also partners with the NCI's Smokefree.gov initiative to provide youth with resources for quitting e-cigarettes. "The Real Cost" connects youth to these resources and since the web content launched in July 2019, there have been over 4.2 million page views with visitors spending over 3 minutes to learn how to quit vaping.

Next Legends – ENDS Prevention

In June 2022, FDA launched "Next Legends" – an e-cigarette prevention campaign that aims to educate American Indian or Alaska Native teens about the harms of vaping. According to data from the 2022 NYTS and the 2021 Youth Risk Behavior Survey, American Indian or Alaska Native teens continue to be susceptible to and show high rates of ever use of e-cigarettes. Furthermore, in comparison to some of their non-Native peers, American Indian or Alaska Native teens show higher levels of current e-cigarette use. To develop effective campaign messages, focus groups and surveys were conducted with American Indian or Alaska Native teens to understand their mindset, values, and behaviors. American Indian or Alaska Native community members and public health partners were also consulted throughout the formative research process to ensure cultural relevancy. Since its launch, "Next Legends" e-cigarette prevention campaign has shown positive results for reach and engagement. Digital metrics has indicated that the campaign has generated over 320 million views from high exposure and high online engagement. Across social media platforms, the campaign has engaged teen audiences with more than 395,000 likes, 14,800 shares, and over 16,800 comments. More information about CTP's public education campaigns is available at: https://www.fda.gov/tobacco-products/public-health-education/public-health-education-campaigns.

Health Equity

Despite the tremendous progress made in tobacco use prevention and cessation over the past 50+ years, the benefits of those efforts have not been experienced by everyone equitably. FDA remains committed to leading, supporting, and promoting activities to improve the health of populations experiencing tobacco-related health disparities, including in our public education efforts, compliance and enforcement actions, research activities, and other regulatory actions.

Currently, FDA is working to issue tobacco product standards to prohibit menthol as a characterizing flavor in cigarettes and prohibit all characterizing flavors (other than tobacco) in cigars. In addition to benefiting the population as a whole, populations that disproportionately use these products – such as people who identify as part of a historically marginalized race and/or ethnicity, people who identify as LGBTQI+, people with mental health conditions, and people with lower household incomes, among others – will have pronounced benefits. For example, published modeling studies estimate that prohibiting menthol cigarettes will prevent between 92,000 to 238,000 deaths among African Americans over the course of 40 years.

FDA also continually updates its data collection efforts to produce the necessary data to assess disparities and promote health equity. For example, the PATH Study uses a health equity framework to guide the study methodology (e.g., sample design and development of interview questions) and prioritizes research questions related to health disparities for analysis and dissemination. Similarly, the 2022 NYTS conducted an oversample of American Indian or Alaska Native and Asian students. A recently published report using the 2022 NYTS data

presented new tobacco use estimates for Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and multiracial population groups, allowing measurement of disparities in tobacco product use affecting these groups.[118]

FDA is also engaging in tailored education campaigns focused on populations at higher risk of tobacco use, such as the "Next Legends" campaign.

CTP is committed to integrating health equity throughout the Center. As part of this commitment, the Center hired its first Senior Advisor for Health Equity to be a member of its leadership team; the first of its kind for the Agency.

PERFORMANCE

The Tobacco Control Act Program's performance measures focus on activities in order to achieve public health goals, as detailed in the following table.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 +/- FY 2024
280005: Total number of compliance check inspections of retail establishments in States under contract. (Outcome)	FY 2023: 108,565 Target: 90,000 (Target Exceeded)	110,000	110,000	Maintain
280010: Number of closed applications and deficiency letters for Premarket Tobacco Product Applications (PMTA). (Output)	FY 2023: 17,283,985 Target: 600 (Target Exceeded)	660	700	+40
280011: Number of closed applications and deficiency letters for Substantial Equivalence (SE) Reports. (Output)	FY 2023: 547 Target: 500 (Target Exceeded)	550	600	+50
280012: Number of closed applications and deficiency letters for Exemption from Substantial Equivalence Requests (EX REQ). (Output)	FY 2023: 1,205 Target: 300 (Target Exceeded)	330	360	+30
280007: Percentage of at-risk youth (12-17-year-olds) that are educated about the harmful effects of tobacco use with campaign messaging. (Output)	FY 2023: 75% Target: 75% (Target Met)	75%	75%	Maintain

Figure 74 - Tobacco Control Act Performance Table

[118] https://www.cdc.gov/mmwr/volumes/71/wr/mm7145a1.htm

Compliance Check Inspections

A key element in enforcing the Tobacco Control Act involves contracts with U.S. state, territory, and tribal agencies, as well as private entities, to conduct retailer compliance checks. FDA generally conducts over 100,000 inspections each fiscal year, except during the COVID-19 pandemic. In FY 2024 and FY 2025, FDA expects jurisdictions and private entities to continue to contract with FDA and for inspections to exceed 100,000 per year.

Premarket Tobacco Product Applications (PMTA)

This performance measure includes any of the following final Agency actions that result in CTP's closure of an application and applies to all tobacco products: Refuse to Accept (RTA); Refuse to File (RTF); Marketing Granted Order (MGO); Marketing Denial Order (MDO). The measure also includes closure of a review cycle through issuance of a Deficiency letter. Generally, Deficiency letters may be issued during the substantive scientific review phase and list additional information that FDA needs to complete its scientific review. The inclusion of the PMTA performance measure is particularly important as PMTAs became a significant proportion of the Center's review work following publication of the deeming rule in 2016 and subsequent court-ordered application submission deadline of September 9, 2020, for ENDS and other deemed tobacco products. FDA received close to 15,000 new product applications in FY 2023. As the Agency continues to receive new PMTAs, many applications provide more complete evidence for FDA's evaluation and thus require significantly more time to review. The significant increase from the FY 2023 target of 600 reflects the closing of a single large submission, submitted in a previous FY, that contained over 17 million products. The submission failed to meet the statutory and regulatory requirements which resulted in the issuance of a RTA letter. Additionally, FDA closed more than 20 other submissions that each included over a thousand products because they did not contain the required information. While CTP's FY 2024 and FY 2025 targets are a reduction from our FY 2023 actuals, they accurately reflect the Center's projected output given the increased complexity of application reviews and CTP's anticipated resource capacity. Targets are expected to increase through FY 2025 as CTP continues to hire more staff to review applications.

Substantial Equivalence (SE) Reports

This performance measure includes any of the following final Agency actions that result in CTP's closure of an application and applies to all tobacco product categories: Refuse to Accept (RTA); Substantially Equivalent (SE); Not Substantially Equivalent (NSE). The measure also includes closure of a review cycle through issuance of a Deficiency letter. Generally, Deficiency letters may be issued during the substantive scientific review phase and list additional information that FDA needs to complete its scientific review. While CTP is strategically reallocating resources from this pathway to support the increased demands of the PMTA pathway, our targets are expected to increase through FY 2025 as we continue to hire more staff to review applications.

Exemption From Substantial Equivalence Requests (EX REQ)

This performance measure includes any of the following final Agency actions that result in CTP's closure of an application and applies to all tobacco product categories: Refuse to Accept (RTA); Exempt (EX); Not Exempt (NEX). The measure also includes closure of a review cycle through issuance of a Deficiency letter (DL). Generally, although FDA does not intend to issue

DLs for EX REQs, a DL may be issued during the substantive scientific review phase and list additional information that FDA needs to complete review. As CTP has more experience and the amount of resources required for reviewing EX REQ is not as extensive as other pathways, it has been able to review and close a larger number of products than was expected. CTP's FY 2024 and FY 2025 targets are a reduction from our FY 2023 actuals because we are strategically reallocating resources from this pathway to support the increased demands of the PMTA pathway.

Educate At-Risk Youth 12-17 Year Olds

FDA's public education campaigns help educate the public—especially youth—about the dangers of regulated tobacco products. FDA's "The Real Cost" e-cigarette and cigarette prevention campaigns and "Next Legends" e-cigarette prevention campaign are active in market.

PROGRAM ACTIVITY DATA

CTP Workload and Outputs	FY 2023 Final	FY 2024 CR	FY 2025 PB
Tobacco Retailer Inspections			
Number of Inspections	108,565	110,000	110,000
Tobacco Manufacture Inspections			
Number of Inspections [1]	840	800	800

[1] Generally, outyear estimates are based on the number of firms registered with FDA. FDA works to inspect each registered firm biennially. The tobacco manufacturer inspections for FY 2023 actuals and outyear estimates include vape manufacturer inspections conducted by contractors.

Figure 75 - CTP Workload and Outputs

FDA HEADQUARTERS

PURPOSE STATEMENT

FDA Headquarters provides strategic direction and a wide array of services, including cross-agency special medical, scientific, and regulatory programs, legal advice and counsel and litigation services across FDA's programs. FDA's Headquarters advances the Agency's mission to protect and promote public health and to meet the challenges of rapid innovation across the industries regulated by FDA.

Authorizing Legislation: The Federal Food Drug and Cosmetic Act (21 U.S.C. 321-399); Radiation Control for Health and Safety Act (21 U.S.C. 360hh-360ss); The Federal Import Milk Act (21 U.S.C. 142-149); Public Health Service Act (42 U.S.C. 201, et seq.); Foods Additives Amendments of 1958; Color Additives Amendments of 1960; Animal Drug Amendments (21 U.S.C. 360b); Controlled Substances Act (21 U.S.C. 801-830); The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); Safe Drinking Water Act (21 U.S.C. 349); Saccharin Study and Labeling Act; Federal Anti-Tampering Act (18 U.S.C. 1365); Medical Device Amendments of 1976; Infant Formula Act of 1980; Drug Enforcement, Education, and Control Act of 1986; Generic Animal Drug and Patent Term Restoration Act; Prescription Drug Marketing Act of 1987; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Prescription Drug Amendments of 1992; Safe Medical Device Amendments of 1992; Nutrition Labeling and Education Act of 1990; Dietary Supplement Health and Education Act of 1994; Animal Medicinal Drug Use Clarification Act of 1994; Animal Drug Availability Act of 1996; Food Quality Protection Act of 1996; Federal Tea Tasters Repeal Act (42 U.S.C. 41); Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349); Food and Drug Administration Modernization Act of 1997; Antimicrobial Regulation Technical Corrections Act of 1998; Medical Device User Fee and Modernization Act of 2002; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Best Pharmaceuticals for Children Act of 2002 (21 USC 355a Sec. 505A); Animal Drug User Fee Act of 2003 (21 U.S.C. 379j-11 - 379j-12); Pediatric Research Equity Act of 2003 (21 USC 351 Sec. 505B); Project Bioshield Act of 2004 (21 U.S.C.360bbb-3); Minor Use and Minor Species Animal Health Act of 2004; Food Allergy Labeling and Consumer Protection Act of 2004 Medical Device User Fee Stabilization Act of 2005; Sanitary Food Transportation Act of 2005 Dietary Supplement and Nonprescription Drug and Consumer Protection Act (21 U.S.C. 379aa-1); Pandemic and All-Hazards Preparedness Act, Food and Drug Administration Amendments Act of 2007; Protecting Patients and Affordable Care Act of 2010; The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31); The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333); FDA Food Safety Modernization Act, Public Law 111-353 (January 4, 2011); The Food and Drug Administration Safety and Innovation Act (P.L. 112-144); Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Drug Quality and Security Act (2013), the 21st Century Cures Act (P.L. 114-255), Food and Drug Administration Reauthorization Act of 2017 (FDARA) (P.L. 115-52), Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (P. L. 115-92).

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
FDA Headquarters	**313,207**	**330,985**	**362,323**	**377,042**	**396,735**	**34,412**
Budget Authority 1/	***193,213***	***204,250***	***222,940***	***232,427***	***250,403***	***27,463***
User Fees	***119,994***	***126,735***	***139,383***	***144,615***	***146,332***	***6,949***
FTE	**944**	**995**	**963**	**988**	**1,018**	**55**

1/ FDA Headquarters Budget Authority shown inclusive of the $1.5M OIG transfer amount

Figure 76 – FDA Headquarters Funding History Table

The FY 2025 President's Budget for FDA Headquarters is $396,735,000 of which $250,403,000 is budget authority and $146,332,000 is user fees. The budget authority increases by $27,463,000 compared to the FY 2023 Final Level. User fees increased by $6,949,000.

FDA Headquarters provides policy direction and oversight, advance scientific development, and provide oversight of the global supply chain. FDA Headquarters works to increase transparency and accountability in the supply chain, developing better enforcement and regulatory tools, encouraging greater responsibility by industry, and enhancing collaboration with international regulatory counterparts and other third parties. FDA Headquarters, along with the Centers and Offices, evaluates and improves the effectiveness of preventive control standards and advances the development of predictive safety models. FDA Headquarters coordinates across FDA to develop improved methods for rapidly detecting, investigating, and stopping foodborne contaminants, as well as develop comprehensive regulatory approaches for integrating pre- and post-approval and compliance functions. In addition, FDA Headquarters will continue to provide program direction and administrative services, ensuring FDA's public health mission is managed effectively and efficiently. FDA Headquarters is committed to delivering cutting-edge technology, innovation, and support to all stakeholders.

BUDGET AUTHORITY

FY 2025 Presiden'ts Budget: FDA Headquarters *Budget Authority - Dollars in Thousands*	
	Total
FY 2023 Final	**222,940**
FY 2025 Budget Authority Changes	**27,463**
Requested Increases	**19,590**
Public Health Employee Pay Costs	8,429
Modernization of Cosmetics	8,000
Enterprise Transformation	293
IT Stabilization & Modernization	1,000
Shortages and Supply Chain-Agency-wide	868
Foreign Office Expansion	1,000
Other Adjustments	**7,873**
ORA Transfer to HQ/OGPS	24,200
FY 2024 Comparability Adjustment	(14,713)
FY 2025 Comparability Adjustment	(1,614)
FY 2025 Budget Net Total: FDA Headquarters	**250,403**

Figure 77 – FDA Headquarters Budget Authority

Requested Increases: $19.6 million / 30 FTE

Public Health Employee Pay Costs: +$8.4 million

The FY 2025 President's Budget includes $114.8 million in new budget authority to fund approximately 72 percent of the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 and FY 2025 Cost of Living Adjustments (COLA). For FY 2025 this assumes a 2.0 percent for Civilian and 4.5 percent Military pay increase for FTE funded through budget authority. Within FDA Headquarter, $8.4 million is provided for pay costs.

Modernization of Cosmetics: +$8.0 million / 24 FTE

The FY 2025 President's Budget provides $8.0 million for Modernization of Cosmetics Implementation, for the Office of the Chief Scientist (OCS). These resources will be used to hire additional staff for continued strategic coordination and implementation of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). Resources will be used for activities to develop proposed and/or final regulations (for Good Manufacturing Practices, asbestos testing of talc-containing cosmetics products, and disclosing fragrance allergens on labeling) and compliance policies. Funds will also be used to maintain and update submission platforms to address MoCRA provisions for registration, product listing, and adverse event reporting, as well as review of such information to ensure industry compliance with those requirements. The new funding would also support hiring additional experts to manage critical projects such as assessments of the use of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetic products. FDA will hire staff across OCS and the Office of Cosmetics and Colors to enable FDA to work toward a modernized cosmetics regulatory program.

MoCRA, signed into law on December 29, 2022, provides the most significant expansion of FDA authority to regulate cosmetics since 1938. However, it did not include new funding to implement these new authorities. Without new resources, FDA's ability to ensure timely implementation and management of the new authorities will be at major risk.

The passage of cosmetics modernization legislation provides FDA an opportunity to better protect the public health by helping to ensure the safety of cosmetic products and ingredients that are in use in the United States and to keep track of cosmetic products and their ingredients that are currently on the market and the establishments in which they are manufactured and processed. With additional resources, FDA will be better positioned to tackle issues such as asbestos contamination of talc-containing cosmetics, tattoo inks and permanent makeup, and hair products (shampoo and conditioners). These resources will also strengthen FDA's post-market surveillance systems and enhance FDA's efforts to protect consumers from unsafe cosmetics.

Enterprise Transformation: +$293,000

The FY 2025 President's Budget provides $2.0 million for Enterprise Transformation, which includes $293,000 for FDA Headquarters to coordinate and lead several high priority agency-wide business process improvement projects for common and mission-critical FDA activities. This work will incorporate efforts to facilitate access to critical data and establish effective governance to enable successful business process and technology changes.

This funding will support the continuation of the critical work of implementation and expansion of the enterprise-wide end-to-end process and platform for inspectional activities. The multitude of FDA regulated products are manufactured or handled at nearly 275,000 registered facilities. Recent challenges have highlighted the need for a more integrated process and technology platform to conduct these vast inspectional activities more effectively and efficiently. Benefits of this funding will include improved communication and data sharing across the life cycle of an inspection, increased access to relevant data to facilitate risk-based decision-making for inspectional activities, and introduction of more modern mobile technology for field work to improve the user experience in the field with an enterprise approach to process, data, and technology. This work will allow for improved risk-based decision making and response for the Agency's essential regulatory oversight activities.

IT Stabilization & Modernization: +$1.0 million

The FY 2025 President's Budget provides $8.3 million for IT Stabilization & Modernization, including $1.0 million for FDA Headquarters to support FDA data and technology modernization efforts by building core programs and infrastructure aligned to the specific needs in both FDA's foods and medical product programs as well as essential enterprise--wide technology capabilities.

FDA has critical needs with respect to data modernization. Until recently, competing priorities for limited Agency resources has prioritized maintaining current technology systems rather than investing in modernization. Meanwhile, recent trends associated with enhanced data capabilities such as common enterprise-wide data lakes to enable effective data sharing, and advanced analytics such as artificial intelligence are forcing the FDA to take a more strategic approach towards data to better meet the challenges of emerging threats, support needs for real-time evaluation, and more continuously access, analyze, and aggregate multiple sources of information, such as for recalls, adverse events, outbreaks, and pandemics. This request will

support additional funding at the enterprise-level efforts to build, scale, and operate an advances data architecture and infrastructure that will serve as a force multiplier to our programs as they carry out their critical mission to protect the health and safety of the American public. This funding will be directed towards the FDA Technology Council, which is the enterprise governing body on strategic decision making for IT operations, funding, strategic roadmap approval, infrastructure, enterprise architecture, prioritization, and investments for prioritization. The Technology Council will provide guidance for IT decisions in alignment with FDA's Technology and Data Strategic Plan.

Shortages and Supply Chain: +$868,000 / 2 FTE

The FY 2025 President's Budget provides $12.3 million for Shortages and Supply Chain, including $868,000 for FDA Headquarters to advance FDA's capabilities to help prepare for, build resilience to, and respond to shortages that are supply-driven and/or demand-driven through improved analytics to identify shortage threats and vulnerabilities as well as regulatory approaches to address disruptions and shortages. These funds will be allocated to two FTE, a Senior Advisor for Shortages and a Policy Analyst, that will contribute to a more formal, structured, and efficient organization of FDA-wide shortage-related activities, strategy, and communication, to complement and support existing functions within OC and the product Centers.

Foreign Office Expansion: +$1.0 million / 4 FTE

The FY 2025 President's Budget provides $1.0 million for Foreign Office Expansion for FDA Headquarters/OGPS. This funding will support and strengthen FDA's oversight of imported products by expanding the agency's foreign office footprint.

USER FEES

Current Law User Fees: +$6.9 million

The FY 2025 President's Budget includes an increase of $6.9 million in current law user fees for FDA Headquarters. The remaining resources will allow FDA to fulfill its mission of promoting and protecting the human and animal health by ensuring safety and efficacy of FDA-regulated products.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

Headquarters provides strategic leadership and coordination to enhance FDA's oversight of production, manufacturing, the global supply chain, and post market product use. FDA Headquarters provides policy direction and expertise to establish standards and guidance to protect patient and consumer safety. FDA Headquarters develops and standardizes policies and best practices across FDA consistent with statutes and regulations.

FDA's oversight activities include:

- inspecting manufacturing and production facilities
- providing surveillance of adverse events
- preventing unsafe products from harming consumers

The following, selected accomplishments demonstrate FDA Headquarters' delivery of its regulatory and public health responsibilities within the context of current priorities.

Office of Operations

The Office of Operations (OO) provides executive direction, leadership, coordination, and guidance for the overall day-to-day administrative and business operations of FDA. In so doing, OO ensures timely and effective implementation and high-quality delivery of services for FDA's Centers, Field operations, and the Office of the Commissioner. OO manages and implements major Agency-wide, strategic changes that enable FDA to operate as a global and mobile workforce. OO also maintains world-class research facilities, ensures ethics compliance, supports FDA hiring for an equitable, diverse, and inclusive workforce. OO serves as FDA's fiduciary steward to ensure FDA delivers on its mission while operating under federal requirements. OO is comprised of the following offices:

- **Office of Equal Employment Opportunity (OEEO)** – sets the laws and policies that mandate all individuals' rights to equal opportunity irrespective of race, religion, color, gender, sexual orientation, national origin, age, disability, or genetic information.
- **Office of Enterprise Management Services** – provides strategic and tactical services through development and implementation of administrative policies, programs, and initiatives.
- **Office of Ethics & Integrity (OEI)** – provides advice and assistance to current and former employees to ensure that the decisions they make and actions they take are not, nor appear to be, tainted by any question of conflict of interest.
- **Office of Facilities Engineering and Mission Support Services (OFEMS)** – creates a high-quality- work environment by providing vital facilities and mission support services to meet the needs of our customers and stakeholders nationwide.
- **Office of Finance, Budget, Acquisition and Planning (OFBAP)** – ensures the strategic alignment and stewardship of FDA's resources to support its expanding responsibilities.
- **Office of Human Capital Management (OHCM)** – provides outstanding operational and strategic human capital services to support this world class institution.
- **Office of Security Emergency Management (OSEM)** – protects FDA's personnel, facilities, and information from security threats, delivers efficient passport and visa services, and ensures that FDA is prepared to manage emergencies and incidents, including those involving FDA regulated- products.
- **Office of Talent Solutions (OTS)** – provide high quality and efficient HR solutions that enable the FDA to hire a talented and qualified workforce.

Office of Food Policy and Response

Unified Human Foods Transformation

To ensure the new Human Foods Program and all other regulatory programs at the FDA are successful, work on an agency-wide transformation effort of how the programs and field functions are organized and operate is underway.

Third-Party Food Safety Standards

In July 2023, FDA concluded the voluntary pilot program to evaluate alignment of private third-party food safety audit standards with applicable FDA regulations and published the findings from the reviews of aligned standards. Findings of alignment could create efficiencies for industry and help give importers and receiving facilities confidence that, in general, the third-party standards used to audit their suppliers adequately address applicable FDA food safety

requirements. This information, along with results of a firm's audits also could help inform the FDA in determining risk prioritization and resource allocation. This goal is consistent with and an important element of our New Era of Smarter Food Safety Blueprint.

Tracking and Tracing of Food

FDA finalized the Food Traceability Rule in November 2022 to facilitate faster identification and rapid removal of potentially contaminated foods from the market, resulting in fewer foodborne illnesses. FDA released a number of new tools and frequently asked questions (FAQs) throughout 2023 to help inform stakeholders about the Food Traceability Rule. In November 2023, updates included a new webpage about traceability lot codes, examples of a traceability plan, new supply chain examples, new FAQs, and a video that highlights technological components of a product tracing system.

Infant Formula

FDA continues to monitor the supply of products that serve as the sole source of nutrition for many infants while ensuring the infant formula can be used safely and provides adequate nutrition. The agency also continues to help ensure that safe and nutritious infant formula products remain available for use in the U.S. Important progress has been made toward improving the infant formula supply in the U.S. and paving the way for a more robust and diverse marketplace for the future.

Office of External Affairs

Communication Products for Consumers, Health Care Professionals and Others

FDA regularly develops communication products about FDA-regulated products, key issues, and other news for consumers, health care professionals, patients, journalists, policymakers regulated industry, and others.

From May 1, 2022 through November 30, 2023, FDA's Office of External Affairs issued or held:

- 287 MedWatch Safety Alerts (FDA's second largest e-list) to over 476,895, subscribers and approximately 55,359 MedWatch X followers;
- More than 315 news releases and other press announcements in English and/or Spanish to more than 100,000 subscribers;
- 100 individual Consumer Updates (both new and updated content) offered in English and Spanish, with all COVID-19 articles also available in four Asian languages, sent to more than 214,000 subscribers in English and 48,000 in Spanish; 132 Consumer Videos with 336,000 views and 146,800 subscribers; 46 FDA Voices perspective articles, sent to 108,000 subscribers; 82 newsletters in English, which reach approximately 75,586 health care professionals, consumers and patients; and 28 newsletters in Spanish with over 14,894 subscribers;
- Approximately 153 Stakeholder events with the FDA Commissioner and senior agency leadership; issued over 185 targeted stakeholder outreach emails.
- Approximately 263 X (formerly Twitter) posts and 117 Facebook posts per month with an estimated 9.7 million views. Of note, FDA has 2.4 million followers on Office of External Affairs accounts, and 3.9 million followers on all social media accounts across FDA.

Communication with Stakeholders – Improvements to FDA.gov and Social Media Channels

From May 1, 2022, through November 30, 2023, FDA continued to make data-driven, iterative improvements to its public-facing website, FDA.gov. During this period, FDA concentrated on the top tasks that visitors are trying to accomplish on each product area and worked with the Centers and Offices to make these top tasks easily available. In addition, FDA concentrated efforts around improving the internal search results for visitors utilizing the search function on FDA.gov. This included a thorough analysis of all search results and coordination with the Centers and Offices to ensure the most appropriate results are returned first.

FDA continues to effectively use social media channels to drive traffic to FDA content and engage with our audiences. To produce more engaging content, the social media team is concentrating on campaign-type promotions utilizing short videos and reels to engage audiences and drive traffic to FDA.gov. This requires constant coordination within OEA and the Centers and Offices to ensure content is up to date and being developed in the most effective manner possible. In addition, FDA established a Threads social media account during this period to engage and promote FDA content. To date, FDA has over 21,000 followers on Threads.

FDA continues to manage an FDA-wide enterprise contract for email marketing through GovDelivery. This state-of-the-art email platform enables stakeholders to quickly sign up to receive critical public health information from FDA. Currently, FDA has over 240 publicly available content topics and over 1.3 million stakeholders who have opted-in to receive information.

Stakeholder Outreach Activities

FDA works closely with Centers and Offices to enhance stakeholder relations to ensure the public's health is advanced and protected. FDA aims to build stronger relationships with health professional organizations, consumer groups, trade associations, patient advocacy organizations, think tanks, academia, and other stakeholders, to better inform FDA's policy making process, to identify policy hurdles or stakeholder misconceptions, and to create strategic collaborations.

From May 1, 2022 through November 30, 2023, FDA executed 151 calls, listening sessions and outreach events with groups on a variety of topics, including but not limited to Agency announcements related to COVID-19 vaccines, therapeutics and testing, the proposed reorganization of the Human Foods Programs and new model for the Office of Regulatory Affairs (ORA), medical product shortages, cannabidiol and other hemp products, proposed rules on menthol and flavors in tobacco products and flu, COVID-19 and RSV prevention.

In an effort to increase transparency, FDA posted video recordings of seven stakeholder calls on FDA's YouTube page, which has over 147,000 subscribers. From May 2022 to the present, these videos have been viewed more than 12,500 times. FDA Headquarters used social media to engage with stakeholders via Facebook, multiple X/Twitter accounts, YouTube, and other channels. The Agency conducted five X/Twitter chats, including three targeting a bilingual (English- and Spanish-speaking) audience.

Finally, FDA managed more than 1,300 speaker requests received from nearly 300 trade associations and industry-based groups for issues that cut across Agency organizational and

product lines, as well as major meetings that involved various FDA Centers and Offices subject matter experts' participation in external meetings, conferences, and workshops.

Office of Clinical Policy and Programs

Jurisdictional Determinations and Support for Combination Products (CPs) Regulation

In FY 2023, FDA Headquarters received and processed 66 formal Request for Designation (RFD) and evaluated and completed 60 informal Pre-RFD submissions regarding product jurisdiction. In addition, FDA Headquarters provided jurisdictional feedback for 79 center requests. These decisions and feedback ensure products are properly regulated.

In FY 2023, FDA Headquarters helped ensure close cross-center coordination of CP activities by providing support for approximately 1958 inter-center consult requests (ICCR), 25 external CP postmarket activities, and 125 internal product-specific requests. These activities contributed to ensuring the timely and effective review and postmarket safety of CPs.

In FY 2023, FDA Headquarters continued to improve our IT systems to increase functionality and efficiency, and to harmonize workflow and data collection. In addition, FDA Headquarters continued to improve an IT solution that enhances the efficiency of conducting FDA's postmarket safety surveillance activities for CPs. The solution integrates CP data from different sources including premarket registration and listing and adverse event reporting systems from all three medical product centers.

In September 2023, FDA Headquarters published a final guidance "Application of Human Factors Engineering Principles for Combination Products: Questions and Answers" which discusses how the unique aspects of a combination product influence human factors engineering considerations. Also, in September 2023, FDA published a draft guidance (for which FDA Headquarters participated in the development) "Regulatory Considerations for Prescription Drug Use-Related Software" that describes how FDA intends to apply its drug labeling authorities to certain software outputs disseminated by or on behalf of a drug sponsor for use with a prescription drug or a prescription drug-led drug-device combination product. FDA Headquarters also continued to lead or participate in the development of important guidance documents mandated by statute or requested by stakeholders (e.g., technical data for drug delivery devices; container closure systems for drugs and biological products).

Overall, FDA Headquarters continued to develop the final rule on product jurisdiction to clarify the scope, streamline and clarify the appeals process, and align the regulation with more recent legislative and regulatory measures. FDA Headquarters also participated in development of the final rule "Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases." FDA Headquarters continued to participate in development of standards applicable to CPs with American Society for Testing and Materials Association and with the Advancement for Medical Instrumentation and continued to train Agency staff on combination products regulation.

Pediatric Coordination

FDA Headquarters continued collaborations with Agency, Centers, and external stakeholders to increase the availability of safe and effective medicines for children. By September 2023, FDA completed more than 1,100 pediatric labeling changes for drugs and biologics.

In FY 2023, for example, FDA Headquarters:

- Enhanced international collaborations through the Pediatric Cluster, which allows Center subject matter experts to discuss pediatric scientific issues with regulatory counterparts in Europe, Canada, Japan, and Australia. Of the 153 issues discussed in FY 2023, the most frequent topics were clinical trial design and trial population.
- Promoted high standards of scientific integrity by providing expert ethical guidance on a variety of issues, including the inclusion of children in research, study design for rare diseases, informed consent requirements for emergency research, and benefit and risk. FDA Headquarters completed more than 80 consultations in FY 2023 and published the FDA Draft Guidance entitled Research Involving Children as Subjects and not Otherwise Approvable by an IRB: Process for Referrals to FDA and OHRP.
- In collaboration with the Centers, continued its process to evaluate post-market pediatric safety events and report issues to the Pediatric Advisory Committee. In FY 2023, we completed 61 pediatric-focused medical product safety reviews of drugs, biologics, vaccines and devices.

Promoted neonatal product development through multiple collaborative efforts, such as:

- Publishing the FDA Draft Guidance: "Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development"
- Working with neonatal consortia to develop tools to streamline development
- Providing neonatal-perinatal medicine consultations across the Centers, with 82 consults completed in FY 2023.
- Workshop planning with key stakeholders (e.g., the March 2023 FDA-Duke Margolis meeting: Measuring Clinical Benefit in Neonatal Randomized Clinical Trials: Challenges and Opportunities)
- Leading and collaborating on regulatory science projects (e.g., platform presentation on failed neonatal trials at the 2023 Pediatric Academic Societies Meeting)

Patient Engagement

FDA Headquarters Patient Affairs Staff (PAS) continued patient-focused initiatives of cross-cutting interest to all FDA medical product centers. The FDA Patient Listening Sessions (PLS) program includes collaborators such as the National Organization for Rare Disorders (NORD) and the Reagan-Udall Foundation for the FDA. In FY 2023, PAS facilitated 18 PLS, 14 requested by patient organizations and 4 requested by FDA review divisions to directly inform their regulatory work. FDA collaborates with the Clinical Trials Transformation Initiative (CTTI) for external outreach and internal coordination. In addition, PAS is a co-chair of the

international Patient Engagement Cluster with the European Medicines Agency (EMA) and Health Canada, to facilitate information sharing and best practices in patient engagement.

Human Subject Protection and Good Clinical Practice Policy

The Cures Act, Section 3023 requires harmonization of the HHS and FDA human subject protection regulations, to the extent practicable given FDA's and HHS's different statutory mandates. FDA is continuing to harmonize differences between its regulations and the Common Rule that was revised January 19, 2017. FDA Headquarters is in the process of finalizing three notices of proposed rulemaking that would mandate use of a single institutional review board for cooperative research in the U.S, harmonizing certain provisions of FDA's informed consent and institutional review board requirements with the Common Rule, and allow an exception from the requirements to obtain informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. In FY 2023, FDA Headquarters issued a final guidance describing FDA's current thinking regarding obtaining and documenting informed consent from research volunteers.

In addition, FDA Headquarters annually provides over 120 formal and informal inter-Center ethics consultations to Centers and Offices on a variety of ethical and clinical trial design concerns identified during the review of research and marketing applications. FDA Headquarters supported over 40 cross-agency policy efforts related to human subject protections, good clinical practice, and clinical trial modernization.

Finally, FDA Headquarters coordinates with the Centers, ORA, and the National Institutes of Health (NIH) on compliance activities related to the ClinicalTrials.gov databank. Since January 1, 2020, FDA has issued 105 Preliminary Notices of Noncompliance with the ClinicalTrials.gov requirements, and 5 Notices of Noncompliance to responsible parties for applicable clinical trials. FDA Headquarters also coordinates with NIH in delivering ClinicalTrials.gov-related training and communications, including development of Reports to Congress required under Section 2052 of the Cures Act.

Office of Orphan Product Development (OOPD)

The Orphan Drug Act (ODA) enacted by Congress in 1983 provides incentives to defray the costs of developing drugs, biologics, devices, and medical foods for rare diseases or conditions. Rare diseases are statutorily defined as those affecting fewer than 200,000 persons in the United States. To encourage development of new medical products for rare diseases and conditions, FDA has three Congressionally mandated grant programs administered by OOPD:

- Orphan Products Grants Program (OPGP) comprised of the Clinical Trials Grants
- Program and the Natural History Studies Grants Program; and
- The FDA Rare Neurodegenerative Disease Grant Program.

A fourth Congressionally mandated grant program—the Pediatric Device Consortia Grants Program—promotes device development for both rare and common conditions for children.

The success of the Clinical Trial Grants Program (CTGP) is reflected in the annual number of products approved for rare diseases that received our funding. In FY 2023, Sezaby (phenobarbital) was approved using CTGP support to treat neonatal seizures in term and preterm infants—a population of 20,000 babies in the United States. With the approval of Sezaby, babies

now have the first FDA-approved product for neonatal seizures with an age-specific formulation and with appropriate dosing and storage instructions.

Additionally, three commercially available products received FDA-approval for new expanded indications using CTGP funding. Of note, two products—Trikafta and Kalydeco—received expanded indications to treat very young children with cystic fibrosis (CF)—a vulnerable population with great unmet need. The CTGP-supported products are:

- Trikafta for treatment of CF in patients aged 2 through five years of age who have a mutation in the cystic fibrosis transmembrane conductance regulator gene;
- Kalydeco (ivacaftor) for treatment of CF in patients 1 month to less than 4 months of age who have at least one genetic mutation that is responsive to ivacaftor; and
- Yervoy (ipilimumab) for treatment of unresectable or metastatic melanoma in adult and pediatric patients 12 years and older in combination with nivolumab.

In FY 2023, FDA also awarded ten new grants with collaborative, innovative designs, early and ongoing patient engagement and use established infrastructure for efficiency. This year's funded projects included: (1) two cancer treatments; (2) a treatment for children with severe heart failure; (3) a treatment for complications linked to bone marrow transplants: and (4) an antidote for snake venom. We also continued investments for approximately 70 other ongoing clinical study projects, including four Phase 3 trials with the potential to support marketing applications for rare disease indications.

OPGP funds a second grant program—the Natural History (NH) Study Grants Program. Natural history studies provide data characterizing the course of a disease over time without investigational treatments. Study results can inform the design of future efficient clinical trials and support regulatory decisions. They are also useful for development and validation of new tools to assess treatment effects in investigational studies. In FY 2023, OOPD continued its financial support for six ongoing natural history studies in diseases.

With the enactment of the ACT for ALS Act on December 23, 2021, Congress established the FDA Rare Neurodegenerative Disease Grant Program. In FY 2023, OOPD funded six new grants for the program. Specifically, five new awards support efficient natural history or biomarker studies for various rare neurodegenerative diseases in children and adults. Characterizing various biomarkers are particularly valuable for diagnosis, monitoring disease progression, and possibly predicting response to treatment. The awards include:

- A biomarker study to develop a diagnostic test for the prodromal phase of ALS before symptoms occur;
- A natural history study for the familial form of ALS and other very rare motor neuron diseases that includes development of "disease agnostic" digital biomarkers;
- A biomarker study to optimize and validate multimodal longitudinal imaging of brain and cervical cord as an ALS disease biomarker; and
- Biomarker studies in each of two inheritable rare neurodegenerative diseases—myotonic dystrophy type 1 and Niemann-Pick type C—both cause early death.

The sixth new grant will support and inform future development of clinical outcome assessments that may be used as endpoints in investigational studies for communication brain-computer interface devices. Such devices may be used in patients with ALS who lose their ability to speak.

In addition, in FY 2023, OOPD: (1) increased support for an ongoing large ALS natural history study funded in FY 2022 to include genetic testing and other work needed to increase its likelihood to be used to inform future clinical trials; (2) co-funded, with funds from CTGP, a clinical trial for familial dysautonomia–a rare hereditary neurodegenerative disease; and (3) continued support for three ongoing natural history and studies two contracts that began in FY 2022.

The Pediatric Device Consortia (PDC) Grants Program encompasses device development for all pediatric diseases and conditions. For the grant reporting period (September 2022-August 2023), the PDC assisted 647 pediatric medical device projects compared to 611 in the previous reporting period. As a direct result of PDC's efforts in FY 2023, two devices, Snoo Smart Sleeper and Neoasis, were granted a De Novo classification and two PDC supported devices received 510(k) clearance for use in pediatric patients—ANNE One and Orchid Safety Release Valve. In addition, during FY 2023 the PDC hosted three Pediatric Device Innovators Forums—a recurring collaborative educational experience designed to connect and foster synergy among innovators. OOPD funded five geographically diverse consortia for the five-year cycle beginning in FY 2023, creating a national network committed to improving health equity for pediatric patients in the medical device space.

Office of the Chief Scientist

The Office of the Chief Scientist provides strategic leadership, coordination, and research expertise that supports the research foundation, science, and innovation underpinning FDA's regulatory mission. It does this through a broad framework that encompasses scientific collaborations, laboratory safety, the transfer of FDA inventions to the private sector, scientific integrity in FDA policy- and decision-making, the professional development of regulatory scientists, and its core research component—FDA's National Center for Toxicological Research (NCTR)—which generates the vital data FDA requires for its regulatory decision-making and development of sound regulatory policy.

Centers of Excellence in Regulatory Science and Innovation

FDA Headquarters provides leadership, coordination and support for academic Centers of Excellence in Regulatory Science and Innovation (CERSI) to provide FDA scientists ready access to leading researchers to assist in addressing high-priority regulatory science questions. In FY 2023, the Office of Regulatory Science and Innovation launched a new funding opportunity for the CERSI program. A new award was made to the University of North Carolina, Chapel Hill, in a partnership with Duke University. The new Research Triangle CERSI plans to partner with North Carolina State University and North Carolina Central University, a historically black college and university (HBCU) on research projects and regulatory science information sharing opportunities. Additionally, the institutions from the last grant cycle were also renewed: Johns Hopkins University, Yale University with Mayo Clinic, University of Maryland, and the University of California San Francisco with Stanford University. In FY 2023, 22 newly established collaborative research projects include science topics that address: digital health technologies to address opioid use disorders, patient-centered input and outcomes, diverse populations, large language models and AI, novel biologics, and neurological biomarkers.

Chief Scientist Challenge Grants

FDA Headquarters established, and now manages and coordinates the review and granting of intramural research award programs that supports four competitive research areas: Medical Countermeasures, Nanotechnology, Minority Health and Health Equity, and Women's Health. Additionally, the Chief Scientist also offers Challenges Grants to cross-agency collaborations. In FY 2023, the Chief Scientist Grants Program funded eight new projects and provided funding for a second year to 10 projects. All projects involve cross-agency collaborations that display rigorous thought, focus, and excellent scientific merit. The scientific areas of the recent projects include nanomaterials, advanced manufacturing to improve lipid nanoparticles, antimicrobial resistance monitoring systems, microbial metagenomics, natural language processing and AI, assessment methods for arsenic in rice grain, diagnostic devices for emergent flavivirus, and surveillance of cannabis-derived products.

Modernization of Cosmetics

Following the enactment of MoCRA on December 29, 2022, the Office of the Chief Scientist has centrally led and managed initial MoCRA efforts, in coordination with the Office of Cosmetics and Colors. Key activities throughout 2023 include: establishing a program for industry to complete mandatory registration and listing of cosmetic product facilities and products;[119] hosting a public meeting on Good Manufacturing Practices (GMP) for Cosmetic Products Listening Session to hear from cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts to help inform FDA efforts in developing regulations to establish GMPs for facilities that manufacture, or process cosmetic products distributed in the United States;[120] and developing a proposed rule to establish and require testing methods for detecting and identifying asbestos in talc-containing cosmetic products.[121]

Technology Transfer Program

The FDA Technology Transfer Program (FDATT) activities fulfill the Agency's federal technology transfer mandate under 15 USC 3710 and related legislation. FDATT provides intellectual property guidance for the Agency, especially for inventions and data rights, and provides technology transfer policy and leadership for FDA. FDATT assists FDA researchers and external collaborators to interact in the development and transfer of FDA invented technologies that improve public health. Through Cooperative Research and Development Agreements (CRADAs) and out-licensing of FDA technologies, the Agency advances regulatory science and innovation in all areas of FDA's mission, including medical therapies, human and animal food safety, medical devices, and enhancement of regulatory processes.

Using federal technology transfer authorities implemented through FDATT programs, the following FY 2023 accomplishments highlight instances where FDATT enabled FDA to

[119] https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products

[120] https://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-good-manufacturing-practices-cosmetic-products-06012023

[121] The proposed rule titled "Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products" was first added to the Unified Agenda of Regulatory and Deregulatory Actions in the Spring of 2023.

successfully engage with external partners to advance regulatory science initiatives, participate in the federal technology transfer mandate through reporting inventions, and update its knowledge of methods to increase the utilization of inventions through collaboration and transfer.

- Provided intellectual property and partnership guidance to FDA, completing over 600 actions including technology and partnership consultations; invention evaluations; patent application drafting and filing; patent prosecution activities; negotiation of research collaboration agreements for staff across the FDA; and protection of FDA logo from misuse.
- Evaluated 12 new inventions for impact of the potential product on improving public health and commercial viability, managed FDA's invention portfolio of over 180 technologies protected by over 485 patents and patent applications arising from research activities throughout the Agency.
- Established 4 new technology license agreements, resulting in 79 total active licenses that make FDA inventions available for use through the commercial sector to support the public health mission.
- Established 2 new Cooperative Research and Development Agreements (CRADAs), making 30 active partnerships using CRADAs to address regulatory science topics.
- Ensured technology transfer policies and processes were up to date and compliant with relevant laws and regulations so that FDA has clarity in its use of technology transfer authorities to protect, develop, and maintain access to its intellectual property; promote the use of its inventions; and engage with partners to advance the Agency's regulatory science priorities.

National and Global Health Security

FDA Headquarters leadership, coordination, and oversight for FDA's work to support national and global health security including:

- Serving as point of entry on policy and planning matters related to global health security
- Serving as a focal point for the FDA's involvement in the HHS-led Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and the Department of Defense (DoD) medical countermeasure (MCM) programs
- Coordinating the Medical Countermeasures Initiative (MCMi) to facilitate the development and availability of safe and effective MCMs against chemical, biological, radiological, and nuclear (CBRN) agents and emerging threats, such as pandemic influenza, Ebola virus, SARS-CoV-2 virus (the causative agent of COVID-19), and mpox virus
- Providing leadership and coordination for FDA responses to health security threats

Key FY 2023 – FY 2024 FDA Headquarters activities include:

- Providing leadership and support for FDA's response to the COVID-19 pandemic including leading the FDA COVID-19 Incident Management Group and COVID-19 Joint Information Center; supporting the development of MCMs; the issuance of emergency use authorizations (EUAs) to enable the emergency use of medical

products, amendments to current EUAs, and numerous EUA revocations; and continually communicating FDA's Agency-wide response efforts.[122]

- Working to improve EUA processes and promote supply chain resilience based on recommendations from the FDA PREPP Initiative.
- Facilitating coordination of FDA response activities to Ebola and Marburg outbreaks in Africa, the mpox in non-endemic countries, and other emerging infectious disease outbreaks including the issuance of EUAs to enable access to available MCMs when necessary.
- Supporting domestic and international policy development activities related to COVID-19, Ebola and mpox virus response including providing technical support to the World Health Organization and international regulatory counterparts.
- Working to prevent MCM shortages and resolve shortages as quickly as possible when they occurred. For example, FDA Headquarters provided critical leadership through the U.S. Government supply chain task force and provided FDA collaboration and technical assistance to USG-wide efforts to mitigate the impact of COVID on shortages of FDA-regulated products.
- Supporting regulatory science under the MCM Regulatory Science Program to advance the development of the tools needed to help establish clear, scientifically supported regulatory pathways for MCMs as well as to support innovation in advanced manufacturing to increase supply chain resilience, increase domestic manufacturing, and support public health emergency preparedness and response.
- Developing and coordinating the implementation policies and procedures to facilitate the availability of MCMs, including safeguarding MCMs from adulteration or disruption of supplies during public health emergencies and enabling access to MCMs through an appropriate mechanism such as an EUA.
- Supporting intra- and interagency global health security efforts, including support for the Global Health Security Agenda Legal Preparedness Action Package and the MCM Professional Development Program.
- Providing public information and education on FDA preparedness and response activities via events, press releases and interviews, the FDA website and social media.
- Coordinating intra-agency and interagency communication and cooperation on public health issues requiring a cross-agency focus in the One Health arena.

Office of Laboratory Safety

The Office of Laboratory Safety (OLS) oversees and leads cross-cutting activities associated with laboratory safety and related security, environmental compliance, laboratory quality management, and laboratory-related occupational safety and health programs across the FDA. These activities focus on the safety and health of the FDA workforce and the generation of high-quality data to support regulatory decision-making. OLS works to reduce risk from laboratory work, enhance laboratory security and data quality, increase efficiencies across the Centers and ORA, and strengthen the culture of responsibility and safety. Additionally, OLS develops new Agency-wide standards and policies; training, tools, and resources associated with implementing

[122] *More information about FDA's COVID response efforts is available on the FDA website at: www.fda.gov/coronavirus*

standards and policies; quality and safety assessment and improvement strategies; and other activities that emphasize the benefits of a safety-oriented culture.

In FY 2023, OLS published 4 new and revised 8 safety manuals; offered 5 new trainings; conducted numerous safety inspections of FDA laboratories; conducted environmental compliance audits; provided monthly safety updates to FDA leadership; and published an annual occupational incident report, an annual laboratory safety inspection report, an annual progress report, and monthly laboratory safety newsletters.

Office of Scientific Integrity

Preserving and Promoting Scientific Integrity

The Office of Scientific Integrity (OSI) continues to coordinate agency-wide efforts to preserve and promote integrity in FDA's scientific decision-making and research, as well as consistency on such issues. OSI identifies the need for additional policies and procedures through its frequent work with agency components to resolve both formal and informal disputes. OSI also continues to work with the Office of Science and Technology Policy at the White House to implement at the agency government-wide requirements and initiatives designed to ensure scientific integrity.

Resolving Agency Disputes

The Office of Scientific Integrity (OSI) continues to coordinate the resolution all disputes elevated to the Office of the Commissioner and most hearing requests on proposed regulatory actions. The disputes may originate with requests from either internal or external stakeholders and typically involve issues related to the underlying science or the Agency's regulatory authority for specific agency actions, including product approvals and emergency use authorizations. The hearing requests come in response to proposed regulatory actions by other components of the agency and involve similar issues. OSI also continues to receive and assess any incoming allegations related to the conduct of scientific research to determine whether they constitute research misconduct under the regulations (i.e., falsification, fabrication, or plagiarism), and refers the allegations to a board of inquiry and/or an investigatory panel, as necessary.

Office of Women's Health

The Office of Women's Health (OWH) provides leadership for the Agency on issues of women's health and coordinates efforts to establish and advance a women's health agenda. OWH funds research which aims to identify sex differences on the safety and efficacy of FDA regulated medical products, promote a better understanding of medical conditions that disproportionately or solely affect women, and advance the science of FDA products used during pregnancy and lactation.

In FY 2022 the Intramural Research Program committed funds for seven new projects on a wide variety of topics relevant to women. In addition, Office of Women's Health also funded three new Centers of Excellence Regulatory Science and Innovation (CERSI) projects in FY 2022, including one study to use machine learning to examine care patterns in the management of post-partum hemorrhage and another to gather data necessary for FDA to assess the risk of topically applied compounded estradiol products. Updates made to OWH's Research Impact and Outcomes (RIO) Framework in FY 2022 were implemented in FY 2023 and will facilitate the evaluation of the potential impact of research submitted for OWH funding. This process is the first step in the planned update to the OWH Research Roadmap which is scheduled for FY 2024.

The OWH Women's Health Research Fellowship Program has two research fellows in FY 2023. Their projects focus on sex differences in efficacy and selected safety events from HIV drugs, studying sex differences in efficacy and adverse event for HCV drugs and a study on cannabis derived products and their impact on adverse events and health outcomes in women.

OWH provides subject matter expertise on FDA policy, advocates for the study and evaluation of sex differences, and encourages the inclusion of females in clinical trials and represents the Agency's interests in women's health on interagency working groups and committees. In addition, OWH delivers numerous scientific lectures each year to a diverse array of stakeholders nationally and internationally to advance FDA's mission to protect, promote and advance the health of women. The Scientific Speaker Series webinars provide education regarding sex and gender differences to support regulatory decision making across FDA.

OWH develops educational initiatives and conducts outreach to connect women with FDA health and safety information. It uses a multi-pronged communication approach that includes a monthly OWH e-newsletter, social media and digital outreach, outreach collaborations and partnerships with stakeholders, stakeholder conference presentations and exhibitions, and dissemination of women's health educational publications. Some key program accomplishments include:

- Launched new resources under the KNOWH (Knowledge and News on Women's Health) campaign designed to educate and share the latest women's health information with stakeholders.
- In May 2021, during National Women's Health Week, launched new OWH blog, *Knowledge and News on Women* to share important information about women's health topics with consumers and healthcare professionals. From January 2021 to date, OWH has published 13 blog posts on a variety of women's health topics. To date, the blog posts have garnered over 23,000 page views.
- During Fibroid Awareness Month, July's blog focused on uterine fibroids and highlighted the agency's approval of a new option to treat heavy menstrual bleeding associated with fibroids in women, research developments on fibroids, and insights from women and their experiences.
- OWH promotes the latest updates on COVID-19 and infant formula information via social media platforms, our "For Women" homepage, and via e-newsletter and e-alerts.
- From October 2021 to date, OWH updated the "Pink Ribbon Guide: Mammography Matters," "Cholesterol Medicines" guide, revised the "Food Safety at Home" fact sheet, created a new "Uterine Fibroids" fact sheet, and "Uterine Fibroids: Tips for Young Women" card.

OWH materials are available electronically in multiple languages to download – www.fda.gov/womenshealthpubs.

Office of Minority Health and Health Equity

The FDA Office of Minority Health and Health Equity (OMHHE) was established in 2010 to protect and promote the health of racial and ethnic minority and tribal populations through research and communication that addresses health disparities and advances health equity. The OMHHE Outreach and Communication Program develops culturally and linguistically tailored strategies, tools, and multilingual health education resources to strengthen consumer's decision

making- regarding FDA-regulated products (e.g., brochures, fact sheets, post cards, infographics, digital content, videos, and social media messages).

Between October 2022 and September 2023, the OMHHE reached more than 18 million consumers through communications activities such as digital outreach, social media, blogs, weekly COVID-19 communications, biweekly newsletter, and over 70 e-alerts, including the following:

- Hosted three Health Equity Lecture Series webinars on clinical trial participation among Latinos, increasing participation in clinical trials and research among tribal and urban indigenous communities, and reducing tobacco-related health disparities.
- Released three new Health Equity Forum podcast episodes.
- Promoted updated COVID-19 Safety and Diversity public service announcement videos, which are translated into multiple languages, including American Sign Language.
- Continued efforts to advance the Skin Facts! Initiative, OMHHE's national multimedia campaign to educate and alert consumers about the potential risks from using skin lightening products that contain hydroquinone or mercury. The campaign used various outreach platforms, reached consumers in 12 major cities, and earned more than 17 million impressions.
- Launched the OMHHE *Equity of Voices* Video Series featuring the stories of seven people living with HIV and the impact of antiretroviral therapy on their lives.
- Launched OMHHE's Health Equity Update, a new bi-weekly newsletter, to promote OMHHE efforts to advance health equity and increase awareness of events, activities, and notifications of other FDA centers. The newsletter has reached more than 47,000 recipients.
- Continued to advance the OMHHE Diversity in Clinical Trials Initiative which includes an ongoing multi-media public education and outreach campaign to help increase diverse participation in clinical trials; published clinical trial diversity resources in 11 languages.
- Continued to promote the bilingual multimedia Let's Take Charge campaign in partnership with the HHS Office of Minority Health to increase diverse participation in lupus clinical trials.

Minority Health Research Engagement

The FDA OMHHE Research and Collaboration Program works with FDA centers, offices, and public- and private-sector stakeholders, including, academia, government agencies, minority owned small businesses and non-profit organizations to advance health equity-focused research, education, and scientific exchange. Since the launch of OMHHE's Enhance Equity Initiative in FY 2021, OMHHE has funded and supported over 50 collaborative research projects with diverse organizations representing Historically Black Colleges and Universities (HBCUs), Minority serving institutions (MSIs), non-profits, academic institutions, federal partners etc. In FY 2023, under the OMHHE Enhance Equity Initiative, OMHHE announced and funded four Notices of Funding Opportunities (NOFOs) totaling more than $6 million:

- Innovation Award: COVID-19 and Health Equity ($2 million) - funded four projects to advance racial and ethnic minority participation in COVID-19 clinical trials, and

increase understanding of diverse patient perspectives, preferences, and unmet needs related to COVID-19. Institutions awarded included MSIs and diverse organizations.

- FDA OMHHE Health Equity Innovation Award: Enhance Equity Funding Opportunity ($1 million) - funded three projects to advance equity in clinical trials by supporting efforts to advance diversity in clinical trials; equitable data efforts by increasing data available on diverse groups; and equity of voices by increasing understanding of diverse patient perspectives, preferences, and unmet needs. Institutions awarded include diverse organizations and academic institutions.
- FDA OMHHE Educational Funding Opportunity: Expanding education on skin lightening products ($0.5 million) - funded two projects to expand and advance OMHHE's work with stakeholders and partners for education, outreach, and public awareness activities on the use of and potential risks from over-the-counter skin lightening products containing hydroquinone or mercury. Institutions awarded include diverse organizations.
- FDA OMHHE Health Equity Innovation Award: Racial and Ethnic Minority Acceleration Consortium (REACH) for Health Equity ($3 million) - funded six awardees that led to the launch of a pilot research consortium that aims to timely and efficiently respond to OMHHE's health equity focused research needs. The pilot research consortium will also support training/mentoring of diverse students, fellows, and/or researchers. Institutions awarded include HBCUs, Tribal colleges and universities, Asian American and Native Pacific Islander serving institutions, Hispanic serving institutions, federally qualified health centers, and other diverse organizations.

During FY 2023, OMHHE also launched the Enhance Equity Research Hub that enables the public to search OMHHE funded research. OMHHE also supported Challenge Grants and awarded funding for two projects totaling $175,000 focused on innovation, intramural minority health and health equity focused research through collaborations across FDA product centers and offices.

In addition, OMHHE continued to support internships and fellowships to expand expertise in regulatory science and diversify the scientific workforce. In FY 2023, OMHHE continued to co-lead with the National Human Genome Research Institute (NHGRI/NIH) the Postdoctoral Fellowship in Genomic Science and Health Equity. The fellowship was selected as a winning proposal for the Secretary's Challenge on Equity. The office also precepted three pharmacy students through the FDA Pharmacy Student Experiential Program and funded three students to attend the NCTR Summer Science Research Program. OMHHE also funded three teachers to attend the CFSAN Professional Development Program in Food Science to learn the accredited "Science and Our Food Supply" curricula.

As a result of OMHHE's intramural and extramural research opportunities and other engagements, OMHHE published five manuscripts in peer reviewed journals.

Office of Policy, Legislation and International Affairs
Office of Policy (OP)

FDA's Office of Policy (OP) advances the agency's public health mission by providing strategic leadership of high priority or cross-cutting FDA policy initiatives and coordinating clearance and issuance of Federal Register documents. OP staff works across the full range of FDA products

and programs. OP establishes procedures for agency policy formulation, directs interagency consultation on regulatory actions, and specializes in leading initiatives with a high degree of novelty, complexity, or fast-moving timelines, such as statutory or court ordered deadlines. OP also manages critical FDA systems to support the development and issuance of regulations, guidance documents, and other Federal Register notices, the volume of which routinely exceeds 700 actions per year. In this role, OP manages the setting of policy priorities and corresponding work agendas; leads final clearance of Federal Register documents within FDA, and as needed by HHS and the Office of Management and Budget (OMB); operates the FDA-wide tracking and control system for Federal Register documents; and develops FDA's portion of the Unified Agenda for Federal Regulatory Actions.

Office of Legislation (OL)

The Office of Legislation (OL) advances FDA and Administration priorities with Congress and provides information requested by Congressional stakeholders to inform policymaking on new issues. Over the past year OL responded to over 1,000 Congressional requests pertaining to relevant policy interests, including on FDA's pandemic preparedness response efforts, shortages, food safety and nutrition, tobacco regulation, and more.

OL led efforts to reauthorize FDA's Animal Drug and Animal Generic Drug User Fee programs which were reauthorized as part of H.R. 5860, the Continuing Appropriations Act, 2024 and Other Extensions Act on September 30, 2023. The five-year reauthorization of the animal product user fee program is the result of months of engagement with Congressional Members and staff. OL has also led engagements, including two hearings, related to reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) which expired on September 30, 2023. OL continues to engage with staff on this reauthorization, including on new authorities to allow FDA to better mitigate and prevent product shortages.

Office of Congressional Appropriations (OCA)

The Office of Congressional Appropriations (OCA) manages FDA's relationship with Congressional appropriators in support of the Agency's resource needs and public health mission. OCA has managed hundreds of congressional inquiries and staff briefing requests, and shared hundreds of FDA announcements, policy updates, and other press and stakeholder materials with Congressional appropriators. OCA work closely with FDA senior leadership to develop, refine, and effectively communicate the Agency's current, short-, and long-term resource and policy needs. OCA works with Congressional appropriators on the development of the annual appropriations bills, helping them better understand FDA's resource needs related to several critical Agency initiatives to enhance food safety and nutrition, advance medical product safety, improve core operations, and modernize FDA's infrastructure, buildings, and facilities. OCA provides timely feedback to appropriator policy questions, requests for technical assistance, and constituent inquiries submitted via appropriations offices.

Intergovernmental Affairs (IGA)

The Intergovernmental Affairs (IGA) staff is the lead staff in the Office of Commissioner that engages with elected/appointed state, local, and territorial officials, facilitating communication regarding FDA policy initiatives and serving as an entry point for these officials when they seek information on and/or assistance with matters under FDA's regulatory purview. IGA also engages with federal intergovernmental partners, including the White House, HHS, and other

federal entities, on issues that implicate FDA equities. IGA serves as the Agency's designated liaison to tribal governments/organizations, device supply chain; dietary supplements; and many others. Some areas of recent engagement by the IGA team include cannabis; drug shortages; drug importation; compounding; food safety; opioids; tobacco; COVID-19 vaccines and therapeutics; stem cell therapies; ensuring the Agency honors and respects the unique government-to-government relationship that exists between the U.S. Government and federally recognized American Indian/Alaska Native tribes. In support of the Administration's commitment to ensure robust, uniform, and centralized engagement and consultation with Tribal Nations, IGA manages all formal interactions with tribes, guiding FDA Centers and Offices on the use of engagement mechanisms such as formal consultation, listening sessions, Dear Tribal Leader Letters, and more. IGA also serves as the interagency tribal liaison for the Agency, including with HHS and its Operating Divisions and coordinates data calls regarding the Agency's interactions with tribal governments. To fulfill its mission with state, local, territorial, and tribal partners, IGA coordinates across all FDA Offices and Centers.

Office of Economics and Analysis (OEA)

FDA's Office of Economics and Analysis (OEA) builds the foundational data and knowledge base that informs FDA's evidence-based policymaking. OEA's multidisciplinary staff works across the full range of FDA products and priorities, such as public health emergencies, market competition, health equity, economic impact analysis of key FDA regulations, and GAO/OIG oversight management. Specifically:

- Critical Public Health and Economics Analyses OEA staff undertake quantitative and qualitative research to inform Agency policy choices. For example, OEA maintains a robust research agenda to better understand the dynamics of competition in drug and biologics markets, to identify policy levers for potential FDA action.
- Economic Analysis and Support for Regulations OEA's economic analyses inform policy decisions throughout the rulemaking process and play a key role in the publication of proposed and final rules that foster innovation and clarify regulatory uncertainty among the regulated industry. OEA also participates in substantive engagements with high level stakeholders within FDA, HHS, and OMB.
- Government Accountability Office/ Office of Inspector General (GAO/OIG) Engagements and Agency Responses OEA's (GAO/OIG) Liaison team leads Agency responses to GAO and OIG studies, which often address sensitive matters such as FDA response to the COVID-19 pandemic, the Abbott infant formula recall, and how FDA guards against political interference in scientific decision making. The Team ensures timely, accurate, and complete responses to GAO and OIG engagements, and prepares regular progress reports.

Office of Global Policy and Strategy

International Inspections, Information Sharing and Strategic Engagement, and Continued Implementation of China Safety Initiative

FDA's Office of Global Policy and Strategy (OGPS) is comprised of three headquarters offices and four foreign offices (China, Europe, India and Latin America) in seven locations: Beijing, China; New Delhi, India; Brussels, Belgium; Amsterdam, Netherlands; Mexico City, Mexico; San Jose, Costa Rica and Santiago, Chile. OGPS collaborates with FDA Centers and Offices to

ensure global issues are reflected in policy and regulatory actions, and that FDA priorities are advanced globally.

Inspections

FDA, India, and Latin the China staff as well as ORA investigators on short term assignment to foreign office America offices conduct inspections in their respective country or region. In FY 2023, OGPS personnel have completed 238 foreign inspections in China (102), India (130), and Latin America (6).

The OGPS offices in India and China have played a critical role in completing unannounced inspections, and in providing logistical and operational support for the foreign unannounced inspection pilot program. The pilot program launched in India during FY 2023 and began in China in Q4 of FY 2023.

Information Sharing and Strategic Engagement

As part of cooperative regulatory activities, the Agency maintains international arrangements that facilitate regulatory cooperation, including the sharing of certain types of non-public information. These information -sharing arrangements and activities have proved critical for responding to global public health challenges including the COVID-19 response and infant formula shortages.

In FY 2023, FDA established one new confidentiality commitment with Indonesia (human foods) and seven new trade secret information confidentiality commitments with EU Member State veterinary drug authorities in support of the U.S. –EU Mutual Recognition Agreement. In addition, the FDA established or renewed new cooperative arrangements to enhance regulatory cooperation: the Republic of Korea (shellfish safety); and Republic of Korea (medical products and artificial intelligence).

FDA also completed a new assessment under the Food, Drug & Cosmetic Act section 708(c) of Switzerland and certified that Switzerland's drug regulator, the Swiss Agency for Therapeutic Products (Swissmedic), has demonstrated ability and authority to protect trade secret information from disclosure. The Commissioner's certification permitted the FDA to sign a new trade secret information confidentiality commitment with Swissmedic to facilitate exchange of certain unredacted trade secrets to support implementation of a mutual agreement with Switzerland.

International Partnerships

FDA builds strategic partnerships to raise awareness and understanding of the role strong regulatory systems play in protecting and promoting public health and facilitating international trade in safe products. In FY 2023, FDA, OECD, European Commission, and multinational organizations formed an informal steering committee to continue an ongoing initiative of advancing a whole of governments approach to countering the threat posed by illicit health products (medicines, medical devices, and foods), and are envisioning two initial projects to promote global public health. Within the WHO, FDA vice-chairs the WHO Member State Mechanism (MSM) for Substandard and Falsified (SF) Medical Products and has begun to lead the development of a strategic plan to combat the manufacture and distribution of these products.

Leveraging the Authority of Foreign Regulators

OGPS is FDA's lead for the negotiation of Mutual Recognition Agreements (MRAs). In May 2023, FDA formally expanded the scope of our mutual recognition agreement with the European Union to include good manufacturing practice inspections of animal drugs facilities. In FY 2023, OGPS concluded negotiations and a capability assessment with counterparts in Switzerland, coming to an agreement on an MRA to rely on inspection reports by Swissmedic.

Supply Chain Resilience

In FY 2023, OGPS coordinated the response to shortage concerns related to oncology drugs from India and China. OGPS leads FDA's engagement with critical stakeholders to mitigate manufacturing and quality risks to medical product supply chains and represents FDA in interagency discussions to (a) identify and address unfair foreign trade practices that have eroded U.S. critical supply chains and encourage adoption of science and risk based regulatory policies; and (b) examine how existing U.S. trade agreements and future trade agreements and measures can help strengthen the resilience of U.S. and global supply chains. OGPS also represented FDA in international supply chain negotiations with 13 countries under the Indo-Pacific Economic Framework initiative.

Oncology Center of Excellence

The Oncology Center of Excellence (OCE) continues to advance the President's Cancer Moonshot efforts to speed up progress against deadly and rare adult and pediatric cancers through exploring efforts to improve cancer diagnosis; target the right treatment to the right people; learn from all patients; diagnose cancer sooner; support patients, survivors, and caregivers; and address inequities. In FY 2023, OCE completed 71 publications including original applied research, perspectives on important drug development issues, and summaries of FDA's review of oncology product approvals exploring regulatory science issues, more than 10 abstracts, 10 draft or final guidances; and substantive external stakeholder engagement through the execution of over 36 oncology symposia/workshops. OCE conducted 89 cross-center FDA forums for engaging multidisciplinary FDA scientists and executed 30 oncology focused curriculum courses. OCE continues to strengthen international regulatory collaboration under Project Orbis. OCE, in collaboration with other FDA Centers, is implementing key provisions under FDORA that advance the Accelerated Approval pathway.

Oncology Research & Development: OCE launched Project Pragmatica, which seeks to introduce efficiencies and enhance patient centricity by integrating aspects of clinical trials with real-world routine clinical practice, which can reduce the burden of trial participation, with the hope to facilitate more diverse trial populations, more rapid enrollment, and reduced attrition. OCE programs intersecting with Pragmatica include the Oncology Real World Evidence Program, Project Silver, Patient Focused Drug Development Program, Project Significant, and Project Equity. As part of a broader effort by NIH and OCE to modernize clinical trials, on April 12, 2023, NIH issued a press release for the Pragmatica-Lung Study (or S2302) stating, in part, this is one of the first NCI-supported clinical trials to use a trial design that removes many of the barriers that prevent people from joining clinical trials. This 'pragmatic' approach aims to increase accessibility to clinical trials." OCE has had four publications under this Project since its launch. Project Optimus, a multi-disciplinary effort to improve dose optimization of cancer drugs and biologics to maximize the efficacy as well as the safety and tolerability of cancer therapeutics, published a draft guidance for industry, *Optimizing the Dosage of Human*

Prescription Drugs and Biological Products for the Treatment of Oncology Diseases, held public sessions at FOCR Annual meeting and ASCO as well as partnered with ASCO to lead the second annual public workshop entitled "Getting the Dosage Right: Optimizing Dosage Selection Strategies in Combination Anticancer Therapies" featuring a multi-stakeholder discussion on strategies to achieve dosage optimization. The OCE Pediatric Oncology Program, promotes the development of safe and effective new drugs and biologics to treat cancer in children. On June 16, 2023, FDA held a Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) meeting to discuss considerations related to dosage optimization of new drug and biological products for pediatric patients with cancer. Project Catalyst provided guidance and educational resources through 20 outreach events and led sessions at major professional society meetings to support informed anticancer therapy development to expedite the availability of directed and novel cancer treatments to the public, working primarily with small pharmaceutical companies and academic life science incubators and accelerators**.** Catalyst, in collaboration with OCE Rare Cancers Program, National Cancer Institute (NCI), and National Institutes of Health (NIH), participated in a public meeting on August 24, 2023, to discuss and develop a public-private partnership to guide and support development of new drugs for the treatment of patients with ultra-rare cancers. OCE established five new research efforts focused on applied (rather than basic) research questions to address specific challenges encountered during drug development that can materially affect the IND and NDA/BLA review process.

Oncology Regulatory Programs: Clinical review of cancer products was supported by OCE Medical Oncology Review and Evaluation (MORE) teams for 109 CBER and CDRH collaborative reviews, representing a 60 percent increase from FY 2022 to FY 2023. OCE's regulatory review supported at least 101 approvals of NDAs or BLAs (including supplements) as well clinical review of at least 27 Breakthrough requests. Under the Global and Regulatory Outreach Program, Project Orbis utilization rate for major FDA applications (new molecular entity and new indication submissions) was 40 percent. The OCE Oncology Regulatory Affairs and Policy Program provides regulatory support across OCE cross-cutting review programs, executes innovative regulatory review tools focused on expedited product review, and runs a novel expanded access program "Project Facilitate" within the Agency and across external partners. Project Facilitate managed 896 single patient INDs (135 applications for pediatric patients), for both emergency and non-emergency applications, representing a 39 percent increase from FY 2022. 92 percent of applications were received and granted by the FDA in less than 24 hours. The OCE Patient-Focused Drug Development (PFDD) program completed 86 product specific consultations, had 5 publications and executed the annual Clinical Outcome Assessment in Cancer Clinical Trial public workshop with over 1400 registrants. PFDD continued to broaden collaborations in the field of patient-reported outcomes within the Agency, across governmental organizations, international working groups and expanded an FDA/OCE-National Cancer Institute collaboration to advance patient-generated data and digital endpoints and deploy measures in early clinical development to assist in dose evaluation and characterization of tolerability. OCE Real World Evidence program (RWE) engages in evidence development modernization through scientific collaboration and policy development to advance the appropriate fit-for-purpose application of RWD to generate RWE to support oncology product development. RWE program supported oncology regulatory review, policy, and research with 67 consults, over 30 external engagement presentations, 22 regulatory science research collaborations, 4 publications and launched the Oncology QCARD initiative, the product of a collaboration with the Reagan-Udall Foundation to evaluate essential data elements that could

provide a starting point for characterizing the data source(s) and study design of an early RWD study proposal. The Oncology QCARD created a set of key design and data source elements that helped to inform information requests from oncology review teams to facilitate meaningful feedback on proposed RWD studies. In December, capecitabine tablets (Xeloda, Genentech, Inc (8 efficacy supplements)) was approved as the first drug to receive a labeling update under Project Renewal, and in September, temozolomide (6 efficacy supplements) was approved, as the second drug to receive a labeling update under OCE Project Renewal, a public health initiative to update labeling information for certain older oncology drugs to ensure information is clinically meaningful and scientifically up to date.

Oncology Health Equity: OCE Diversity in Oncology Program expanded external engagements and contributed significantly to Moonshot 2.0 goals. OCE's Project ASIATICA is a new initiative to bring focus and awareness to Asian American & Native Hawaiian Pacific Islander (AA&NHPI) patients with cancer. Asian Americans are a population for which cancer is the leading cause of death, and the AA&NHPI communities face significant healthcare challenges and disparities. Project ASIATICA launched works on advocacy, research, and policy, with a goal of bringing greater awareness and understanding to AA&NHPI patients with cancer of clinical trial participation. The OCE developed and published culturally and linguistically tailored oncology toolkits for AA and NHPI communities. ASIATICA held a Conversations on Cancer public panel discussion, and published an article on advancing therapies for this group. OCE's Project Equity is the lead on FDA's recent draft guidance *Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability* " and continues to co-lead an Agency-wide working group to promote consistent implementation of policy. Project Equity engagement on scientific and policy issues related to clinical diversity and health equity included over 25 presentations, roundtables, and symposia with a wide group of stakeholders from academia, professional organizations, nonprofit organizations focused on cancer, patient advocacy policy groups, and pharmaceutical sponsors. Project Community, a OCE national initiative introducing the work of FDA oncologists and hematologists to people in the community, especially under-represented and underserved, participated in multiple, national roundtables, meetings, and panels. Project Community held 16 external engagements including the 3rd National Black Family Cancer Awareness Week, which enlisted Cancer Moonshot goals as daily themes, featured a week-long social media campaign, #BlackFamCan, and a public panel discussion which received +3000 YouTube views to date . Lastly, OCE launched a new Cancer Community Resources webpage to provide fact sheets, videos, and links to additional information for patients, families, and community organizations in addition to the inaugural Advocates' Newsletter informing patients, advocates, families and others of OCE activities.

PERFORMANCE

The FDA Headquarters' performance measures focus on emergency response, women's health, science, global cooperation, premarket application review of orphan, pediatric and combination products, outreach, and organization efficiency, as detailed in the following table.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 +/- FY 2024
292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products.(Output)	FY 2023: Developed 78 mapping products in support of FDA's emergency preparedness, response, and recovery activities. Participated in eleven exercises during the year.* (All Targets Met or Exceeded)	Develop 60 mapping products in support of FDA's emergency preparedness, response, and recovery activities. Participate in seven exercises during the year.	Develop 60 mapping products in support of FDA's emergency preparedness, response, and recovery activities. Participate in seven exercises during the year.	Maintain
291101: Percentage of scientists retained at FDA after completing Fellowship or Traineeship programs. (Outcome)	FY 2023: 55% Target: 20%* (Target Exceeded)	20%	20%	Maintain
293205: Percentage of requests for combination product designations processed within the 60-day statutory requirement. (Output)	FY 2023: 100% Target: 95% (Target Exceeded)	95%	95%	Maintain
293203: Number of pediatric scientific, ethical, product, and product class issues identified through collaboration with the 27 European Union countries coordinated with the EMA, Japan, Canada, and Australia. (Output)	FY 2023: 142 Target: 100 (Target Exceeded)	100	100	Maintain
291306: The number of targeted engagements, which are strategic interactions between FDA and stakeholders that produce a tangible result in support of FDA's global mission. (Outcome)	FY 2023: 204 Target: 50 (Target Exceeded)	60	70	+10
291406: Percentage of invoices issued on time within predefined dates in the month. (Output)	FY 2023: 100% Target: 98%* (Target Exceeded)	98%	98%	Maintain

Figure 78 - FDA Headquarters Performance Table

The following selected items highlight notable results and trends detailed in the performance table.

Traineeship and Fellowship Programs

To support the Department's mission and FDA's scientific expertise, FDA launched a new FDA Traineeship Program while continuing other fellowship programs. This performance goal focuses on FDA's efforts to retain a targeted percentage of the scientists who complete these programs. Additionally, it is important to realize that whether "graduates" from these programs continue to work for FDA or choose to work in positions in related industry and academic fields, they are trained in using an FDA-presented understanding of the complex scientific issues in emerging technologies and innovation, which furthers the purpose of this strategic objective. FDA reset the retention target to 20 percent in FY 2021 to reflect the new expanded program's expected baseline. Although the Traineeship program has not yet been fully implemented, FDA has met the initial target of 20 percent in FY 2023. FDA will continue to monitor and adjust the target for retention moving forward as necessary. For now, the target will remain at 20 percent in FY 2024 and 2025.

INFRASTRUCTURE – GSA RENT, OTHER RENT, AND WHITE OAK

PURPOSE STATEMENT

The Infrastructure Program directly supports FDA's priorities by providing secure, modern, and cost-effective office and laboratory space that empowers FDA's workforce to protect and promote the safety and health of families; to foster the competition and innovation that will improve healthcare, expand access to medical products, and advance public health goals; to empower consumers and patients to make better choices; and to strengthen science and efficient risk-based decision making.

Authorizing Legislation: The Federal Food Drug and Cosmetic Act (21 U.S.C. 321 399); Radiation Control for Health and Safety Act (21 U.S.C. 360hh 360ss); The Federal Import Milk Act (21 U.S.C. 142 149); Public Health Service Act (42 U.S.C. 201, et seq.); Foods Additives Amendments of 1958; Color Additives Amendments of 1960; Animal Drug Amendments (21 U.S.C. 360b); Controlled Substances Act (21 U.S.C. 801 830); The Fair Packaging and Labeling Act (15 U.S.C. 1451 1461); Safe Drinking Water Act (21 U.S.C. 349); Saccharin Study and Labeling Act; Federal Anti-Tampering Act (18 U.S.C. 1365); Medical Device Amendments of 1976; Infant Formula Act of 1980; Drug Enforcement, Education, and Control Act of 1986; Generic Animal Drug and Patent Term Restoration Act; Prescription Drug Marketing Act of 1987; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Nutrition Labeling and Education Act of 1990; Prescription Drug Amendments of 1992; Safe Medical Device Amendments of 1992; Dietary Supplement Health and Education Act of 1994; Animal Medicinal Drug Use Clarification Act of 1994; Animal Drug Availability Act of 1996; Food Quality Protection Act of 1996; Federal Tea Tasters Repeal Act (42 U.S.C. 41); Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349); Food and Drug Administration Modernization Act of 1997; Antimicrobial Regulation Technical Corrections Act of 1998; Medical Device User Fee and Modernization Act of 2002; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Animal Drug User Fee Act of 2003 (21 U.S.C. 379j 11 - 379j 12); Project Bioshield Act of 2004 (21 U.S.C.360bbb 3); Minor Use and Minor Species Animal Health Act of 2004; Food Allergy Labeling and Consumer Protection Act of 2004 Medical Device User Fee Stabilization Act of 2005; Sanitary Food Transportation Act of 2005 Dietary Supplement and Nonprescription Drug and Consumer Protection Act (21 U.S.C. 379aa 1); Food and Drug Administration Amendments Act of 2007; The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111 31); Protecting Patients and Affordable Care Act of 2010; The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333); FDA Food Safety Modernization Act, Public Law 111 353 (January 4, 2011); The Food and Drug Administration Safety and Innovation Act (P.L. 112 144); the Drug Quality and Security Act (2013).

BUDGET REQUEST

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
FDA White Oak Campus	**53,053**	**49,589**	**56,293**	**55,061**	**55,061**	**-1,232**
Budget Authority	*45,914*	*46,664*	*48,414*	*52,498*	*52,498*	*4,084*
User Fees	*7,139*	*2,925*	*7,879*	*2,563*	*2,563*	*-5,316*
Other Rent and Rent Related	**146,293**	**147,911**	**164,550**	**161,127**	**162,749**	**-1,801**
Budget Authority	*98,262*	*99,762*	*106,095*	*154,879*	*156,479*	*50,384*
User Fees	*48,031*	*48,149*	*58,455*	*6,248*	*6,270*	*-52,185*
GSA Rental Payments	**212,103**	**216,190**	**244,884**	**231,328**	**221,533**	**-23,351**
Budget Authority	*153,119*	*153,286*	*166,286*	*166,286*	*155,386*	*-10,900*
User Fees	*58,984*	*62,904*	*78,598*	*65,042*	*66,147*	*-12,451*

Figure 79- Narrative by Activity

The FY 2025 President's Budget for the Infrastructure Program is $439,343,000, of which $364,363,000 is budget authority and $74,980,000 is user fees. At this level, the budget authority increases by $43,568,000 compared with the FY 2023 Final Level, and user fees decrease by $69,952,000.

The increase in budget authority reflected for OR&RR is needed to offset the user-fee reductions required to comply with FDARA Section 905 and meet cost escalations associated with security, operations and maintenance contracts, utilities, and Energy Savings Performance Contract payments for FDA's owned and GSA-managed buildings nationwide. Additionally, the OR&RR increase is also needed to address more demands for repairs and non-standard maintenance requests as FDA's owned buildings continue to age and equipment and systems failures occur.

The increase in budget authority reflected for the FDA White Oak Campus is needed to offset the user fee reductions required to comply with FDARA Section 905 and meet operating costs for the Campus, including ongoing, above GSA-standard repairs and improvements required to meet program needs, such as campus utility infrastructure capacity and reliability improvements, security infrastructure, and the campus safety program. Operating costs at the White Oak Campus continue to increase with inflation and because several of the buildings on Campus are 10 or more years old.

The decrease in budget authority reflected for GSA Rent considers the expected cost of rental payments to GSA for FDA's approximately more than 6.8 million square feet of GSA-managed space.

The Infrastructure Program supports FDA's offices and labs across the country and its headquarters White Oak Campus in Silver Spring, Maryland. The program provides the infrastructure and scientific facilities necessary for FDA's workforce to effectively protect and promote the safety and health of families. Therefore, supporting FDA's facilities will provide the high-quality infrastructure and facilities needed for FDA to achieve its priorities.

GSA Rental Payments

The FY 2025 President's Budget for GSA Rental Payments is $221,533,000, of which $155,386,000 is budget authority and $66,147,000 is user fees. The budget authority decreases by $10,900,000 compared with the FY 2023 Final Level and user fees decrease by $12,451,000.

The GSA-managed properties that provide office and laboratory space for FDA employees are essential facilities. The FY 2025 President's Budget request for GSA Rental Payments covers the cost of rental payments to GSA for FDA's approximately 6.8 million square feet of GSA -managed space. FDA's real property footprint, which includes relocated laboratories as part of FDA's laboratory modernization effort, is required for FDA to fully execute its expanding mission and public health responsibilities by increasing its presence in the field.

The requested budget level for GSA Rent considers new leases coming online for which rent will begin and expected market rates for GSA-owned and leased locations.

Other Rent and Rent-Related

The FY 2025 President's Budget for Other Rent and Rent-Related is $162,749,000, of which $156,479,000 is budget authority and $6,270,000 is user fees. The budget authority increases by $50,384,000 compared with the FY 2023 Final Level and user fees decrease by $52,185,000.

The increase in budget authority reflected in the Budget Request is needed to offset the user fee reductions required to comply with FDARA Section 905 and to allow FDA to operate, maintain, and secure its facilities in an appropriate and sustainable manner to support the FDA mission. It will also provide funding to address increased utility, operations and maintenance costs associated with FDA's aging owned buildings as well as increased security costs across all FDA facilities.

White Oak

The FY 2025 President's Budget for White Oak is $55,061,000, of which $52,498,000 is budget authority and $2,563,000 is user fees. The budget authority increases by $4,084,000 compared with the FY 2023 Final Level and user fees decrease by $5,316,000.

The increase in budget authority in the Budget Request is needed to offset the user fee reductions required to comply with FDARA Section 905 and to provide the necessary resources for increased above GSA-standard repairs and improvements as well as the most critical White Oak Campus utility infrastructure capacity and reliability improvements. It also provides needed funding for daily mission support services for employees and contractors, as well as visitors, on the White Oak Campus, including, transportation services, labor and loading dock services, and a centralized safety program. Additionally, this request ensures that FDA has the necessary resources to move forward with additional infrastructure and reliability improvements, prevent facilities from degrading, and assure that facilities remain state-of-the-art to support ever evolving science.

Reliability of the utility infrastructure at White Oak is critical to Campus operations, especially laboratory operations. For example, utility outages adversely impact CBER laboratory activities supporting efforts to control COVID-19 and U.S. readiness for seasonal and pandemic influenza. CBER's laboratories play several critical roles in the development and manufacture of vaccines, from participating in global surveillance for circulating virus strains and developing candidate vaccine strains to deriving and distributing critical reagents for manufacturers to use in their

assessment of vaccine quality. If utility outages disrupt any one of these activities, it could delay vaccine availability to the public, thus negatively impacting public health and increasing deaths.

BUDGET AUTHORITY

FY 2025 President's Budget: Infrastructure *Budget Authority - Dollars in Thousands*	
	Total
FY 2023 Final	**320,795**
FDA White Oak Complex	48,414
Other Rent and Rent Related	106,095
GSA Rental Payments	166,286
FY 2025 Budget Authority Changes	**(9,300)**
FDA White Oak Complex	-
Other Rent and Rent Related	1,600
GSA Rental Payments	(10,900)
Other Adjustments	**52,868**
FDARA Sec. 905 BA Shift	-
FDA White Oak Complex	4,084
Other Rent and Rent Related	48,784
FY 2025 Budget Net Total: Infrastructure	**364,363**
FDA White Oak Complex	52,498
Other Rent and Rent Related	156,479
GSA Rental Payments	155,386

Figure 80 - Infrastructure Budget Authority

Total Request: -$9.3 million

Security Screening: +1.6 million

This increase is part of the Other Rent and Rent Related increase in budget authority and is required to support enhanced security screenings and protect FDA's personnel, facilities, and information from threats. FDA will implement enhanced physical security measures, including additional equipment and officers, nationwide.

GSA Rent Savings: -$10.9 million

This reduction in budget authority will allow FDA to meet its rent obligations based on estimates for rent changes including those associated with continuing occupancies for which renewal rents will reset to market.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Infrastructure Program directly supports FDA's priorities by providing safe, secure, modern, and cost-effective office and laboratory space that empowers FDA's workforce to protect and promote the safety and health of families; to foster the competition and innovation that will improve healthcare, expand access to medical products, and advance public health goals; to

empower consumers and patients to make better choices; and to strengthen science and efficient risk-based decision making. The Infrastructure Program consists of:

- General Services Administration (GSA) Rental Payments
- Other Rent and Rent Related Activities
- White Oak

The Infrastructure Program supports FDA's offices and labs across the country and its White Oak Campus headquarters in Silver Spring, Maryland. Investing in FDA's facility objectives will provide the high-quality infrastructure and facilities needed for FDA employees to work and ensure FDA can achieve its priorities. Without adequate investment, FDA would be unable to respond to food-safety, medical-product, and public health emergencies, such as the COVID-19 pandemic, opioid addiction and abuse, tobacco use by American youth, and antimicrobial resistance. Programmatic funds may also support improvements critical to FDA's mission.

As FDA strategically manages its infrastructure, it focuses on creating high-quality work environments that effectively support FDA's public health priorities, optimize the use of taxpayer dollars, enhance workforce productivity, and ensure efficient operations. FDA promotes the efficient use of federal workspace and ensures that the appropriate information regarding the space required to support its escalating responsibilities is communicated to the Department for inclusion in the Capital Plan that HHS submits to the Office of Management and Budget.

Additionally, FDA's energy saving projects decrease long-term energy usage and operating and maintenance costs, while increasing facility life spans and efficiency to support Executive Order 13834, Efficient Federal Operations; Executive Order 14008, Tracking the Climate Crisis at Home and Abroad; and Executive Order 14057, Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability.

FDA replaced some of its geographically disparate headquarters' facilities with new, state-of-the-art laboratories, office buildings, and support facilities as part of the White Oak Campus consolidation onto the Federal Research Center; however, FDA's geographic consolidation of its headquarters facilities is still incomplete. As part of a space optimization initiative made possible by FDA's business-driven hybrid-workplace model, FDA is planning to further consolidate headquarters GSA-leased locations onto the White Oak Campus.

FDA also collaborated with GSA to update the master plan for the FDA-owned Muirkirk Road Complex (MRC) in Laurel, Maryland, as a good management practice and to ensure current information is available to consider all options related to headquarters space management. The master plan was approved in July 2023.

GSA Rental Payments

The GSA Rental Payments account includes rental payments for FDA's GSA-managed office and laboratory facilities. These facilities enable FDA to protect consumers and patients by keeping contaminated, adulterated, counterfeit, and defective food and medical products from reaching the marketplace and by swiftly and effectively addressing food-safety, medical-product, and public health emergencies that arise. Without these strategically located facilities FDA staff could not conduct boots on the ground operations including:

- Conducting inspections of regulated products and manufacturers annually
- Collecting and analyzing thousands of samples of regulated products annually

- Recalling unsafe products
- Reviewing millions of distinct product lines offered for entry into the U.S.
- Swiftly identifying the causes of foodborne illnesses that threaten the health and lives of Americans, like outbreaks caused by *E. coli*, *listeria monocytogenes*, *Cyclospora*, and *salmonella*
- Interdicting opioids at International Mail Facilities (IMFs) to combat the addiction crisis, which is a dominant public health problem in the U.S., killing more than 100,000 individuals in the U.S. in 2022
- Conducting criminal investigations, which result in arrests, convictions, billions of dollars of assets forfeited and seized, and billions of dollars in fines and restitution annually

FDA occupies approximately 6.8 million rentable square feet of GSA-owned and GSA-leased office, laboratory, warehouse, and border/inspection-station space.

Approximately 68 percent of the GSA rent charges for GSA-controlled space are for headquarters facilities in the Maryland suburbs of Washington, D.C. FDA occupies GSA-controlled space in approximately 265 buildings, including district offices, laboratories, resident posts, border stations, and field offices across the nation and in Puerto Rico.

The GSA Rental Payments account ensures that the FDA workforce has the space necessary to carry out FDA's public health mission. FDA strives to be cost effective and energy efficient in its acquisition, disposition, and use of the space in accordance with nationally recognized standards.

In FY 2023, FDA:

- continued coordinating design activities required to replace an aging facility and improve the operations of the ORA laboratory near Atlanta, Georgia, that houses the Southeast Food and Feed Laboratory and the Southeast Tobacco Laboratory
- continued coordinating design activities required to replace an aging facility and improve operations of ORA's human and animal foods laboratory near Denver, Colorado
- continued coordinating the construction activities required to renovate and expand operations at ORA's Forensic Chemistry Center located in Cincinnati, Ohio
- continued coordinating leasing/relocation activities for ORA resident posts, border stations, district offices, and field offices to enhance inspection and criminal-investigation operations to protect public health
- continued coordinating leasing, design, and construction activities required to expand ORA's presence in eight IMFs, enhance opioid interdiction efforts, and combat the addiction crisis threatening American families
- substantially completed construction activities for a new CDER laboratory near the White Oak Campus to house a pilot plant for simulating the processing of drug substances and products manufacturing
- continued renovating an existing building to provide additional storage on the White Oak Campus to support FDA's expanding operations and growing workforce
- began developing a space-optimization implementation plan based on FDA's business -driven hybrid-workplace model.

In FY 2024, FDA plans to:

- initiate construction activities required to replace an aging facility and improve the operations of the ORA laboratory near Atlanta, Georgia, that houses the Southeast Food and Feed Laboratory and the Southeast Tobacco Laboratory
- continue coordinating design activities required to replace an aging facility and improve operations of ORA's human and animal foods laboratory near Denver, Colorado
- complete construction activities required to renovate and expand operations at ORA's Forensic Chemistry Center located in Cincinnati, Ohio
- continue coordinating leasing/relocation activities for ORA resident posts, border stations, district offices, and field offices to enhance inspection and criminal-investigation operations to protect public health
- continue coordinating leasing, design, and construction activities required to expand ORA's presence in eight IMFs, enhance opioid interdiction efforts, and combat the addiction crisis threatening American families
- complete renovating an existing building to provide additional storage on the White Oak Campus to support FDA's expanding operations and growing workforce
- continue developing a space-optimization implementation plan based on FDA's business driven hybrid-workplace model.

Other Rent and Rent-Related Activities

The Other Rent and Rent-Related Activities account includes rent-related charges that are not part of the GSA Rental account. These funds cover costs for operating, maintaining, and securing FDA and GSA facilities located nationwide. Costs include:

- operation and maintenance contracts
- operation and maintenance repairs
- janitorial and grounds maintenance contracts
- DHS basic and building-specific security
- above-standard security and guard services contracts
- standard utilities in FDA-owned facilities
- essential overtime utilities in GSA-controlled laboratories and data centers that operate continuously and beyond the GSA standard 10-hour day
- other above-standard level services required to operate FDA facilities not provided by GSA in GSA-controlled facilities

This account ensures that FDA's offices and labs are functional and support the FDA workforce in meeting its public health mission by providing safe, efficient, reliable, and secure facilities. Without the services and repairs funded by this account, critical FDA operations, including research and regulatory work, would cease.

Additionally, FDA is implementing energy efficiencies that, over time, will result in significant utility cost savings in the Other Rent and Rent-Related Activities account. These projects support:

- Executive Order 13834, Efficient Federal Operations
- Executive Order 14008, Tracking the Climate Crisis at Home and Abroad

- Executive Order 14057, Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability
- HHS' Efficient Energy Management Assessments
- Energy Policy Act of 2005
- HHS Sustainable and High-Performance Buildings Policy
- HHS Sustainable Buildings Plan
- 2006 Federal Leadership in High Performance and Sustainable Buildings Memorandum of Understanding
- Energy Independence and Security Act of 2007

For the White Oak Campus, GSA entered into Energy Savings Performance Contracts (ESPCs) with Honeywell Corporation to build a Central Utility Plant (CUP), provide utilities, and perform operations and maintenance activities in a phased approach consistent with the construction and occupancy of the Campus. FDA entered into a memorandum of understanding with GSA and committed to a long-term occupancy of the Campus, including an agreement to pay a share of the costs associated with the ESPCs. Under this agreement, FDA's share of these costs is less than their utility costs would be otherwise due to the energy saving features provided by the ESPC.

Benefits of the ESPC, in addition to annual energy cost savings, include improving Campus electrical power reliability, which safe-guards ongoing medical product research, and reducing recurring maintenance costs. In addition to monetary benefits to the taxpayer, the CUP provides electric power through efficient cogeneration and photovoltaic equipment, funded by the ESPC, to reduce the environmental impact (pollution) of the Campus compared to supporting the Campus by more traditional power sources.

When each ESPC phase began to provide benefits to the Campus, including utilities to FDA occupied buildings, FDA was required to pay its agreed-upon share. The most recent example is GSA's "ESPC III," which covers the expansion of the CUP. The CUP expansion provided the utilities needed to operate the new Life Sciences – Biodefense Laboratory Complex (LSBC).

Awarding additional UESCs, procuring renewable energy, and incorporating energy efficiency measures in FDA's newly constructed facilities will contribute to HHS sustainability goals established in the HHS Strategic Sustainability Plan developed in accordance with Executive Order 13834, Efficient Federal Operations; Executive Order 14008, Tracking the Climate Crisis at Home and Abroad; and Executive Order 14057, Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability. FDA's activities related to UESCs, renewable energy and energy conservation measures will mitigate the effect of FDA's operations on the environment.

White Oak

Most of FDA Headquarters operations are on the White Oak Campus. Occupied in phases between 2003 and 2014, the Campus replaced geographically disparate, out-of-date facilities with new, state-of-the-art laboratories, office buildings, and support facilities in one location. The total number of employees and contractors currently assigned to the White Oak Campus is approximately 11,600 as a result of FDA's business-driven hybrid-workplace model, which includes increased telework.

By consolidating much of its headquarters workforce, FDA increased opportunities for staff to collaborate face-to-face, while reducing overall facility costs. In-person collaboration fast-tracks

advances and innovation in science, policy, and regulation that protect public health and accelerate access to lifesaving and life-improving products. Additionally, the consolidation centralized headquarters decision-making. As part of a space optimization initiative made possible by FDA's business-driven hybrid-workplace model, FDA is planning to further consolidate headquarters GSA-leased locations onto Campus.

During public health crises, such as the COVID-19 pandemic, and emergencies, FDA's emergency operations center on Campus coordinates communications and actions across FDA programs, ORA, and federal, state, local, tribal, territorial, and foreign regulatory public health counterparts.

Figure 81 – The White Oak Campus

Figure 82 – State-of-the-Art Buildings at White Oak

Figure 83 – Anechoic Chambers Laboratory

Figure 84 – Nuclear Magnetic Resonance Laboratory Supporting CBER and CDER

Figure 85 – State-of-the-Art White Oak Infrastructure: Advanced Air Terminal Units Supporting Laboratories

Figure 86 – Flow Cytometry Core Facility: Highly Specialized and Expensive Equipment for Vaccine and Cell Therapy Studies

The GSA appropriation funded the design and construction of new base buildings and funds the operations and maintenance of existing base buildings at White Oak. FDA's White Oak budget funds the Campus infrastructure, building fit-out, and specialized equipment required to make the base buildings operational (often called above-standard or above-GSA-standard items), as well as costs for moves, alterations, above-standard operations, and logistics.

White Oak funding supports Campus operations and requirements including:

- infrastructure modifications and improvements to meet the needs of rapidly changing laboratory research and medical product review programs
- above-standard Campus and building infrastructure design and construction required by laboratory functions, without which Campus operations would be limited and/or disrupted
- FDA information technology and security infrastructure, equipment, cabling, and audiovisual, without which Campus activities would come to a halt
- commissioning and certification of the specialized laboratories required for scientific evaluation and research necessary for medical product approvals and regulations
- support services, including conference center management, labor and loading dock services, and operations and maintenance services, including maintenance of vital specialized laboratory equipment, without which the Campus could not reliably function
- transportation services, including parking management and a campus shuttle and circulator bus program critical to support the growing Campus staff and operations
- a centralized safety program to support expanded lab operations and Campus occupancy and protect the health and well-being of the federal workforce

In addition to funding Campus operations, White Oak funding supports above-GSA-standard repair and improvement projects required by FDA's specialized functions to ensure that facilities do not degrade, remain state-of-the-art, and support program requirements.

BUILDINGS AND FACILITIES

PURPOSE STATEMENT

As with the Infrastructure Program, the Buildings and Facilities (B&F) Program directly supports FDA's strategic policy areas. The program is responsible for ensuring that FDA's owned offices and labs across the country function optimally and empower FDA's workforce to carry out its public health mission, respond to food-safety and medical-product emergencies, and protect and promote the safety and health of American families. Improving the condition of site infrastructure and buildings at FDA's owned locations, most of which are in poor condition, and modernizing them are essential to strengthening FDA's scientific workforce.

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Public Health Service Act (42 U.S.C. §238); Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. §§471 et seq.); National Historic Preservation Act of 1966 (P.L. 89-665; 16 U.S.C. 470 et seq.); Chief Financial Officers Act of 1990 (P.L. 101-576); Federal Financial Management Act of 1994 (P.L. 103-356); Energy Policy Act of 2005 (P.L. 109-058); Energy Independence & Security Act of 2007 (P.L. 10-140, 121 Stat. 1492).

Allocation Methods: Direct Federal/Contract

(Dollars in Thousands)	FY 2021 Actuals	FY 2022 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	President's Budget (+/-) FY 2023 Final
Buildings and Facilities (Budget Authority)	11,091	15,120	12,788	12,788	12,788	---

Figure 87- Funding History

BUDGET REQUEST

FY 2025 President's Budget: Buildings and Facilities *Budget Authority - Dollars in Thousands*	
	Total
FY 2023 Final	**12,788**
FY 2025 Budget Authority Changes	**-**
FY 2025 Budget Net Total: B&F	**12,788**

Figure 88 – Budget Request

The FY 2025 President's Budget is $12,788,000 which is flat compared to the FY 2023 Final Level, consisting solely of budget authority.

FDA will continue to sustain the current condition of FDA's six mission-critical, owned facilities, including the site infrastructure and buildings. At this funding level, FDA will continue to prioritize the most urgent and critical needs across owned infrastructure and facilities.

Gulf Coast Seafood Laboratory - Dauphin Island, Alabama

No projects are being planned for this facility in FY 2025.

Jefferson Laboratories Complex (JLC) - Jefferson, Arkansas

FDA will initiate facility improvement projects to:

- renovate the guard station
- renovate the Building 50 elevator.

Muirkirk Road Complex (MRC) - Laurel, Maryland

FDA will initiate facility improvement projects to:

- replace de-aerating system for MOD1 clean steam generators
- replace MOD1 fluorescent lighting with LED lighting
- renovate six MOD1 restrooms and provide gender-neutral restrooms
- replace MOD1 water-source heat pump
- replace air conditioning in the MOD1 computer center
- assess campus fire-protection and potable water distribution piping.

Pacific Southwest Laboratory - Irvine, California

FDA will initiate facility improvement projects to:

- renovate a lab space
- replace isolator exhaust system for certain lab spaces
- replace a five-ton air-conditioning unit.

San Juan District Office and Laboratory - San Juan, Puerto Rico

No projects are planned for this facility in FY 2025.

Winchester Engineering and Analytical Center (WEAC) – Winchester, Massachusetts

No projects are planned for this facility in FY 2025.

The following table provides an allocation plan by site for use of the FY 2025 funds.

FY 2025 BUILDINGS AND FACILITIES ALLOCATION PLAN

BUILDINGS AND FACILITIES ALLOCATION PLAN FY 2025	
Site	**President's Budget**
CFSAN Gulf Coast Seafood Laboratory – Dauphin Island, AL	$0
Jefferson Laboratories Complex (NCTR & ORA Arkansas Lab) – Jefferson, AR	$2,000,000
Muirkirk Road Complex (MOD1, MOD2, BRF) – Laurel, MD	$8,288,000
ORA Pacific Laboratory SW – Irvine, CA	$2,500,000
San Juan District Office and Laboratory – San Juan, PR	$0
Winchester Engineering and Analytical Center – Winchester, MA	$0
B&F Project Total	**$12,788,000**

Figure 89 - Buildings and Facilities Allocation Plan

In FY 2025, sustaining the condition of FDA-owned real property assets and site infrastructure will continue to be a priority. Completion of these projects is necessary for FDA to achieve its critical mission. In addition, several of these projects will contribute to HHS sustainability goals established in the HHS Sustainability Implementation Plan. More specifically, projects planned in FY 2025 will help reduce Scope 1, 2, and 3 greenhouse gas emissions by replacing or repairing aged building equipment.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

As with the Infrastructure Program, the Buildings and Facilities (B&F) Program directly supports FDA's strategic policy areas. The program is responsible for ensuring that FDA's owned offices and labs across the country function optimally and empower FDA's workforce to carry out its public health mission, respond to food-safety and medical-product emergencies, and protect and promote the safety and health of American families. Improving the condition of site infrastructure and buildings at FDA's owned locations, most of which are in poor condition, and modernizing them are essential to strengthening FDA's scientific workforce.

B&F objectives are tied to providing FDA's workforce with the work environments necessary to effectively evaluate and regulate medical, food, and tobacco products. The currently poor overall condition of FDA's owned buildings and facilities, especially its labs, directly affects FDA's ability to foster the scientific innovation necessary to improve healthcare, expand access to medical products, and advance public health goals. Investing in FDA's facilities will provide the high-quality infrastructure and work environment needed for FDA employees to ensure FDA can achieve its critical mission.

Supporting the FDA Mission

The B&F Program is a critical element of FDA's real property Asset Management Program (AMP) and laboratory modernization efforts, and directly supports FDA's public health mission. FDA recruits, develops, retains, and strategically manages a world-class workforce, improves the overall operation and effectiveness of FDA, and invests in infrastructure to enhance productivity and capabilities. Accordingly, FDA strives to provide high-quality, safe, reliable buildings that support FDA's mission-critical work. B&F funding is used to:

- construct new mission-critical laboratory, office, and support space
- renovate and repair site infrastructure and buildings – an inventory of 78 existing FDA owned facilities at six sites in the United States and Puerto Rico

Figure 90 – Newly Renovated Lab Building at the Jefferson Labs Complex

HHS developed a real property AMP to outline a framework and holistic approach for acquiring, managing, and disposing of real property assets.

The AMP contains performance measures and benchmarks that monitor key, real property asset-management criteria, including:

- mission criticality
- safety
- utilization
- facility condition
- operating costs

The physical condition of FDA assets is critical. A safe, suitable, and reliable work environment is essential for FDA to protect the nation's health, security, and economy. Improving and maintaining facilities often positively affects associated utilization and operating costs.

An important component of FDA real property asset management is periodically conducting facility condition assessments to evaluate:

- site infrastructure – utility distribution systems, roads, and sidewalks
- buildings, including physical systems – architectural, civil, mechanical, electrical
- code compliance
- life and other safety conditions
- finishes and aesthetics.

The assessments result in:

- a list of maintenance and repair deficiencies with associated costs known as the Backlog of Maintenance and Repair (BMAR)
- a plant replacement value – the cost to replace an infrastructure item or a facility
- a Facility Condition Index (FCI) score.

The BMAR identifies and estimates costs associated with addressing needed maintenance, repairs, and replacement of equipment and building systems that are approaching – or past – their useful lives. The BMAR also identifies and prioritizes short- and long-term projects using B&F funding.

FDA uses funds to accomplish both mission and BMAR-driven projects. The goal is to improve the condition of these assets and the site infrastructure and to ensure the suitability and reliability of FDA-owned assets, especially laboratories that require modernization.

FDA has 22 labs located at the following six owned sites:

- Gulf Coast Seafood Laboratory, Dauphin Island, Alabama
- Jefferson Labs Complex, Jefferson, Arkansas
- Muirkirk Road Complex, Laurel, Maryland
- Pacific Southwest Laboratory, Irvine, California
- San Juan District Office and Laboratory, San Juan, Puerto Rico
- Winchester Engineering and Analytical Center, Winchester, Massachusetts

Activities in FY 2023 and Planned for FY 2024
Gulf Coast Seafood Laboratory – Dauphin Island, Alabama

The Gulf Coast Seafood Laboratory (GCSL) is FDA's sole marine laboratory and represents 80 percent of FDA research capacity for addressing seafood safety.

In FY 2023, FDA began the process to acquire excess U.S. Coast Guard property on Dauphin Island to allow FDA to replace certain lab operations in its aged and functionally obsolete existing lab building.

In FY 2024, FDA plans to complete the acquisition of the U.S. Coast Guard property and begin developing a specific strategy for laboratory revitalization that will include relocating certain laboratory operations to the newly acquired property.

Jefferson Laboratories Complex (JLC) – Jefferson, Arkansas

The JLC houses the National Center for Toxicological Research (NCTR) and the Office of Regulatory Affairs (ORA) Arkansas Laboratory (ARKL). Additional details of the vital NCTR

scientific research that takes place at the Complex can be found in the NCTR Narrative. ARKL provides analytical laboratory support to FDA's regulatory mission in the Southwest Region.

In FY 2023, FDA:

- continued construction of motor control center and capacitor renovations campus wide
- continued construction of a new main sewer line from JLC to the Pine Bluff Arsenal's wastewater treatment plant
- continued the design of roof renovations for Building 26 and initiated the design of roof renovations for Building 50
- completed the design for the renovation of Building 62 and initiated the construction project
- completed the design for Phase 2 of a critical Pathology lab
- completed the design and installation of a renovated campus fire-alarm system
- completed exterior lighting upgrades
- completed the design of Building 26 exterior upgrades
- completed the design of guard station renovation
- initiated the design of water tower upgrades.

In FY 2024, FDA plans to:

- provide additional funding to support the renovation of Building 62 large-animal holding area upgrades
- provide additional funding to support the construction of a new Chiller Plant
- complete design of water tower upgrades
- complete roofing project for Building 15
- initiate a project to make motor control center modifications
- initiate projects to renovate roofs on various buildings
- initiate a project to upgrade the fuel system serving campus boilers and emergency generators.

Muirkirk Road Complex (MRC) – Laurel, Maryland

The Muirkirk Road Complex is a campus shared by the Foods and Animal Drugs and Feeds programs to conduct research in the following areas:

- Food and Animal Drug Safety: Isolating, identifying, and characterizing microorganisms potentially harmful to animals and humans, particularly the effects of antimicrobial use in animals on efficacy against pathogens, changes in the environmental microbial ecology, and the development of antimicrobial resistance in pathogenic and commensal microorganisms
- Toxicology: Reproductive toxicology, neurotoxicology, immunotoxicology, molecular toxicology, and in vitro toxicology, with special emphasis on developing higher throughput methods in hepatotoxicity, neurotoxicity, renal toxicity, cardiotoxicity, dermal and nanoparticle toxicity
- Microbiology: Foodborne parasites and viruses and immunobiology

- Molecular Biology: Genetic and biomarkers, microbial genetics, including molecular epidemiology and molecular virology, and foodborne allergens and glutens

In FY 2023, FDA:

- continued projects to replace generators and correct main-laboratory air handling units (AHUs)
- completed construction of a new backflow preventer for the entire campus
- continued upgrading and renovating the aquaculture facility (Building H)
- completed an update of the campus master plan
- continued Utility Energy Service Contract (UESC) Phase 8, which includes upgrades of the HVAC system across the campus
- continued UESC Phase 9, which includes construction of new generators and panel boards for the campus
- initiated a project to add exhaust fans to Building E and an air-conditioning unit to Building F.

In FY 2024, FDA plans to:

- complete projects to replace generators and correct main laboratory AHUs
- continue a project to add exhaust fans to Building E and an air-conditioning unit to Building F
- complete upgrading and renovating the aquaculture facility (Building H)
- complete UESC Phase 8, which includes upgrades of the HVAC system across the campus
- complete UESC Phase 9, which includes construction of new generators and panel boards for the campus
- initiate a project to install epoxy flooring in Building C3.

Pacific Southwest Laboratory – Irvine, California

The Pacific Southwest Laboratory provides analytical laboratory support to FDA's regulatory mission in the Pacific Region.

In FY 2023, FDA:

- completed an assessment of exterior wall cracks
- continued a construction project addressing interior cracks in the building
- continued construction of a nitrogen-system upgrade
- initiated a project to replace the facility's vacuum-pump system.

In FY 2024, FDA plans to:

- continue remediation of exterior and interior wall cracking
- complete construction of a nitrogen-system upgrade
- complete replacing the facility's vacuum-pump system
- initiate a project to add a dedicated cooling system for the local area network (LAN) room
- initiate a project to replace the existing fire-alarm system that is past its useful life.

San Juan District Office and the Pharmaceutical Laboratory – San Juan, Puerto Rico

The San Juan Pharmaceutical Laboratory specializes in pharmaceutical analysis. Drug analyses include, but are not limited to, method validation, drug surveillance testing, poison screenings, and the Department of Defense (DOD) Shelf-life Extension Program (SLEP). The DOD maintains significant pre-positioned stocks of critical medical material. SLEP defers drug replacement costs for these date-sensitive stocks by extending their useful life. The SLEP assures that only safe and effective drugs are made available to personnel during war and other significant events; in the last few years, this program was extended to include CDC's National Strategic Stockpile samples.

In FY 2023, FDA:

- continued construction activities for the new office building addition for the District Office funded with both B&F and Non-recurring Expenses Fund (NEF)
- Initiated a project to upgrade the HVAC system in Building 1.

In FY 2024, FDA plans to:

- complete construction of the new office building addition for the District Office funded with both B&F and NEF
- replace five rooftop HVAC units and supply and return ducts in Building 1
- initiate a project to replace the north perimeter fence
- initiate a project to add exterior lighting for improved security
- initiate a project to replace Building 1 fire protection systems
- initiate a project to address Building 1 settlement issues.

Winchester Engineering and Analytical Center (WEAC) – Winchester, Massachusetts

WEAC is a specialty laboratory used to:

- test the safety and performance of medical devices, microwaves, and radiopharmaceuticals
- conduct radionuclide testing with food samples
- ensure seafood freshness.

In FY 2023, FDA completed construction of the new laboratory.

In FY 2024, FDA has no planned projects.

PROGRAM ACTIVITY DATA

Facility			
	FY 2023 Operating	FY 2024 President's Budget	FY 2025 Estimate
CFSAN Gulf Coast Seafood Laboratory	81	80	79
Jefferson Laboratories Complex	70	70	70
Muirkirk Road Complex	62	63	64
ORA Pacific Southwest Laboratory	89	89	89
San Juan District Office and Laboratory	61	61	61
Winchester Engineering And Analytical Center	99	99	99

Figure 91 – Program Activity Data

NONRECURRING EXPENSES FUND

BUDGET SUMMARY

(Dollars in Thousands)

	FY 2023[123]	FY 2024[124]	FY 2025[125]
Notification[126]	$109,070	$62,600	$113,900

Authorizing Legislation:

Authorization……. Section 223 of Division G of the Consolidated Appropriations Act, 2008

Allocation Method…….……. Direct Federal, Competitive Contract

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Nonrecurring Expenses Fund (NEF) permits HHS to transfer unobligated balances of expired discretionary funds from FY 2008 and subsequent years into the NEF account. Congress authorized use of the funds for capital acquisitions necessary for the operation of the Department, specifically information technology (IT) and facilities infrastructure acquisitions.

Historically, FDA's Buildings & Facilities (B&F) and Infrastructure budgets have been unable to correct deficiencies in its backlog of maintenance and repairs, and in turn, the condition of FDA's owned assets have worsened. Additionally, the annual B&F funding levels have not provided adequate funding for owned-laboratory repairs, improvements, and replacements. Except for the White Oak provision that provides funds for laboratory repairs only on the White Oak Campus, FDA's Infrastructure budget does not provide funding for the relocation, repair, or improvement of FDA's General Services Administration (GSA)-owned and GSA-leased laboratories, forcing FDA to use program funds for these purposes.

BUDGET ALLOCATION FY 2025

Jefferson Labs Complex, Building 62 Electrical Infrastructure Replacement – Building 62 houses various research functions for NCTR. This project will replace the original, aged electrical distribution and backup power systems in a building constructed in 1964 that contains critical equipment necessary for the scientific research performed at Jefferson Labs Complex. The systems are at risk of failure. A failure could interrupt operations in the building for an

[123] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on September 23, 2022.

[124] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 19, 2023.

[125] HHS has not yet notified for FY 2025.

[126] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use.

extended period, which would compromise the execution of NCTR's mission, damage research, and imperil research animals housed in the building.

Jefferson Labs Complex, Replace Water Towers – The Jefferson Labs Complex is not served by a public water system, and water towers provide potable, equipment, and firefighting water service to the entire complex. The existing towers have aged beyond their useful lives and are out of compliance with Arkansas Department of Health regulations. This project will replace the existing towers and provide a modern, reliable, safe water source. If the existing towers failed due to their age and condition, the entire complex would shut down from a lack of water service, compromising the regulatory science required to protect public health. Irreplaceable research could be lost, wasting significant research funding previously expended.

Jefferson Labs Complex, Replace Air Handling Units in Laboratory Buildings 5, 26, and 53 – Air handling units (AHUs) serving Buildings 5, 26, and 53 have an extraordinarily long maintenance history, are well past their useful lives and are at risk of catastrophic failure. In addition to eliminating this risk, replacing these AHUs will increase the sustainability of building systems in response to Executive Order 14008, Tackling the Climate Crisis at Home and Abroad. If this project is not completed, there is a risk that one or more of the buildings would not be able to safely and reliably function and would be closed for an excessively long, unacceptable period, with a significant potential to lose critical research and endanger research animals.

Pacific Northwest Laboratory Infrastructure – The existing laboratory mechanical and electrical systems are antiquated and unreliable. Malfunctions and breakdowns often compromise stringent laboratory environmental conditions, which threatens the health and safety of staff in the building, especially scientists working in the laboratories. This project will retrofit and/or replace various mechanical and electrical system components to improve the safety and reliability of operations until long-term plans for the building (i.e., significant renovation with an addition to or a complete relocation of the lab) can be developed and implemented over the next six to eight years.

San Juan Laboratory, Building and Infrastructure Improvements – This project will replace the campus' potable water system, roadways and parking lots, and the windows in Building 1. It will also abate asbestos and lead in a vacant portion of Building 1 and renovate the vacant space to allow the program to consolidate their operations and move out of multiple dispersed buildings that have structural deficiencies. If left in their current state, any one of these building and infrastructure components could fail, causing the temporary suspension of research activities and hindering mission execution.

End of Life (Computer and Storage Modernization) – Replacing and modernizing the FDA enterprise IT infrastructure by replacing end-of-life (EoL) equipment and technology will further FDA's mission through ensuring the FDA's IT environment is secure, efficient, and compliant. IT infrastructure which includes essential compute and storage components serves as the foundation for all systems, business processes, program activities that enable the FDA to carry it out its mission. These improvements will enable the Agency to respond to nationwide emergencies such as the detection of unsafe food products, the COVID-19 pandemic, and the growing Opioid crisis.

End of Life (Backup and Network Modernization) – Modernize IT infrastructure and reduce the percentage of devices on the network that are considered beyond their useful life and are a cybersecurity risk. By continuing to run aging hardware, the risk of service disruptions increase as the equipment is more prone to failure and unable to be secure from cyber-attacks. By replacing the EoL technology with new, supported, secure, and superior technologies the Agency will gain improved functionality, enhanced security, and increased efficiency. This will result in a more stable network with fewer disruptions to mission critical activities.

BUDGET ALLOCATION FY 2024

Jefferson Labs Complex, Chiller Plant Supplemental – This project will install equipment in a new, strategically located building constructed to replace two separate chiller plants that have reached the end of their useful lives. The new chiller plant will be modular and simpler to operate and will meet the needs of new facilities identified in the campus master plan. The project will also increase the reliability of campus infrastructure. If the existing chillers failed, the entire complex would shut down, regulatory science required to protect public health would be compromised, and irreplaceable research could be lost, wasting significant research funding previously expended.

Jefferson Labs Complex, Pathology Lab Fit Out – This budget allocation supplements the FY 2023 allocation for this project and is required by unprecedented construction cost increases. This project will relocate, consolidate, and modernize pathology operations on this FDA-owned complex in keeping with the campus master plan. Relocating the pathology suite will consolidate operations for efficiency and provide cutting-edge labs and storage for the program.

Jefferson Labs Complex, Data Recovery Center – This budget allocation supplements the FY 2023 allocation for this project and is required by unprecedented construction cost increases. FDA will construct a Disaster Recovery Center on its FDA-owned complex in Arkansas to accommodate agencywide Information Technology disaster-recovery equipment and operations. The project is part of FDA's data center consolidation plan and will ensure continuity of operations in the event of a man-made or natural incident affecting the primary data center. It will also allow the relocation of the NCTR Data Center to address critical reliability concerns, replace equipment and systems that have aged past their useful lives, and support implementation of the campus master plan.

CFSAN Renovation of Wiley Building 3rd and 4th Floor Labs, College Park, MD – This budget allocation supplements the FY 2023 allocation for this project and is required by unprecedented construction cost increases. The project will create state-of-the-art microbiology and sequencing laboratories with flexible spaces that can easily be reconfigured to accommodate current and future laboratory tasks and operations. The renovation will also include important safety measures for staff.

ICAM Modernization – The ICAM project will provide FDA with a modern and enterprise approach towards Access Management for on premise and cloud applications, provide a virtual directory service necessary for ICAM solution and facilitate FDA data collaborations with external stakeholders.

Secure Access Service Edge (SASE) Capability transformation – The SASE solution represents a Cybersecurity Zero-Trust approach to accessing FDA applications both on premise and within Amazon and Azure cloud services. The solution includes a zero-trust access to non-FDA resources such as other federal resources (Department of Treasury, GSA, SAM.GOV) or commercial sites (Staples, Dell, Pharmaceutical partners).

Software Defined Networking (SDN) for FDA Network Infrastructure – NEF funds will be used to purchase software and hardware, including professional services for migration. Software Defined Networks are a modern approach towards networking and afford FDA Infrastructure engineers to dynamically and efficiently perform network configurations to improve performance and monitoring. In addition, the FDA infrastructure and cybersecurity engineers will initiate a Proof of Concept for Zero-Trust Policy Enforcement Point for Virtual Routing.

Internet Protocol Version 6 - IPv6 – The IPv6 project will help FDA comply with federal standards and HHS requirements, completing the transition to Internet Protocol Version 6 (IPv6). The IPV6 project will involve the upgrade and configuration of infrastructure components to IPV6 industry standard. Benefits include the ability to handle packets more efficiently, improve performance and increase security.

BUDGET ALLOCATION FY 2023

Southeast Laboratory, Atlanta, GA – Based on steeply rising costs throughout the construction industry, construction contingency funding for this critical lab relocation project was inadequate at early stages of the design project. Providing contingency funding in FY 2023 will allow programs operating in the functionally obsolete existing building to be appropriately accommodated in the new facility.

Muirkirk Road Complex Office Annex to Laboratory Building – FDA will design and construct an office annex to the MOD2 laboratory building and a new cage washing area. These construction projects are required to accommodate a future laboratory renovation and expansion in MOD2. The office annex will house MOD2 laboratorians who must be relocated from MOD2 to provide the space needed to expand laboratory operations.

Pacific Southwest Laboratory Infrastructure Improvements, Irvine, CA – This project will renovate infrastructure systems and add a steam boiler to provide the lab and office space with properly functioning building systems that are fully redundant in operation, so vital work performed in this facility can continue without interruption.

CFSAN Renovation of Wiley Building 3rd and 4th Floor Labs, College Park, MD – This project will create state-of-the-art microbiology and sequencing laboratories with flexible spaces that can easily be reconfigured to accommodate current and future laboratory tasks and operations. The renovation will also include important safety measures for staff. This budget allocation is supplemented by the FY 2024 allocation required by unprecedented construction cost increases.

Jefferson Labs Complex, Data Recovery Center – FDA will construct a Disaster Recovery Center on its FDA-owned complex in Arkansas to accommodate FDA-wide Information Technology disaster-recovery equipment and operations. The project is part of FDA's data center consolidation plan and will ensure continuity of operations in the event of a man-made or natural

incident affecting the primary data center. It will also allow the relocation of the NCTR Data Center to address critical reliability concerns, replace equipment and systems that have aged past their useful lives, and support implementation of the campus master plan. This budget allocation is supplemented by the FY 2024 budget allocation required by unprecedented construction cost increases.

Jefferson Labs Complex, Pathology Lab Fit Out – This project will relocate, consolidate, and modernize pathology operations on this FDA-owned complex in keeping with the campus master plan. Relocating the pathology suite will consolidate operations for efficiency and provide cutting-edge labs and storage for the program. This budget allocation is supplemented by the FY 2024 budget allocation required by unprecedented construction cost increases.

BUDGET ALLOCATION FY 2022 AND PRIOR

From FY 2015 through FY 2022, FDA received a total of $392.7 million from the NEF to replace one owned laboratory, significantly renovate two owned laboratories, address other urgent owned-facilities and infrastructure needs, relocate three aged and deteriorated leased laboratories, and build an office building addition. NEF resources have allowed FDA to fund replacement of the ORA's functionally obsolete owned laboratory at FDA's Winchester Engineering and Analytical Center in Winchester, Massachusetts, with an efficient, modern laboratory and to renovate laboratory Buildings 14 and 53A as well as an animal research processing area in Building 53B for NCTR located at FDA's owned Jefferson Labs Complex, in Jefferson, Arkansas.

Funds were also used for building and site infrastructure improvements, such as renovations, building system upgrades, roadway/drainage repairs, and building equipment replacement, at FDA-owned locations. NEF resources have also allowed FDA to initiate the process to relocate ORA's aged, leased laboratories in Kansas City, Kansas, Atlanta, Georgia, and Denver, Colorado, into new, modern, and efficient leased laboratories designed to meet ORA's mission. Funding received has also provided the resources needed to construct a new chiller plant for the FDA-owned Jefferson Labs Complex and a new office building addition at the FDA-owned location in San Juan, Puerto Rico. Without NEF resources received for projects at FDA-owned sites, FDA would have to use its limited B&F funds, which would delay mission-critical improvements, cause facilities and infrastructure to further deteriorate, and hamper the execution of FDA's public health mission. Without NEF resources received for leased-laboratory relocations, ORA would have had to cut critical items in its foods programs, such as delaying hiring, which would reduce ORA's ability to train staff and conduct inspections, and/or delaying laboratory equipment purchases required to keep up with changing technology.

SUPPLEMENTAL ITEMS

OBJECT CLASS TABLES

BUDGET AUTHORITY BY OBJECT CLASS

(Dollars in Thousands)	FY 2023 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2024 President's Budget	FY 2025 President's Budget	FY 2025 PB +/- FY 2023 Final	
Personnel Compensation and Benefits:							
Personnel Compensation:							
Full-time permanent (11.1)	1,070,466	1,138,638	1,180,160	1,213,357	1,207,801	69,163	.65091390
Other than full-time permanent (11.3)	76,319	81,180	84,140	86,507	86,111	4,931	.04640710
Other personnel compensation (11.5)	53,241	56,632	58,697	60,348	60,072	3,440	.03237425
Military Personnel - Basic Allowance for Housing (11.6)	96	96	100	100	103	7	.00105772
Military personnel (11.7)	82,113	82,102	85,304	85,304	88,183	6,081	.90469464
Special personnel services payments (11.8)	763	811	841	864	860	49	.00046368
Subtotal, Personnel Compensation	**1,282,998**	**1,359,458**	**1,409,241**	**1,446,479**	**1,443,130**	**83,671**	
Benefits:							
Civilian benefits (12.1)	443,769	472,031	489,244	503,006	500,703	28,672	.26984107
Military benefits (12.2)	8,554	8,553	8,887	8,887	9,187	633	.09424764
Benefits to former personnel (13.0)	---	---	---	---	---	---	---
Subtotal, Benefits	**452,323**	**480,584**	**498,130**	**511,892**	**509,889**	**29,306**	
Total Personnel Compensation and Benefits	**1,735,322**	**1,840,042**	**1,907,371**	**1,958,372**	**1,953,019**	**112,977**	
Contractual Services and Supplies							
Contractual Services:							
Travel and transportation of persons (21.0)	41,103	38,219	36,597	44,557	39,542	1,323	.0240882139
Transportation of things (22.0)	3,783	3,517	3,368	4,101	3,639	122	.0022168477
Rental payments to GSA (23.1)	167,793	166,286	166,286	156,686	155,386	-10,900	
Rent payments to others (23.2)	765	711	681	829	736	25	.0004483615
Communication, utilities, and misc. charges (23.3)	14,475	13,459	12,888	15,692	13,925	466	.0084831005
Printing and reproduction (24.0)	647	602	576	702	623	21	.0003793332
Subtotal, Contractual Services	**228,565**	**222,794**	**220,396**	**222,567**	**213,851**	**-8,943**	
Other Contractual Services:							
Consulting services (25.1)	75,923	70,596	67,600	82,305	73,041	2,445	.0444949396
Other services (25.2)	448,194	416,746	399,062	485,866	431,177	14,432	.2626642263
Purchase of goods and svcs from Govt Acts. (25.3)	547,090	508,704	487,115	593,074	526,318	17,614	.3206224722
Operation and maintenance of facilities (25.4)	76,246	70,896	67,887	82,654	73,351	2,455	.0446838847
Research and Development Contracts (25.5)	33,889	31,511	30,174	36,737	32,602	1,091	.0198606446
Medical care (25.6)	18,766	17,449	16,709	20,343	18,053	604	.0109978055
Operation and maintenance of equipment (25.7)	67,654	62,907	60,237	73,340	65,085	2,178	.0396486490
Subtotal, Other Contractual Services	**1,267,761**	**1,178,809**	**1,128,785**	**1,374,321**	**1,219,628**	**40,819**	
Supplies and Materials:							
Supplies and materials (26.0)	51,244	47,648	45,626	55,551	49,298	1,650	.0300314802
Equipment (31.0)	40,253	37,428	35,840	43,636	38,724	1,296	.0235901448
Land and Structures (32.0)	59,500	55,325	52,977	64,501	57,241	1,916	.0348698445
Grants, subsidies, and contributions (41.0)	226,047	210,186	201,267	245,046	217,464	7,278	.1324748767
Insurance claims and indemnities (42.0)	758	705	675	822	730	24	.0004444758
Interest and dividends , Refunds (43.0, 44.0)	1						
Receivables-collected (61.7)							
Subtotal, Supplies and Materials	**377,803**	**351,293**	**336,385**	**409,556**	**363,457**	**12,164**	
Total Contractual Services and Supplies	**1,874,129**	**1,752,896**	**1,685,566**	**2,006,444**	**1,796,936**	**44,040**	
Total Budget Authority by Object Class	**3,609,451**	**3,592,938**	**3,592,938**	**3,964,816**	**3,749,955**	**157,017**	

Figure 92 – Budget Authority by Object Class

REIMBURSABLE BY OBJECT CLASS

(Dollars in Thousands)	FY 2023 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2024 President's Budget	FY 2025 President's Budget	FY 2025 PB +/- FY 2023 Final	
Personnel Compensation and Benefits:							
Personnel Compensation:							
Full-time permanent (11.1)	1,023,014	960,303	1,119,015	1,004,512	1,147,448	187,146	.63395633
Other than full-time permanent (11.3)	87,023	81,689	95,190	85,449	97,608	15,920	.05392783
Other personnel compensation (11.5)	80,315	75,392	87,852	78,863	90,085	14,693	.04977104
Military Personnel - Basic Allowance for Housing (11.6)	1	1	1	1	1		.00001266
Military personnel (11.7)	76,744	76,744	79,737	79,737	82,428	5,684	.87713378
Special personnel services payments (11.8)	204	192	224	201	229	37	.00012665
Subtotal, Personnel Compensation	**1,267,302**	**1,194,320**	**1,382,019**	**1,248,764**	**1,417,800**	**223,479**	
Benefits:							
Civilian benefits (12.1)	423,141	397,202	462,849	415,488	474,610	77,407	.26221814
Military benefits (12.2)	10,749	10,749	11,168	11,168	11,545	796	.12285356
Benefits to former personnel (13.0)	---	---	---	---	---	---	---
Subtotal, Benefits	**433,890**	**407,951**	**474,017**	**426,656**	**486,155**	**78,204**	
Total Personnel Compensation and Benefits	**1,701,192**	**1,602,271**	**1,856,036**	**1,675,420**	**1,903,954**	**301,683**	
Contractual Services and Supplies							
Contractual Services:							
Travel and transportation of persons (21.0)	57,075	64,267	61,040	67,911	66,434	2,167	.04439026
Transportation of things (22.0)	1,107	1,246	1,183	1,317	1,288	42	.00086066
Rental payments to GSA (23.1)	57,660	78,598	65,043	72,876	66,160	-12,438	
Rent payments to others (23.2)	136	153	145	161	158	5	.00010545
Communication, utilities, and misc. charges (23.3)	112	126	119	133	130	4	.00008679
Printing and reproduction (24.0)	42	47	45	50	49	2	.00003274
Subtotal, Contractual Services	**116,130**	**144,436**	**127,576**	**142,448**	**134,219**	**-10,218**	
Other Contractual Services:							
Consulting services (25.1)	145,400	163,721	155,501	173,006	169,243	5,522	.11308544
Other services (25.2)	402,144	452,815	430,079	478,496	468,087	15,272	.31276878
Purchase of goods and svcs from Govt Acts. (25.3)	447,178	503,523	478,242	532,080	520,506	16,982	.34779417
Operation and maintenance of facilities (25.4)	28,224	31,780	30,184	33,582	32,852	1,072	.02195115
Research and Development Contracts (25.5)	29,968	33,744	32,050	35,658	34,882	1,138	.02330753
Medical Care (25.6)	16,708	18,814	17,869	19,881	19,448	635	.01299497
Operation and maintenance of equipment (25.7)	51,728	58,246	55,321	61,549	60,210	1,964	.04023166
Subtotal, Other Contractual Services	**1,121,351**	**1,262,643**	**1,199,246**	**1,334,252**	**1,305,227**	**42,585**	
Supplies and Materials:							
Supplies and materials (26.0)	14,528	16,359	15,538	17,287	16,911	552	.01129948
Equipment (31.0)	3,775	4,251	4,037	4,492	4,394	143	.00293613
Land and Structures (32.0)	1,099	1,237	1,175	1,307	1,279	42	.00085465
Grants, subsidies, and contributions (41.0)	86,532	97,435	92,542	102,961	100,721	3,286	.06730014
Insurance claims and indemnities (42.0)	---	---	---	---	---	---	---
Interest and dividends , Refunds (43.0, 44.0)	---	---	---	---	---	---	---
Receivables-collected (61.7)	---	---	---	---	---	---	---
Subtotal, Supplies and Materials	**105,934**	**119,282**	**113,293**	**126,047**	**123,305**	**4,023**	
Total Contractual Services and Supplies	**1,343,416**	**1,526,361**	**1,440,114**	**1,602,747**	**1,562,751**	**36,390**	
Total User Fees by Object Class	**3,044,607**	**3,128,632**	**3,296,150**	**3,278,167**	**3,466,705**	**338,073**	

Figure 93 – Reimbursable by Object Class

PROGRAM LEVEL BY OBJECT CLASS

(Dollars in Thousands)	FY 2023 Actuals	FY 2023 Final	FY 2024 Annualized CR	FY 2024 President's Budget	FY 2025 President's Budget	FY 2025 PB +/- FY 2023 Final
Personnel Compensation and Benefits:						
Personnel Compensation:						
Full-time permanent (11.1)	2,093,479	2,098,940	2,299,175	2,217,869	2,355,249	256,309
Other than full-time permanent (11.3)	163,342	162,868	179,329	171,956	183,719	20,851
Other personnel compensation (11.5)	133,557	132,024	146,549	139,211	150,157	18,132
Military Personnel - Basic Allowance for Housing (11.6)	97	97	101	101	104	7
Military personnel (11.7)	158,857	158,846	165,041	165,041	170,611	11,765
Special personnel services payments (11.8)	967	1,003	1,064	1,065	1,090	87
Subtotal, Personnel Compensation	**2,550,300**	**2,553,779**	**2,791,260**	**2,695,243**	**2,860,929**	**307,151**
Benefits:						
Civilian benefits (12.1)	866,910	869,233	952,093	918,494	975,312	106,080
Military benefits (12.2)	19,303	19,302	20,055	20,055	20,732	1,430
Benefits to former personnel (13.0)	---	---	---	---	---	---
Subtotal, Benefits	**886,213**	**888,535**	**972,148**	**938,549**	**996,044**	**107,509**
Total Personnel Compensation and Benefits	**3,436,513**	**3,442,313**	**3,763,407**	**3,633,792**	**3,856,973**	**414,660**
Contractual Services and Supplies						
Contractual Services:						
Travel and transportation of persons (21.0)	98,178	102,485	97,637	112,469	105,976	3,491
Transportation of things (22.0)	4,889	4,763	4,551	5,417	4,927	164
Rental payments to GSA (23.1)	225,452	244,884	231,329	229,562	221,546	-23,338
Rent payments to others (23.2)	901	864	826	991	894	30
Communication, utilities, and misc. charges (23.3)	14,587	13,585	13,008	15,824	14,055	470
Printing and reproduction (24.0)	689	649	621	752	672	22
Subtotal, Contractual Services	**344,696**	**367,231**	**347,972**	**365,015**	**348,070**	**-19,161**
Other Contractual Services:						
Consulting services (25.1)	221,324	234,317	223,101	255,311	242,283	7,966
Other services (25.2)	850,338	869,561	829,141	964,362	899,264	29,704
Purchase of goods and svcs from Govt Acts. (25.3)	994,268	1,012,227	965,357	1,125,154	1,046,823	34,596
Operation and maintenance of facilities (25.4)	104,470	102,676	98,072	116,237	106,203	3,527
Research and Development Contracts (25.5)	63,857	65,255	62,223	72,395	67,484	2,229
Medical care (25.6)	35,474	36,263	34,578	40,224	37,502	1,239
Operation and maintenance of equipment (25.7)	119,382	121,153	115,559	134,890	125,296	4,143
Subtotal, Other Contractual Services	**2,389,113**	**2,441,451**	**2,328,031**	**2,708,573**	**2,524,855**	**83,404**
Supplies and Materials:						
Supplies and materials (26.0)	65,772	64,007	61,164	72,838	66,209	2,202
Equipment (31.0)	44,028	41,679	39,877	48,128	43,119	1,439
Land and Structures (32.0)	60,599	56,562	54,152	65,808	58,520	1,957
Grants, subsidies, and contributions (41.0)	312,578	307,621	293,809	348,007	318,185	10,564
Insurance claims and indemnities (42.0)	758	705	675	822	730	24
Interest and dividends , Refunds (43.0, 44.0)	1	---	---	---	---	---
Receivables-collected (61.7)	---	---	---	---	---	---
Subtotal, Supplies and Materials	**483,737**	**470,574**	**449,678**	**535,603**	**486,762**	**16,187**
Total Contractual Services and Supplies	**3,217,545**	**3,279,257**	**3,125,681**	**3,609,191**	**3,359,687**	**80,430**
Total Program Level by Object Class	**6,654,058**	**6,721,570**	**6,889,088**	**7,242,983**	**7,216,660**	**495,090**

Figure 94 – Program Level by Object Class

SALARIES AND EXPENSES TABLE

Salary and Expenses Food and Drug Administration *(Budget Authority in Thousands)*	FY 2023 Final	FY 2024 Annualized CR	FY 2025 President's Budget	FY 2025 PB +/- FY 2023 Final
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	1,138,638	1,180,160	1,207,801	69,163
Other than full-time permanent (11.3)	81,180	84,140	86,111	4,931
Other personnel compensation (11.5)	56,632	58,697	60,072	3,440
Military personnel (11.7)	82,102	85,304	88,183	6,081
Special personnel services payments (11.8)	811	841	860	49
Subtotal, Personnel Compensation	**1,359,362**	**1,409,141**	**1,443,027**	**83,664**
Benefits:				
Civilian benefits (12.1)	472,031	489,244	500,703	28,672
Military benefits (12.2)	8,553	8,887	9,187	633
Benefits to former personnel (13.0)	---	---	---	0
Subtotal, Benefits	**480,584**	**498,130**	**509,889**	**29,306**
Total Pay Costs	**1,839,946**	**1,907,272**	**1,952,916**	**112,970**
Travel and transportation of persons (21.0)	38,219	36,597	39,542	1,323
Transportation of things (22.0)	3,517	3,368	3,639	122
Rental payments to GSA (23.1)	166,286	166,286	155,386	-10,900
Rent payments to others (23.2)	711	681	736	25
Communication, utilities, and misc. charges (23.3)	13,459	12,888	13,925	466
Printing and reproduction (24.0)	602	576	623	21
Subtotal, Contractual Services	**222,794**	**220,396**	**213,851**	**-8,943**
Other Contractual Services:				
Advisory and assistance services (25.1)	70,596	67,600	73,041	2,445
Other services (25.2)	416,746	399,062	431,177	14,432
Purchase of goods and svcs from Govt Acts. (25.3)	508,704	487,115	526,318	17,614
Operation and maintenance of facilities (25.4)	70,896	67,887	73,351	2,455
Research and Development Contracts (25.5)	31,511	30,174	32,602	1,091
Operation and maintenance of equipment (25.7)	62,907	60,237	65,085	2,178
Subtotal, Other Contractual Services	**1,161,360**	**1,112,076**	**1,201,574**	**40,215**
Supplies and materials (26.0)	47,648	45,626	49,298	1,650
Total Non-Pay Costs	**1,431,802**	**1,378,099**	**1,464,724**	**32,921**
Total Salary and Expense	**3,271,748**	**3,285,371**	**3,417,640**	**145,891**
Direct FTE	**10,484**	**10,484**	**10,566**	**82**

Figure 95 – Salaries and Expenses

DETAIL OF FULL-TIME EQUIVALENTS

Food and Drug Administration
Detail of Full-Time Equivalents (FTE)
Program Level

	FY 2023 Actuals			FY 2024 Annualized CR			FY 2025 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Center for Food Safety and Applied Nutrition	1,185	42	1,227	1,185	42	1,227	1,214	42	1,256
Center for Drug Evaluation and Research	5,290	451	5,741	6,017	451	6,468	6,035	451	6,486
Center for Biologics Evaluation and Research	1,184	43	1,227	1,363	43	1,406	1,364	43	1,407
Center for Veterinary Medicine	729	10	739	723	10	733	753	10	763
Center for Devices and Radiological Health	1,944	58	2,002	1,986	58	2,044	2,010	58	2,068
National Center for Toxicological Research	285	1	286	285	1	286	285	1	286
Office of Regulatory Affairs	4,814	307	5,121	4,687	307	4,994	4,786	307	5,093
Headquarters and Office of the Commissioner	907	56	963	892	56	948	922	56	1,018
Export Certification	26	---	26	26	---	26	26	---	26
Color Certification	37	---	37	37	---	37	37	---	37
Family Smoking Prevention and Tobacco Control Act	1,171	47	1,218	1,296	47	1,343	1,226	47	1,273
Priority Review Vouchers (PRV) Pediatric Disease	11		11	11		11	11		11
21st Century Cures (BA Only)	185	2	187	187		187	187	---	187
Cancer Moonshot (BA Only)			---			---	---	---	---
Total	**17,767**	**1,018**	**18,785**	**18,694**	**1,016**	**19,710**	**18,855**	**1,016**	**19,911**

Five Year History of GS/GM Average Grade

Year	Grade
FY 2019	13
FY 2020	13
FY 2021	13
FY 2022	13
FY 2023	13

* FTE figures do not include an estimated 74 reimbursable, 4 FOIA, 31 PEPFAR, 5 IDDA and 169 COVID Supplemental.

Figure 96 – Detail of Full-Time Equivalents

DETAIL OF POSITIONS

Food and Drug Administration
Detail of Positions

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget
Executive Level			
Executive Level I	---	---	---
Executive Level II	---	---	---
Executive Level III	---	---	---
Executive Level IV	1	1	1
Executive Level V	---	---	---
Total Executive Level	**1**	**1**	**1**
Total - Exec. Level Salaries	**$205,212**	**$212,292**	**$220,571**
Executive Service (ES)			
Executive Service	46	46	46
Total Executive Service	**46**	**46**	**46**
Total - ES Salary	**$9,439,752**	**$9,765,423**	**$10,146,275**
General Schedule (GS)			
GS-15	796	859	873
GS-14	3,148	3,398	3,452
GS-13	4,612	4,977	5,057
GS-12	1,877	2,026	2,058
GS-11	564	609	618
GS-10	4	4	4
GS-9	335	361	367
GS-8	18	20	20
GS-7	248	267	272
GS-6	17	18	18
GS-5	23	25	25
GS-4	15	16	16
GS-3	5	6	6
GS-2	4	5	5
GS-1	4	4	4
Total General Schedule	**11,669**	**12,594**	**12,795**
Total - GS Salary	**$1,389,824,576**	**$1,511,245,744**	**$1,566,456,343**
Administrative Law Judges (AL)	---	---	---
Scientific/Senior Level (ST/SL)	1	1	1
Senior Biomedical Research Service (RS)	56	56	56
Scientific Staff Fellows (RG) (Title 42)	1,078	1,078	1,078
Distinguished Consultants/Senior Science Managers (RF) (Title 42)	101	101	101
Former Performance Mgmt Recognition System Employees (GM)	---	---	---
Physicians and Dentists - (GP) (Title 38)	361	361	361
Commissioned Corps (CC):			
Commissioned Corps - 08/07/06	280	280	280
Commissioned Corps - Other	797	797	797
Total Commissioned Corps	**1,077**	**1,077**	**1,077**
Administratively Determined (AD) (includes Title 42)[2]	3,749	3,749	3,749
Wage Grade	9	9	9
Consultants[2]	1,714	1,714	1,714
Total FTE (End of Year)[1]	**19,862**	**20,787**	**20,988**
Average ES Level	1	1	1
Average ES Salary	$205,212	$212,292	$220,571
Average GS grade	13	13	13
Average GS Salary	$119,104	$119,997	$122,427
Average GM Salary	$0	$0	$0
Average GP Salary	$220,060	$221,710	$226,200

[1] Does not include FTE estimates for 82 reimbursable, 2 FOIA, 47 PEPFAR, 1 IDDA and 129 COVID Supplemental.
[2] Includes consultants appointed under 5 U.S.C. 3109, those appointed under similar authorities, and those appointed to serve as advisory committee members. However, scientists hired under Title 42 are now included in the Distinguished Consultants/Senior Science Managers (RF) category.

Figure 97 - Detail of Positions

CYBERSECURITY FUNDING

Resources for Cyber Activities
Food and Drug Administration

(Dollars in millions)

Cyber Category	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2024
Cyber Human Capital	0.030	0.050	0.050	--
Sector Risk Management Agency (SRMA)	--	--	--	--
Securing Infrastructure Investments	--	--	--	--
Other NIST CSF Capabilities:				
Detect	9.800	9.320	9.390	+0.070
Identity	17.050	17.680	18.050	+0.370
Protect	38.910	43.870	25.680	-18.190
Recover	0.310	1.000	1.000	--
Respond	5.460	5.660	5.850	+0.190
Total Cyber Request	**71.560**	**77.580**	**60.020**	**-17.560**
Technology Ecosystems (non-add)	--	--	--	--
Zero Trust Implementation (non-add)				

Figure 98 - Resources for Cyber Activities

FDA SPECIFIC ITEMS

FDA DRUG CONTROL PROGRAM AGENCY

Budget Authority (in millions)			
	FY 2023	FY 2024	FY 2025
	Final	CR	President's Budget
Drug Resources by Function			
Research and Development: Treatment & Prevention (CDER)	$23.50	$23.50	$23.50
Harm Reduction (non-add)	*$10.00*	*$10.00*	*$10.00*
Research and Development: Treatment & Prevention (CDRH)	*$1.50*	*$1.50*	*$1.50*
Interdiction (ORA)	$54.50	$54.50	$54.50
Total Drug Resources by Function	**$79.50**	**$79.50**	**$79.50**
Drug Resources by Decision Unit			
Center for Drug Evaluation and Research	$23.50	$23.50	$23.50
Center for Devices and Radiological Health	$1.50	$1.50	$1.50
Office of Regulatory Affairs	$54.50	$54.50	$54.50
Total Drug Resources by Decision Unit	**$79.50**	**$79.50**	**$79.50**
Drug Resources Personnel Summary			
Total FTEs (direct only)	196	196	196
Drug Resources as a Percent of Budget			
Total Agency Budget (in Billions)	$3.591	$3.591	$3.748
Drug Resources percentage	2.21%	2.21%	2.12%

Figure 99 – FDA Drug Control Program Agency

PROGRAM SUMMARY

Mission

The Food and Drug Administration (FDA) is the agency within the U.S. Department of Health and Human Services (HHS) responsible for protecting and promoting public health by ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of human and animal food, cosmetics, and radiation emitting products; and regulating tobacco products. FDA's customers and key stakeholders include American patients and consumers; healthcare professionals; veterinarians; regulated industry; academia; and, state, local, federal, and international governmental agencies.

The agency recognizes that the nation continues to face a multifaceted drug overdose crisis that has evolved beyond prescription opioids. In recent years illicit opioids, largely driven by fentanyl and its analogues, have become key contributors to the overdose crisis. Other controlled substances, including benzodiazepines and stimulants (particularly methamphetamine), are also being used in combination with opioids, as are emerging substances of concern, such as xylazine.

FDA also recognizes the risk of prescription opioids and other controlled substances as well as the benefits of these drugs for patients who need them, including those with debilitating chronic conditions. It will take carefully developed, coordinated, and sustained action by multiple stakeholders to reduce the incidence of drug misuse, abuse, addiction, overdose, and death, while preserving appropriate access to these drugs for patients who need them. Doing our part to ensure the safe use of prescription opioids and other controlled substances and ameliorate the overdose crisis is among FDA's highest priorities. FDA is engaging in many ongoing activities aimed at furthering these goals.

In alignment with HHS's Overdose Prevention Strategy, FDA has identified four specific priorities under our Overdose Prevention Framework to focus our actions to address the crisis:

- Supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing
- Encouraging harm reduction through innovation and education
- Advancing development of substance use disorder treatments
- Protecting the public from unapproved, diverted, and counterfeit drugs presenting serious overdose risk

Methodology

FDA identified the drug control budget by using the dedicated budget authority for activities involving prescription opioids and other controlled substances. This includes opioids dedicated base activities conducted by the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), and the Office of Regulatory Affairs (ORA).

BUDGET SUMMARY

The FY 2025 Budget includes $79.5 million, flat with FY 2024 Continuing Resolution (CR) Level, for drug control program activities at FDA.

Center for Drug Evaluation and Research (CDER): FY 2025 Request: $23.5 million, flat with FY 2024 CR

The FY 2025 Budget for drug-related activities includes $23.5 million for CDER to further develop and advance strategies to confront the opioid crisis. CDER is committed to supporting research that addresses questions that are critical to our work on the overdose crisis. In particular, the FY 2019 appropriation provided CDER with base funding for regulatory science, enforcement, and innovation activities, to combat the opioid epidemic. CDER utilizes the $23.5 million in opioids base funding to further develop and implement evidence-based actions to address FDA's priority areas.

Some of CDER's recent research initiatives include:

- Advancing the development of multiple evidence-based clinical practice guidelines on management of acute dental pain, management of post-operative pain in obstetric patients who have undergone surgery, management of post-operative pain in patients who have undergone laparoscopic abdominal surgeries, management of acute low back pain, and safe tapering of benzodiazepines; the first four guidelines are part of SUPPORT Act Sec. 3002 implementation
- Researching chronic pain therapies to inform the ongoing discussion about the appropriate use of opioid analgesics in chronic pain management
- Studying how comparative feedback to providers would impact the number of leftover opioid pills to help inform and improve safety of opioid prescribing practices for acute pain
- Enhancing FDA's opioids systems model, a U.S. population-level systems dynamics model used to improve understanding of and reaction to the opioid crisis to help FDA and other stakeholders identify high-impact opioid-related interventions, assess potential unanticipated consequences of potential policies, and identify needs for further research
- Exploring distribution of naloxone in the U.S. and the potential impacts of a change in the prescription-only status of naloxone
- Examining considerations for buprenorphine maintenance and care, including real-world experiences and scientific evidence for buprenorphine initiation strategies as well as medication dosing and management during continued treatment across care settings
- Exploring the impact of different packaging components of packaged opioids on opioid use as experienced by patients, prescribers, and pharmacists
- Assessing trends in opioid analgesic use in patients with and without cancer to understand the impact of opioid-reduction efforts on cancer patients
- Supporting development and regulatory assessment of new and generic intranasal naloxone sprays by generating new testing and evaluation models
- Exploring the evolving context surrounding fatal overdoses to inform product development and public health interventions to manage overdose

- Conducting preliminary assessment of kratom safety, pharmacokinetics, and pharmacodynamics characteristics
- Modernizing sample testing to ensure quality for opioids and other high-risk products in the pharmaceutical supply chain and enhance detection of adulterated drug products
- Examining falsified, counterfeit, and unapproved medication use in general population and enriched population of individuals seeking treatment for substance use disorders.
- Exploring concrete strategies for drug development and clinical research that support the mitigation and reduction of risks associated with human exposure to xylazine
- Examining the diagnosis and treatments of adults with ADHD, including challenges and opportunities for drug development and strategies for assessing the risks and benefits of ADHD medication treatment in adult populations

FDA-supported research initiatives have enhanced our understanding of appropriate use of prescription opioids for pain treatment, as well as risks and mitigating factors to address opioid misuse, abuse, overdose, and death. However, as fatal overdoses continue to increase in the United States, further work is needed to address the overdose crisis, including the impact of other addictive substances as well as the enduring impact of the COVID-19 pandemic.

Center for Devices and Radiological Health (CDRH): FY 2025 Request: $1.5 million, flat with FY 2024 CR

The FY 2025 Budget for opioid-related activities includes $1.5 million for CDRH to continue supporting the use of digital health medical devices to help address opioid use disorder (OUD).

CDRH is using funds appropriated in FY 2023 to hire two subject matter experts in OUD to establish a streamlined framework for FDA market authorization based on evolving science and technology, leveraging real-world data to support evaluation of OUD digital health technology, and incentivizing the development of new safe, effective, high-quality digital risk assessments and, diagnostics.

To support these efforts, CDRH used prior year funding to hold two connected public workshops with the National Institutes of Health (NIH) "Diagnostic and Monitoring Medical Devices for Opioid Use" and "Risk Prediction Devices of Opioid Use and Opioid Use Disorder – Opportunities and Challenges." The workshops allowed people living with OUD to share their experiences and begin suggesting opportunities or features of digital health technologies to support their recovery. A contractor completed a literature review and focus groups are being used to inform the quantitative patient preference study for people living with OUD. This work will continue through FY 2024. CDRH used prior year funding to collaborate with the Research Triangle Center for Excellence in Regulatory Science to assess whether digital health technologies can be used to assess whether a person is relapsing.

In addition, CDRH is continuing to encourage the development of new and innovative medical devices to broaden the number of options and increase the effectiveness of OUD treatment during FY 2024, including:

- Research, engagement, and partnership with academic and community medical centers and others for development of digital health technologies for OUD;
- leveraging real-world data to inform medical device regulatory decision making by improving premarket assessment; and
- leveraging post-market surveillance data of devices used to assess, monitor, treat and manage OUD.

Going forward, CDRH will build upon these efforts by using the funds to:

- Use the framework developed in FY 2023 to leverage real world data to support novel, digitally derived endpoint development and pilot the use of real-world performance to further understand how digital health technologies can support the effective treatment of OUD;
- Continue research, engagement, and partnership with academic medical centers and others for the development of digital health technologies for OUD; and
- Use data gathered on patient preferences to help inform clinical trial design as well as assist in fostering shared decision-making for clinicians treating people living with OUD.

Office of Regulatory Affairs (ORA) – Field Activities: FY 2025 Request: $54.5 million, flat with FY 2024 CR

In response to the current opioid crisis, ORA prioritized protecting the public health by monitoring FDA-regulated products shipped into the nation's eight IMFs to prevent unsafe, counterfeit, and unapproved drugs from entering the United States. FDA's IMF staff works diligently to examine parcels referred by U.S. Customs and Border Protection (CBP) that appear to contain drug products. With mail parcels not being declared accurately to the agency, it is estimated that FDA is only able to physically inspect a small percentage of the packages that are presumed to contain drug products. As the opioid crisis continues and more parcels are shipped through IMFs and courier hubs, it is essential that FDA, in conjunction with the United States Postal Service (USPS) and CBP, continue to inspect parcels looking for opioids and other unapproved drugs.

In 2022, FDA was able to fully staff the IMFs with investigators and reviewed more than 100,000 products at the IMFs. This doubled the number of products reviewed in FY 2020. As the IT systems continue to improve at the IMFs, in cooperation with the USPS and the General Services Administration (GSA), efficiency of parcel processing will continue to increase.

A record volume of FDA regulated commodities are being introduced for import inspection at the southern border. With additional funding provided in the FY 2022 budget request, ORA will bolster coverage at critical ports of entry, including enhancing IT infrastructure and tools as well as enhancing staff presence.

In FY 2018, with the implementation of FDASIA 708, ORA destroyed approximately 6 percent of refused drug products. After the SUPPORT Act was signed into law, FDA raised the overall

destruction rate to 48 percent in FY 2019. As additional APIs have been added to the 801(u) list FDA has continued to increase the destruction rate which reached nearly 83 percent in FY2023. Improvements at IMFs will continue, as ORA implements new authorities included in the SUPPORT Act.

FDA's Forensic Chemistry Center (FCC) is currently working with CBP's Laboratories and Scientific Services (LSS) to assist in the establishment of chemical fingerprints or signatures of illicit materials to aid in these investigations.

FDA's efforts to combat the opioid crisis includes criminal investigations by ORA's Office of Criminal Investigations (OCI). OCI continues to bring to justice medical professionals who misuse their unique position and compromise public health by tampering with opioids intended for patients. For example, as a result of OCI's investigation, a registered nurse was sentenced to more than four years in prison by a federal judge in January 2023 for tampering with opioids. The nurse, who worked in a nursing home, tampered with a bottle of morphine sulfate prescribed to the patients suffering from dementia by removing the morphine and adding water to the remaining supply. A nurse on a subsequent shift administered the adulterated morphine to a patient before the tampering was discovered.

Furthermore, OCI targets online marketplaces and vendors that sell counterfeit opioids. Through an initiative dubbed "Operation CyberPharma," OCI's investigations have led to the arrest of 60 darknet vendors, 26 convictions, the takedown of a major darknet marketplace, and the seizure of more than $8.4 million in virtual currencies, drug counterfeiting tools and other assets.

OCI also works closely with its domestic and international counterpart agencies to protect consumers from illegal pharmaceutical drugs, including illicit opioids, that are shipped to the United States. OCI works to identify the source and destination of these drugs and in collaboration with other federal agencies, such as CBP and the Postal Inspection Service. OCI also conducts joint enforcement activities with its global law enforcement partners.

Section 3022 of the SUPPORT Act also amended section 306 of the FD&C Act to give FDA new authority to debar persons from importing drugs into the U.S. if they have been convicted of a felony for conduct related to the importation of any drug or controlled substance. Since 2019, FDA has finalized 29 final orders of debarment for drug importers, 25 of those were based on federal felony conviction.

ORA continues to increase analytic capability and capacity at the IMFs. Based on benchmarking with Federal partners and discussions with OCC, ORA identified specially trained field-based scientists using an established set of analytical tools to be the most scientifically reliable and efficient approach to rapid identification of illicit FDA-regulated products, such as unapproved and counterfeit pharmaceuticals, including opioids, and adulterated supplements. FDA continues to partner with CBP/LSS in the Chicago IMF satellite laboratory and resumed operations there in June 2021. Since resuming operations, approximately 500 samples have been analyzed at the satellite laboratory and over 350 of these have been found to contain at least one API. Two scientists were hired, trained and now permanently staff the CHI IMF satellite laboratory as of

March 2022. Efforts to establish full operations at the Miami IMF satellite laboratory are progressing with facility modifications. Two permanent staff will be hired for this location. CBP/LSS has agreed to share lab space with ORA/ORS within the JFK IMF until the FDA space has been completed. Lab space to conduct operations within the Secaucus IMF is moving forward. A Satellite Laboratory organizational chart has been established, a Branch has been established at the Forensic Chemistry Center, and a branch director has been hired. Laboratories to support the satellite lab effort including an opioid focused laboratory space are nearing completion at the FCC. The cadre trained to staff IMF satellite laboratory operations has been expanded to 20 personnel. Discussions about space near the LAX IMF and other IMF and courier hub locations continues.

GEOGRAPHICAL DISTRIBUTION OF FDA FACILITIES

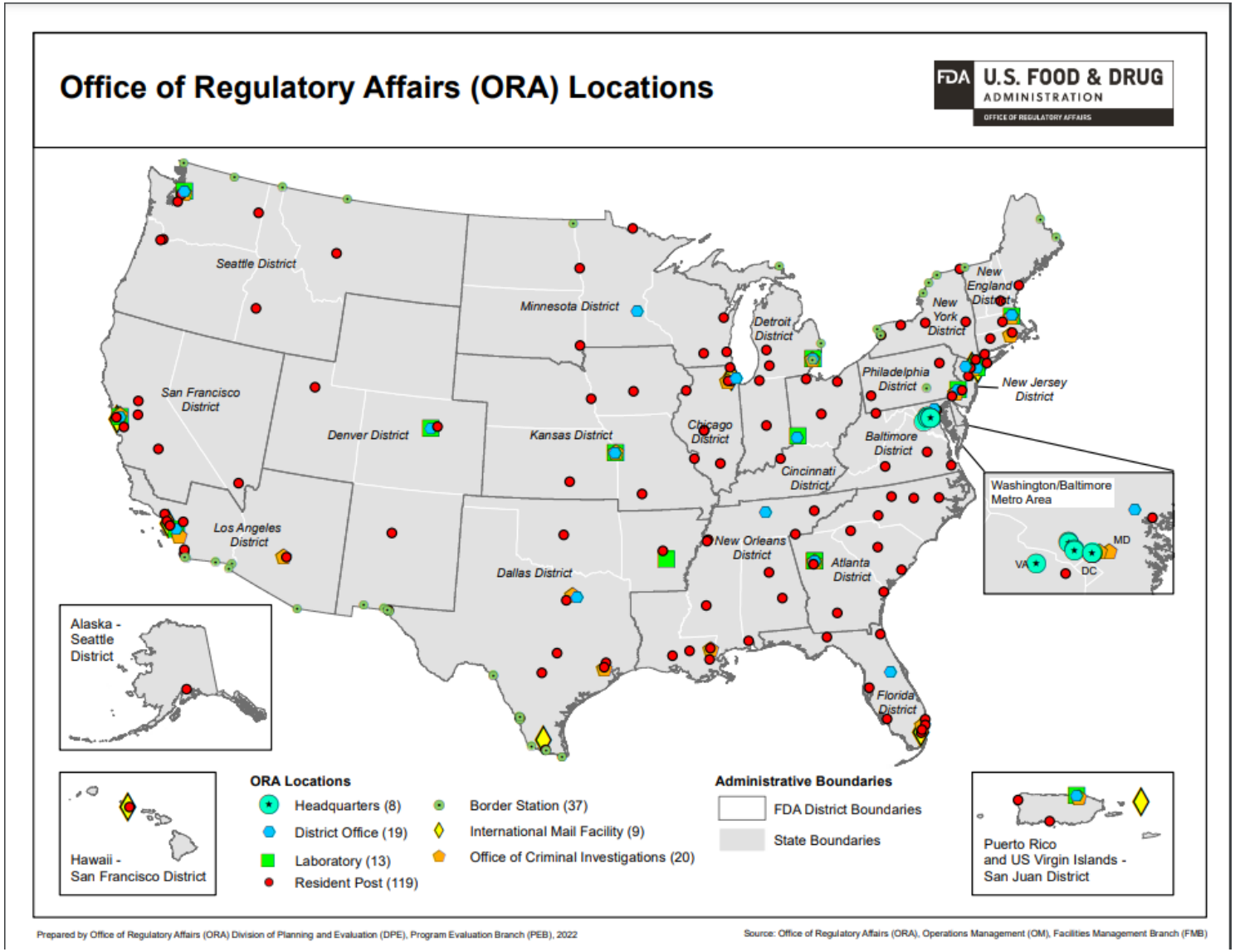

Figure 100 - ORA Locations

CROSSCUTS

Food and Drug Administration
FY 2023 - FY 2025 Crosscutting Information
(Program Level in Thousands)

(dollars in thousands)	FY 2023 Estimate	FY 2024 Estimate	FY 2025 Estimate
Alzheimer's Disease	15,158	15,551	15,923
HIV/AIDS	62,315	63,981	63,549
Antimicrobial Resistance	58,282	59,678	60,804
Bioterrorism-Medical Countermeasures	173,102	176,536	182,338
Cosmetics	16,372	16,170	24,662
Diabetes	27,553	28,408	29,106
Drug Abuse	17,059	17,848	18,306
Global Health	37,593	38,170	38,905
Immunization	185,252	189,054	196,154
Mental Health	20,314	21,065	21,572
Minority Health	13,349	14,053	13,494
Opioids 1/	79,500	79,500	79,500
Pandemic Influenza	39,685	40,469	41,734
Patient Safety	752,380	767,477	778,462
Pediatric Drugs	34,104	35,162	35,989
Tobacco 2/	712,000	812,000	826,240
Women's Health	78,467	78,399	79,661

*Crosscut estimates are based on FDA's current level of effort at time of publication and are subject to change based on application review, inspection workload, and response efforts.
**All estimates reflect total Program Level, including BA and UF, where applicable.
***Total Program Level differs from the FDA Operating Plan due to inclusion of UF estimates.
1/ Opioids BA estimates shown are consistent with the FY 2023 Operating Plan.
2/ Reflects proposed increase of $100M in FY 2024 estimate for the Family Smoking Prevention and Tobacco Control Act, and $114.24M in FY 2025.

Figure 101 - Crosscutting Information

FDA CENTRAL ACCOUNTS

Program (dollars in thousands)	FY 2023 Actuals		FY 2024 Estimates		FY 2025 Estimates	
	BA	UF	BA	UF	BA	UF
Foods	**21,865**	-	**21,798**	-	**21,798**	-
Center	5,986	-	6,545	-	6,545	-
Field	15,879	-	15,253	-	15,253	-
Human Drugs	**17,339**	**34,285**	**14,748**	**40,398**	**14,748**	**40,398**
Center	12,667	32,437	10,273	38,397	10,273	38,397
Field	4,672	1,848	4,475	2,001	4,475	2,001
Biologics	**6,002**	**5,542**	**5,609**	**7,447**	**5,609**	**7,447**
Center	4,651	5,468	4,322	7,371	4,322	7,371
Field	1,351	74	1,287	76	1,287	76
Animal Drugs and Feeds	**4,427**	**1,274**	**4,133**	**1,651**	**4,133**	**1,651**
Center	2,593	1,274	2,338	1,651	2,338	1,651
Field	1,835	-	1,795	-	1,795	-
Devices and Radiological Health	**10,559**	**7,341**	**9,758**	**9,995**	**9,758**	**9,995**
Center	7,663	7,140	7,035	9,793	7,035	9,793
Field	2,896	200	2,723	202	2,723	202
National Center for Toxicological Research	**1,335**	**-**	**1,564**	**-**	**1,564**	**-**
Family Smoking Prevention and Tobacco Control Act	-	**9,611**	-	**9,976**	**-**	**9,976**
Center	-	9,227	-	9,575	-	9,575
Field	-	384	-	401	-	401
FDA Headquarters	**6,695**	**4,595**	**6,175**	**4,572**	**6,175**	**4,572**
Total	**68,223**	**62,648**	**63,784**	**74,039**	**63,784**	**74,039**

Figure 102 - Central Accounts

HHS CHARGES AND ASSESSMENTS

FOOD AND DRUG ADMINISTRATION DHHS Charges and Assessments FY 2023 Actual, and FY 2024 and 2025 Estimates			
Activity	**FY 2023 Estimate**	**FY 2024 Estimate**	**FY 2025 Estimate**
Assessments	**$ 554,493**	**$ 599,851**	**$ 644,334**
Fee for Service	**$88,770,300**	**$88,786,990**	**$ 98,103,000**
Program Support Center/OS	$ 24,556,566	$ 24,298,567	$ 27,172,000
Occupational Health Portfolio	$ 1,275,187	$ 1,350,000	$ 1,350,000
Information System Management Service	$ 45,983,825	$ 45,790,038	$ 49,317,000
Office of Human Resource Services	$ 16,954,722	$ 17,348,385	$ 20,264,000
Jointly Funded Services	**$ 4,381,771**	**$ 4,343,210**	**$ 5,515,994**
Total	**$93,706,564**	**$93,730,051**	**$104,263,328**

Figure 103 - HHS Charges and Assessments Summary

Food and Drug Administration
Department of Health and Human Services Charges and Assessments
Fiscal Year 2023 Actuals

	FY23		FY24		FY25
Assessments:	**554,493**		**599,851**		**644,334**
NIH eRA Grants Management System Pilot phase to support migration of FDA Grants Data into the Department's consolidated eRA Grants Management System	362,499		404,203		445,906
National Telecommunication Information Administration Radio frequency spectrum, a scarce, public resource used by the federal agencies, is essential to U.S. domestic and international communications on a daily basis to provide critical and diverse public services.	10,014		10,500		11,000
Federal Audit Clearinghouse	2,612		3,500		3,500
Credit Monitoring Services OPM shall provide credit monitoring and identity protection to impacted employees.	143,044		145,033		147,022
Federal Interagency Management Councils Support multiple management councils to ensure projects which will drive performance improvement and deliver tangible, measurable impacts.	19,297		19,297		19,297
Federal Government Priority Goals Cross-Agency Priority (CAP) Goals.	17,027		17,318		17,609

Figure 104 - HHS Charges and Assessments Detail 1/5

Fee For Service:	**88,770,300**		**88,786,990**		**98,103,000**
Program Support Center/ Office of the Secretary Provides various services to the FDA, including some Information	**24,556,566**		**24,298,567**		**27,172,000**
Financial Management Portfolio	597,354		679,474		665,000
Real Estate and Logistics Portfolio Includes facility building operations, shredding, storage, property disposal, forms and travel mgmt., board of corrections, printing, mail, property mgmt., shredding, storage, HHS Emergency mgmt., transportation policy, supply fulfillment	11,945,224		11,450,275		13,163,000
Equal Employment Opportunity Compliance and Operations Includes Complaint Investigations, FAD/Counseling, Mediation, National final agency decision	2,065,034		2,131,245		2,401,000
Assistance Secretary for Administration Labor and employee relations, Office of operations mgmt.	620,348		762,159		685,000
Miscellaneous Services Includes AIM, Acquisition Reform, Category Mgmt., Commissioned Corps Force Mgmt. (CCFM), Departmental Contracts Information System Program (DCIS), Ethics Program, Grants, Broadcast studio, Media Monitoring, OGC Claims, Small Business Consolidation, Strategic Planning, Data PMO, National Security Case Mgmt., Division of Workforce development, Office of Program Audit.	9,328,606		9,275,414		10,258,000
Occupational Health Portfolio FDA agency health units and services	**1,275,187**		**1,350,000**		**1,350,000**
Information & System Management Services	**45,983,825**		**45,790,038**		**49,317,000**
Unified Financial Management Systems (UFMS) Includes services for Consolidated Financial Reporting System (CFRS), Financial Business Intelligence System (FBIS), Financial Systems Control/Program Management and UFMS O&M support	15,041,957		15,155,150		17,218,000
HCAS Operations and Maintenance HCAS O&M services provide support for daily operations of the HCAS application.	3,100,752		3,101,000		3,380,000
Office of Enterprise Services	2,394,450		2,487,166		2,567,000
Office of Chief Information Officer Services include activities for HHS' civilian employees and Commissioned Corps Officers, and maintenance and operation of the systems housing current and historical pay and leave records. Application support, Design & development, Platform services, System integration.	7,269,092		7,045,117		7,620,000
Office of Chief Data Officer Data strategy and integration	1,365,300		1,349,948		1,226,000
Office of Information Security Includes Governance, Risk and compliance, HHS Security enclave and Internet.	7,566,244		7,420,657		7,670,000
Digital Communications	9,246,030		9,231,000		9,636,000
Office of Human Resource Services Includes Enterprise services, HR system operations, HRIT service, Payroll, Personnel Deployment division	**16,954,722**		**17,348,385**		**20,264,000**

Figure 105 - HHS Charges and Assessments Detail 2/5

Jointly Funded Projects	**4,381,771**		**4,343,210**	**5,515,994**
International Health Bilateral Agreement Agreement to provide funding in support of the bilateral-multilateral activities performed on behalf of the Public Service by the Office of Global Health Affairs	1,581,155		1,581,155	1,743,224
CFO Audit of Financial Statements The audit of the Department's financial statements and the accompanying notes, and a review of its internal controls and compliance with laws and regulations. OIG oversees the contract to an independent audit firm to conduct the HHS financial statement audits and financial management related services.	591,557		637,727	670,375
Advisory Committee for Blood and Tissue Safety and Availabi Agreement to provide funding for the advisory committee on Blood Safety	300,000		300,000	350,000
Office of Regional Health Operations IAG with OS/Office of Public Health & Science to support ten Regional Health Administrators. Their core mission is to promote understanding of and control functions within their respective regions improvements in public health and to conduct specific management.	308,010		308,010	325,000
Intra-department Council on Native American Affairs IAG with DHHS, Administration on Children and Families, for staff and administrative support for the Interdepartmental Council for Native American Affairs Committee meetings and assignments.(ICNAA), to conduct semi-annual Council meetings, Executive	17,000		17,000	17,000
National Science Advisory Board for Biosecurity Agreement with NIH to develop improved biosecurity measures for classes of legitimate biological research that could be misused to threaten public health or national security	225,000		225,000	225,000
NIH Negotiation of Indirect Cost Rates Agreement with NIH/OD to support costs associated with the negotiation of indirect cost rates with commercial organizations	42,087		42,826	44,895
OPM USAJOBS Fees charged by OPM to Federal Agencies to cover the cost of providing Federal Employment Information and services. OPM assesses an annual per-capita-fee based on each OPDIV percentage of the Departments total FTE on all paid employees with access to USAJOBs. The cost is distributed within HHS based on each OPDIV percentage of the Departments total FTE.	148,476		158,868	169,261
President's Advisory Committee on Combating Antibiotic-Resistant Bacteria Combating Antibiotic Resistant Bacteria, directs that “the Federal Government will work domestically and internationally to detect, prevent, and control illness and death related to antibiotic-resistant infections by implementing measures that reduce the emergence and spread of antibiotic-resistant bacteria and help ensure the continued availability of effective therapeutics for the treatment of bacterial infections“	175,000		175,000	175,000

Figure 106 - HHS Charges and Assessments Detail 3/5

Biosafety and Biosecurity Coordinating Council This will support the administrative management of the Council in efforts to coordinate and collaborate on biosafety and biosecurity issues within HHS.	87,759	87,759	91,712
Implementation of the Digital Accountability and Transparency	68,278	67,692	75,277
Tick-Borne Disease Working Group The work group will provide expertise and review all efforts within the Department of HHS related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap and to examine research priorities.			
Secretary's Tribal Advisory Committee and Tribal Consultatio Outreach with Tribal Governments and Organizations; communication and coordination of HHS activities and initiatives, which enhance the government-to-government relationship that HHS has with Indian Tribes. In addition IEA will find ways to educate HHS and guide the Department in developing future programs, initiatives, and other interactions with tribal governments and tribal organizations.	12,000	12,000	375,000
Secretary Policy System SPS is the official records repository of the Immediate Office of the Secretary (IOS) for documents relevant to the Secretary, Deputy Secretary, Chief of Staff, and Executive Secretary. It is used to manage regulations, reports to Congress, correspondence, memoranda, invitations, and other documents.	43,789	43,789	51,391
GAO Audit Activity Augmentation To support the HHS GAO Portfolio's strategic plan to improve the management and coordination of HHS GAO audit activity across the Department. Ongoing maintenance, licensing agreements, and IT enhancements of the newly developed Information Management Platform for Reporting, Organizing, Vetting and Evaluating (IMPROVE) platform.	22,708	28,432	34,114
Dietary Reference Intakes Updates National Academies of Sciences, Engineering and Medicine (NASEM) committee will assess current relevant data and update the Dietary Reference Intakes for energy and provide guidance to the overall macronutrient project.	150,000	150,000	150,000

Figure 107 - HHS Charges and Assessments Detail 4/5

Federalwide Assurance Institutional Review Board Registration Database Modernization To modernize database tools used to fulfill statutory and regulatory responsibilities for the protection of human research subjects.	40,000	40,000	-
Commission on Asian Americans, Native Hawaiians, and Pacific Islanders Develop, monitor and coordinate executive branch efforts to advance equity, justice and opportunity for AA, NH and PI communities throughout the entire federal government by working in collaboration with the White House.	395,643	294,643	654,000
Development of the Dietary Guidelines for Americans The Dietary Guidelines is required by statute to be published jointly by HHS and the USDA every 5 years.	140,000	140,000	200,000
Language Access Services Coordination of the Language Access Steering Committee.	33,309	33,309	164,745
Healthcare and Public Health Sector Risk Management Agency Program Management The Assistant Secretary for Preparedness and Response (ASPR) coordinates the Sector Risk Management Agency (SRMA) responsibilities on behalf of HHS. Supporting risk mgmt., assessing risk across the sector, conduct day-to-day coordination across federal, state, local, tribal and territorial government and private sector owner-operators, facilitating information sharing related to sector risk and supporting incident management and emergency preparedness efforts.	100,000	100,000	654,545

Figure 108 - HHS Charges and Assessments Detail 5/5

WORKING CAPITAL FUND

INTRODUCTION

In FY 2014, FDA launched a multi-year initiative to define and evaluate the cost of centrally administered services provided internally to Centers and Offices. The aim of this initiative was to create a structure to be managed under a Working Capital Fund (WCF) that provides FDA with greater visibility into budget and management decisions for these services.

As an intra-governmental revolving fund, the WCF allows FDA to operate in a more efficient business environment by relying on the collection of funds through customer billings. The fund helps FDA achieve the following:

- Enhance budget justifications and user fee negotiations with additional cost information on centrally administered services
- Streamline budget decisions under an integrated governance and financial infrastructure
- Create a customer-focused and service-oriented mechanism by improving customer investment and management decisions

Authorizing Legislation: The FY 2018 Appropriation included the legislative language needed to establish and put a WCF into operation at the beginning of FY 2019.

STRUCTURE

PROGRAM MANAGEMENT

To directly support the operation of the WCF, FDA has established a WCF program management team to be responsible for the fund's management and execution, communications, financial and performance reports, policy and documentation management, and change management activities. The group is in the Office of Finance, Budget, Acquisitions and Planning (OFBAP) within the Office of Operations.

Governance

In FY 2017, FDA established a governance structure to support the eventual WCF. This governance structure, referred to as the Working Capital Fund Council (WCFC), consists of:

- FDA's Chief Operating Officer (COO)
- Center Directors (customers)
- Business Managers (Operations service providers)

This group serves as a steering committee for the WCF Program at large and represents the decision-making body for topics such as budget, cost recovery, and policy direction.

A Working Group made up of Deputy Executive Officers from each of FDA's Centers supports the WCFC by reviewing Program operations and making recommendations to the WCFC. Additionally, the Working Group includes representatives from service providers, customers, and the OFBAP. This Working Group reviews service catalogs, consumption metrics, and proposed budgets for the annual Cost Allocation assessments associated with the WCF.

While the scope of these governance bodies is expected to evolve as the Program matures, its roles and responsibilities will, at a minimum, include the following:

- Provide direction and oversight to activities and policies of the WCF
- Review activities and services to be included or excluded in the WCF
- Coordinate with councils to review and approve cost allocation frameworks, service rates, efficiency and performance targets, and parameters to manage risk
- Provide support for any needed reviews of WCF financial and operational processes and present findings to FDA leadership

PROGRAM DESCRIPTION

The WCF provides funding for a wide array of centrally administered services across FDA's programs, managed by Offices housed in FDA Office of Operations and FDA Super Offices. Each of the services fall under categories described in more detail in this section. Each service was identified as an ideal candidate for a WCF based on the following criteria:

- Services are centrally managed and provided for internal customers across FDA, appropriate for a charge-back structure
- Data regarding consumption-based activities and services with appropriate and suitable cost data is available to assess and approximate the full costs to FDA
- Services provided at the Agency level reduce or eliminate redundancy and achieve economies of scale.

INFORMATION TECHNOLOGY

The WCF also supports Information Technology (IT) services provided by the Office of Digital Transformation (ODT). FDA customers with information, communication, knowledge infrastructure and quality customer service delivery to enhance and sustain systems and IT operations. These services support:

- personal and mobile computing
- enterprise applications
- professional IT services
- related training and support resources

Informatics and technology-based innovation needs are addressed through the study, development, and testing of prototypes to make recommendations addressing:

- key mission activities related to big data and analytics
- cloud and high-performance scientific computing
- mobility
- digitization
- open data

IT support further ensures the appropriate security controls are applied to FDA systems to protect privacy and ensuring confidentiality, integrity, and availability of FDA information in accordance with Federal, Department and Agency regulations. The IT function manages technology strategies to reduce costs through the elimination of duplication efforts and adopting new

technology to improve services, and leverage knowledge and resources to reduce security and system failures.

Human Resources

Human Resources (HR) services support FDA's workforce through the provision of labor support services. These support services include:

- benefits and retirement
- worker's compensation
- HR policy development and accountability
- staffing services
- FDA University employee development programs and training opportunities

HR support allows FDA to work with labor unions and address labor practices through the employee and labor relations programs, as well as the ability to address the Commissioned Corps' unique needs. Additional information systems support, workforce and demographic data reporting, and information dissemination strategies are managed Agency-wide to support enterprise human resources system needs.

Facilities and Environmental Management

Facilities and Environmental Management services incorporate a broad range of vital needs to support a safe and sustainable working environment. These services include:

- lease and facilities project management
- maintenance and logistics support
- strategy and performance management

To maintain a safe working environment, FDA centrally manages occupational safety and health programs, special security operations, and physical and personnel security. These services require collaboration and communication with the Department's other HHS Operating Divisions to meet a wide range of policy requirements.

Finance and Procurement

Finance and Procurement services enable FDA to perform budgetary, financial, acquisition, and grants functions. The support includes:

- contracts, grant awards and administration
- the implementation of all FDA policies and procedures governing acquisitions
- inter-agency agreements
- grants management

In addition, financial, accounting, managerial and reporting services are provided to stakeholders, along with policy guidance and travel support in accordance with standards and requirements. Budget execution, control and compliance services further enable FDA to provide guidance, high-level analysis, and reliable data to ensure dollars are utilized in accordance with the Congressional intent and FDA's mission.

Administrative

Administrative operations provide FDA employees and stakeholders with additional services to further support day-to-day functions and needs. These services include:

- equal employment opportunities
- a work environment that values and supports diversity
- ethics and integrity assistance to help current and former employees avoid conflicts of interest and follow laws and regulations in their business activities